No. 23-10362

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE, AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; SHAUN JESTER, D.O.; REGINA FROST-CLARK, M.D.; TYLER JOHNSON, D.O.; GEORGE DELGADO, M.D.,

Plaintiffs-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION, ROBERT M. CALIFF, COMMISSIONER OF FOOD AND DRUGS; 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; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellants,

v.

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellant.

On Appeal from the United States District Court for the Northern District of Texas, No. 2:22-cv-00223-Z

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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American College of Pediatricians
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STATEMENT REGARDING ORAL ARGUMENT

Oral argument has been scheduled for May 17, 2023. This case involves important legal questions regarding a federal agency's ability to thwart the rule of law and federalism principles all to the detriment of women and their doctors. Oral argument is necessary for full consideration of these issues.

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INTRODUCTION

The Administrative Procedure Act (APA) requires courts to set aside unlawful agency action. That basic principle governs this case. It applies to FDA's unprecedented actions to put politics above women's health, including (1) classifying pregnancy as an "illness," (2) approving mifepristone for use without the safeguards under which it had been tested, (3) failing to respond to Plaintiffs' citizen petitions for over 16 years, (4) removing every meaningful safeguard that FDA once found necessary to mitigate the dangers of mifepristone, and (5) authorizing mailing of the drug in violation of federal law. These actions do not reflect "scientific" judgment but politically driven decisions to unlawfully push a dangerous regimen.

No agency is infallible. The crux of Plaintiffs' arguments is that FDA's judgment *was not based on the required scientific evidence*. The agency's position—that no court is worthy of checking FDA's work—reeks of hubris and is contrary to the APA.

To avoid merits scrutiny, FDA spends the bulk of its brief on procedural roadblocks. But the district court's meticulous decision holds that Plaintiffs have standing, their claims are timely, and the public interest weighs in favor of taking a dangerous drug with no meaningful safeguard off the market.

FDA's actions also subvert the promise of *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), which returned to

the people the power to protect women's health, unborn life, and the integrity of the medical profession by regulating abortion. *Id.* at 2284. Yet the considered judgments of states that have chosen to do so are rendered meaningless by FDA's mail-order abortion scheme. And that's no accident. The Biden Administration has directed FDA to ensure that abortion drugs are as widely accessible to women as possible "no matter where they live."[1] The Administration has even singled out for "monitoring" state laws that regulate abortion.[2] Instead of respecting federalism, the Biden Administration and FDA have worked to dismantle it. The district court's order should be affirmed in full.

STATEMENT OF JURISDICTION

Appellees agree with Appellants' Statement of Jurisdiction.

STATEMENT OF THE CASE

A. FDA's statutory requirements

The Food, Drug, and Cosmetic Act (FDCA) requires companies seeking to market any new drug to obtain FDA's approval by filing a new drug application (NDA). 21 U.S.C. § 355(a), (b). FDA must reject the NDA if: (1) clinical investigations "do not include adequate tests …

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[1] Fact Sheet: President Biden to Sign Presidential Memorandum on Ensuring Safe Access to Medication Abortion, The White House (Jan. 22, 2023), http://bit.ly/3I160Vn.

[2] Memorandum on Further Efforts to Protect Access to Reproductive Healthcare Services, The White House (Jan. 22, 2023), http://bit.ly/3kEZrPl.

to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling," *id.* § 355(d)(1); (2) "the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions," *id*. § 355(d)(2); (3) the agency "has insufficient information to determine whether such drug is safe for use under such conditions," *id.* § 355(d)(4); or (4) "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use … in the proposed labeling," *id.* § 355(d)(5).

B. Mifepristone's regulatory history

FDA's chemical abortion regimen requires two drugs: mifepristone (also known as "RU-486" and "Mifeprex"), a synthetic steroid that blocks nutrition to the unborn baby, and misoprostol, which induces contractions to expel the baby from the mother's womb. ROA.90–91. During the early 1990s, the Population Council—a nonprofit founded to address world "overpopulation"—obtained the U.S. patent rights to mifepristone. ROA.107. The Council granted Appellant Danco Laboratories, LLC—a Cayman Islands-based company with no other pharmaceutical products—an exclusive license to market in the U.S. ROA.115.

1. 2000 Approval

In 2000, FDA approved mifepristone under Subpart H, 21 C.F.R. § 314.500 (2000 Approval). ROA.600. This regulation authorized 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 approving mifepristone, FDA had approved fewer than 40 drugs under Subpart H—including 20 "for 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. ROA.372. To invoke Subpart H, FDA branded pregnancy an "illness" and said it provides a "meaningful therapeutic benefit" over surgical abortions.

Given known adverse complications, Subpart H was the only mechanism available to FDA to approve mifepristone. ROA.111. FDA's 2000 Approval thus imposed numerous safeguards, including a seven-week gestational limit, prescribing authority limited to physicians, three in-person office visits, and an adverse-event reporting requirement. ROA.592–98. FDA also required and approved Danco's distribution plan for mifepristone, which authorized shipments from the manufacturer or importer to distributors and prescribers. ROA.113.

2. 2011 REMS

In 2007, the Food and Drug Administration Amendments Act (FDAAA) amended the FDCA to codify FDA's post-approval restrictions for drugs authorized under Subpart H. These changes require a risk evaluation and mitigation strategy (REMS) when "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). Without addressing the merits of any particular drug approval, the FDAAA provided that a drug previously approved under Subpart H was "deemed to have in effect an approved [REMS]." H.R. 3580, 110th Cong. (2007).

3. 2002 Citizen Petition and 2016 Petition Denial

In 2002, Plaintiffs AAPLOG and CMDA timely filed a citizen petition with FDA challenging the 2000 Approval (2002 Citizen Petition). ROA.353–448. *Fourteen years later*, FDA rejected that petition (2016 Petition Denial). ROA.634–67.

4. 2016 Major Changes

The *same day* in 2016, FDA approved Danco's supplemental new drug application (sNDA) to make significant changes to the 2000 Approval, removing crucial safeguards (2016 Major Changes). ROA.688–96. FDA acknowledged that "these major changes are interrelated." ROA.703. 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; (3) allowed non-doctors to prescribe; (4) removed the in-person misoprostol administration requirement; (5) changed the dosages of both drugs; and (6) eliminated the requirement for prescribers to report non-fatal adverse events. ROA.700, 724.

5. 2019 Citizen Petition

In March 2019, Plaintiffs AAPLOG and ACPeds timely filed another citizen petition opposing the 2016 Major Changes (2019 Citizen Petition). Plaintiffs also asked FDA to strengthen the original terms and conditions of the 2000 Approval by requiring an ultrasound and expanding adverse events reporting, and, pursuant to 21 C.F.R. § 10.25, to refrain from removing the in-person dispensing. ROA.740–66.

6. 2019 ANDA Approval

One month later, FDA approved GenBioPro, Inc.'s abbreviated new drug application (ANDA) for a generic version of mifepristone, relying on the safety data from the 2000 Approval and the 2016 Major Changes (2019 ANDA Approval). ROA.767–73.

7. 2021 Non-Enforcement Decision

In 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). ROA.788.

8. 2021 Petition Response

Later that year, FDA denied almost all the 2019 Citizen Petition (2021 Petition Response). ROA.802–42. FDA also announced that it had decided to *permanently* allow chemical abortion by mail. ROA.808.

C. FDA's reliance on flawed studies

FDA has uniformly relied on studies that did not measure mifepristone's safety and effectiveness "under the conditions prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. § 355(d).

1. 2000 Approval

FDA relied on one U.S. and two French studies when it initially approved mifepristone. The U.S. study incorporated numerous safeguards, including: (1) an ultrasound to confirm gestational age and exclude ectopic pregnancies; (2) requiring prescribing physicians to have experience performing surgical abortions and admitting privileges at emergency medical facilities; (3) all women were within one hour of emergency facilities; and (4) monitoring women for adverse events four hours after taking misoprostol. ROA.4355. Both French studies also included ultrasounds to determine gestational age and at least four hours of observation after taking misoprostol. ROA.378–79. Yet FDA "included *none* of these requirements" on the labeling. ROA.4355.

Even with these safeguards, surgical intervention was needed in a shocking 7.9% of women in the U.S. trial and 4.5% of women in the

French studies at gestational ages 49 days or less. ROA.591. Surgical intervention was needed for 17% of women at 50–56 days' gestation and 23% of women at 57–63 days' gestation in the U.S. study. Irving M. Spritz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the U.S.*, The New England Journal of Medicine (Apr. 30, 1998), Stay.Opp.App.6. This study concluded that "the regimen is less effective and the incidence of adverse events is higher" for gestational ages over 49 days. *Id.*

FDA offered no evidence showing the safety of mifepristone *without* the studies' crucial safeguards. Instead, FDA said no ultrasound was required because a doctor could use "other clinical methods." ROA.595. But FDA did not cite any evidence, testing, or information to show "other clinical methods" would have similar safety and effectiveness outcomes. *Id.* Similarly, FDA did not require providers to have surgical training because providers could refer—yet there was no evidence that such referrals would lead to similar safety outcomes. *Id.*[3]

[3] FDA relies on two Government Accountability Reports, FDA.Br.39, but those reports did not offer serious legal scrutiny of FDA's mifepristone actions. They merely compared the *process* for those actions with other drug reviews; here, Plaintiffs challenge the substance of FDA's actions. For instance, under its plain text, the Subpart H process was unavailable to FDA. Regardless, GAO opinions "are not binding on [a] court." *Delta Chem. Corp. v. West*, 33 F.3d 380, 382 (4th Cir. 1994).

2. 2016 Major Changes

None of the studies FDA relied on in the 2016 Major Changes evaluated the interrelated changes as a whole. Nor did any study evaluate the conditions of use under the new proposed labeling, contrary to the FDCA, 21 U.S.C. § 355(d)(1). ROA.4230–46.

For example, FDA relied on a study to extend the maximum gestational age to 70 days, change the dosing regimen, and authorize a repeat dose of misoprostol if the first fails—a study led by a former Population Council employee—ROA.128–29. Not only did the study fail to evaluate the interrelated 2016 Major Changes *as a whole*, but the study investigators also (1) performed "routine ultrasounds" on every participant, (2) required participants to return for follow-up care, including an ultrasound, and (3) "intervened surgically" when necessary. ROA.129. None of these safeguards are on the 2016 Major Changes labeling. *Id.*

FDA also relied on a systematic review that "covered 20 studies including over 30,000 women." ROA.704. In this review, 76% of the data was from two retrospective studies. Christina A. Cirucci, MD, *Self-Managed Medication Abortion: Implications for Clinical Practice*, The Linacre Quarterly (2022), Stay.Opp.App.12. One of the primary studies—the 2015 Gatter study—included 13,373 women but failed to track ER visits and lacked any safety outcomes for 15.5% of participants. *Id.* That study also incorporated ultrasounds, in-person follow-up

visits, and prophylactic antibiotics *not* included in the 2016 Major Changes labeling. ROA.736.

The other major study—the 2012 Goldstone study—included 11,155 women but also failed to report ER visits or hospitalizations while lacking safety outcomes for 16% of participants. Cirucci, Stay.Opp.App.12. This study again included safeguards discarded by the 2016 Major Changes (or never required at all)—namely, ultrasounds, in-person follow-up visits for 85% of women, a gestation age of 63 days or less, and prophylactic antibiotics for women at a high infection risk. ROA.4235.

3. Actions to remove in-person dispensing

To remove in-person dispensing requirements, FDA relied on its Adverse Event Reporting System (FAERS), despite concluding that the database "cannot be used to calculate the incidence of an adverse event … in the U.S." ROA.845.

FDA also cited studies to support eliminating the in-person dispensing requirement but conceded that "the studies [it] reviewed are not adequate on their own to establish safety of the model of dispensing mifepristone by mail." ROA.837. FDA acknowledged: (1) "the ability to generalize the results of these studies to the United States population is hampered"; (2) "the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes with regard to both safety and efficacy"; and (3) FDA "did not find any

large clinical studies that were designed to collect safety outcomes in healthcare systems similar to the United States." ROA.830.

In summarizing the studies, FDA acknowledged that "the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail." *Id.*

SUMMARY OF ARGUMENT

For more than two decades, FDA has evaded judicial review, placing politics above women's health, unborn lives, and the rule of law. The district court correctly determined that FDA's actions must be set aside. Yet FDA and the abortion industry now ask this Court to ignore the illegal approval and deregulation of mifepristone.

At the outset, FDA advances a radical view of standing. The government says that, even if "hundreds of thousands of women *will* … need emergency care" and even if "plaintiff doctors and their associations *will necessarily* be injured by the consequences" of chemical abortion gone wrong, Article III standing does not exist. FDA.Br.24 (citing ROA.4396) (emphasis added). This is not the law. *Summers v. Earth Island Institute*, 555 U.S. 488 (2009), does not hold that future relief is unavailable when plaintiffs "will necessarily be injured." *Cf.* FDA.Br.24. Defendants' theory implies that only parties who profit from a drug—manufacturers and prescribers—can sue over its unlawful approval or deregulation.

Here, Plaintiffs have suffered specific, concrete injuries because of FDA's approval and deregulation of mifepristone. These include the forced participation in elective abortions contrary to deeply held beliefs, interference with Plaintiffs' medical practice, consumption of crucial and limited resources, enormous stress caused by emergency treatment from chemical abortion gone wrong, and increased liability risk.

Those harms are not speculative. They have already occurred, and there is a "substantial risk" they "will occur" again. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) ("SBA List") (cleaned up). For instance, Plaintiff AAPLOG member Dr. Skop has alone "cared for *several dozen* women in the emergency department" including at least a dozen who have required surgery. ROA.277–78 (emphasis added). According to Defendants' own evidence, hundreds of thousands of women have suffered adverse events. And as the district court found, risks to women and girls have increased after FDA eliminated safeguards such as in-person visits and physician-only prescriptions.

On the merits, FDA failed to engage in the reasoned decision-making the APA requires. Pregnancy is not an "illness." And FDA lacked any evidence that mifepristone is safe without an ultrasound. As for the 2016 Major Changes, FDA points to no study that examined what would happen if FDA removed *all* safety guardrails simultaneously. This is akin to an agency no longer requiring seatbelts,

airbags, and antilock brakes based on a study that evaluated only the safety of removing airbags.

FDA's 2021 Petition Response is also arbitrary. In removing the in-person dispensing requirement, FDA relied heavily on FAERS. But FDA abandoned requirements for prescribers to report nonfatal adverse events years before. As the stay panel concluded, "[t]his ostrich's-head-in-the-sand approach is deeply troubling" and "unreasonable." ROA.4412. And the district court correctly held that FDA's mail-order abortion regimen violates the federal Comstock laws. ROA.4344.

Plaintiffs will suffer irreparable injury, as the district court determined. Absent equitable relief, a dangerous drug will remain on the market without critical safeguards, resulting in physical complications, emotional trauma, and death for women. It will also harm Plaintiffs by forcing them to participate in elective abortions, violating their conscience rights, interfering with their medical practices, and requiring them to divert valuable resources. And it will harm the rule of law as a nationwide mail-order abortion regime is imposed by agency fiat. This Court should affirm the district court in full.

STANDARD OF REVIEW

The district court stayed "the effective date of FDA's [2000 Approval] of mifepristone and all subsequent actions related to that approval." ROA.4373. A stay under 5 U.S.C. § 705 is "an interim or

lesser form of vacatur under Section 706," *Texas v. Biden*, No. 2:21-cv-067-Z, 2022 WL 17718634, at *7 (N.D. Tex. Dec. 15, 2022), and "a less drastic remedy" than a preliminary injunction, *Texas v. United States*, 40 F.4th 205, 219 (5th Cir. 2022) (per curiam) (cleaned up). This Court reviews such a stay for an abuse of discretion. *Data Mktg. P'ship, LP v. U.S. Dep't of Lab.*, 45 F.4th 846, 860 (5th Cir. 2022). "The district court's findings of facts are reviewed for clear error and its legal conclusions *de novo*." *Texas*, 40 F.4th at 215.

ARGUMENT

I. Plaintiffs have 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." *SBA List*, 573 U.S. at 157–58 (cleaned up). An Article III injury must be both "concrete and particularized" and "actual or imminent." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (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 (emphasis added) (cleaned up).

A. Individual physician and associational standing

The district court correctly concluded that individual plaintiff doctors have standing. Plaintiff medical associations also have associational standing because the named plaintiff members have individual standing. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977).

Plaintiffs have standing to sue because they allege that FDA's actions: (1) force doctors into situations where they must *participate in an elective abortion* contrary to their most deeply held beliefs, ROA.4313–14; (2) place "enormous stress and pressure" on plaintiff doctors during these emergencies, ROA.4391; (3) "consume crucial limited resources," ROA.4313; and (4) cause "Plaintiffs to face increased exposure to allegations of malpractice and potential liability, along with higher insurance costs," ROA.4314.

1. *Conscience rights*. FDA's unlawful actions force plaintiff doctors to violate their conscience rights. Because FDA's deregulatory actions have increased the number of complications related to chemical abortions, "more physicians with ethical and medical objections to abortion will be forced to participate in completing unfinished elective chemical abortions in emergency situations." ROA.269; ROA.283 (FDA's actions "may force me to end the life of a human being in the womb"); ROA.256 (FDA's actions "will force [plaintiff] CMDA members to complete an unfinished elective abortion in an emergency situation,

causing immediate emotional and moral distress for our members who are opposed to elective abortion").

Plaintiff doctors are injured by being forced to perform and participate in elective abortions contrary to their most deeply held beliefs. ROA.269–70. A dilation and curettage abortion, for example, involves a surgical procedure in which the uterine lining is often scraped out with a spoon-shaped instrument to remove the unborn baby and pregnancy tissues. *Dilation and Curettage (D and C)*, Johns Hopkins Medicine, bit.ly/3HKCZg6 (cleaned up). Meanwhile, suction aspiration abortions involve a machine or handheld syringe sucking the baby and pregnancy tissue into a cannister. Lynn Borgatta et al., *Surgical Techniques for First-Trimester Abortion*, Global Women's Medicine (May 2012), https://bit.ly/3VIlfIg. Plaintiff doctors must then examine the cannister's contents to make sure that the complete embryo or fetus, as well as pregnancy tissue, have all been extracted. *Id.*

Defendants do not (and could not) claim that emergency room doctors would suffer a conscience harm from treating an asthmatic child or gunshot victim. These hypothetical doctors may object to environmental and gun regulations (or lack thereof), but they are not being compelled to participate in ending the life of another person. FDA.Br.23–24; Danco.Br.22–23. And these hypothetical doctors would still be required to prove unlawful agency action. Plaintiff doctors suffer concrete and specific harms from FDA's illegal actions that have forced

them to participate in an elective abortion, "end[ing] the life of a human being in the womb for no medical reason" as they save the life of the mother. ROA.159; *see Dobbs*,142 S. Ct. at 2236 ("Abortion is different because it destroys what *Roe* termed 'potential life' and what the law challenged in this case calls an 'unborn human being.'").

FDA also tries to erase Plaintiffs' conscience harms by pointing to various federal conscience protections. FDA.Br.26; Danco.Br.22–23. Yet the government recently argued in federal court that those protections *do not apply* when women come to hospitals injured by chemical abortion. In July 2022, the Biden Administration issued a mandate attempting to rewrite the Emergency Medical Treatment and Active Labor Act (EMTALA) to force emergency room doctors to complete chemical abortions. *Reinforcement of EMTALA Obligations Specific to Patients Who Are Pregnant or Are Experiencing Pregnancy Loss*, Centers for Medicare & Medicaid Services (July 11, 2022), https://bit.ly/42pSK46 (requiring completion of "incomplete medical abortion"). That abortion mandate said nary a word about the federal conscience laws that FDA now trumpets. On the contrary, when many of the same plaintiff doctors in this appeal sued, the government asserted that EMTALA trumps those very conscience laws and requires doctors to perform emergency abortions. Defs.' Br. in Supp. Mot. Dismiss at 27, *Texas v. Becerra*, No. 5:22-cv-185-H (N.D. Tex. Aug. 15, 2022) ("[T]here is no evidence that Congress intended, *sub silentio*, for

any of the Conscience Provisions to override EMTALA."). Accordingly, a federal district court found it likely the federal government might prosecute doctors who object to completing chemical abortions. *Texas v. Becerra*, No. 5:22-cv-185-H, 2022 WL 3639525, at *11–12 (N.D. Tex. Aug. 23, 2022).

2. *Mental and emotional harm*. FDA's actions have placed "enormous" mental and emotional stress on plaintiff doctors during these emergency situations. ROA.288. It grieves Plaintiffs to treat women and girls suffering regret or trauma from a chemical abortion. ROA.1157. One doctor testified that "[u]nsupervised chemical abortion is heartbreaking to me because it causes women to suffer unnecessarily, and my patients deserve quality medical care." ROA.282. Another testified that caring for "women who have a great deal of regret from undergoing the chemical abortion regimen … is some of the most emotionally taxing work I have done in my career." ROA.953. This independent emotional injury "significantly affect[s]" the doctors' "quality of life." *Sierra Club v. Morton*, 405 U.S. 727, 734–35 (1972). The Supreme Court has recognized that this sort of mental distress, along with Plaintiffs' other actual emotional and psychological harms, ROA.158–60, "could suffice for Article III purposes." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2211 & n.7 (2021).

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. ROA.4391. 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." ROA.4313. Patients may require "overnight hospitalization, intensive care, and even surgical abortions." ROA.4390. Hospitalists often supervise multiple laboring patients, and an emergency surgery means they may be unavailable to their other patients. ROA.282. One doctor describes such a case:

> After taking the chemical abortion drugs, [my patient] 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. [ROA.267–68.]

"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., geo-

graphic areas where there are not a large number of OB/Gyn providers for patients)." ROA.244.

4. *Increased liability*. FDA's actions have "put[ ] more doctors into riskier, emergent medical situations," exposing "physicians to increased claims of liability." ROA.255; ROA.4314 (increased exposure "to allegations of malpractice and potential liability, along with higher insurance costs"). As one doctor testified, "FDA's deregulation of these dangerous drugs increases our exposure to liability." ROA.960; ROA.946 (same). Another doctor elaborated: "FDA's actions have created a culture of chaos for emergency room physicians. . . [and] increase[d] our exposure to claims of malpractice and liability." ROA.940; *see also* ROA.233 (FDA's "elimination of necessary safeguards" leaves "doctors at increased risk of liability and could impact their ability to render the best care possible to the patient"); ROA.255 ("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.").

Defendants call these harms speculative. FDA.Br.67. But these harms have already occurred, and there is a "substantial risk" they "will occur" again. *SBA List*, 573 U.S. at 158 (cleaned up). For example, Plaintiff AAPLOG member Dr. Skop is an obstetric hospitalist who testified that she "often treat[s] patients admitted through the hospital's emergency department with complications from chemical

abortions." ROA.277. She has "cared for *several dozen* women in the emergency department who were totally unprepared for the pain and bleeding they experienced from chemical abortion." *Id.* (emphasis added). And she has "cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion." ROA.278.

Further, Dr. Skop has "cared for approximately five women who, after a chemical abortion, have required admission for a blood transfusion or intravenous antibiotics or both." *Id.* She has also treated many patients experiencing trauma from chemical abortion, including a dozen patients who expressed "significant emotional distress" over viewing "the body of their unborn child in the toilet after the chemical abortion." *Id.* Given her experience, Dr. Skop "expect[s] to see and treat more patients presenting with complications from chemical abortion." *Id.*

Dr. Skop testified that FDA's 2016 and 2021 actions "increased the frequency of complications from chemical abortion." *Id.* "Deregulated chemical abortion harms my practice because it increases the number of women who come to the emergency department with complications." ROA.282. These actions harm women, and in turn their treating doctors, "because without proper oversight, chemical abortions can become even more dangerous than when they are supervised." ROA.280. In such circumstances, many women are "inadequately prepared for the effects of the drugs, the severity of the pain and

bleeding they will experience, [and] the human tissue they will expel, and some are unaware that they have complicating factors such as ectopic implantation, more advanced gestation than estimated, and Rh-negative blood type." *Id.* This harms plaintiff doctors because "in many cases there is no [prior] doctor-patient relationship, so [the women] often present to overwhelmed emergency rooms in their distress, where they are usually cared for by physicians other than the abortion prescriber." *Id.*

Defendants say it is "implausible" that FDA's post-2015 actions could harm Plaintiffs. FDA.Br.28. But the stay panel correctly concluded that FDA's "virtual elimination of controls" has led to "an increasing number of women coming to the emergency room with complications from chemical abortions." ROA.4394. And the stay panel correctly found an increased risk of harm to Plaintiff doctors and medical associations "because FDA has removed almost all of mifepristone's REMS." ROA.4394.

Turning to causation, these harms to the plaintiff doctors and associations flow from each of the relevant FDA actions. So Plaintiffs can challenge all of them.

1. *2000 Approval.* As the stay panel found, FDA's Patient Agreement Form makes it impossible for FDA to "deny that serious complications from mifepristone are certainly impending." ROA.4389. That form indicates that complications from chemical abortions have

forced between 100,000 and 350,000 women to speak with their provider "about a surgical procedure to end [their] pregnanc[ies]." ROA.4389–90 (cleaned up).

Defendants ask this Court to ignore these startlingly high numbers because the Form directs women to discuss their injuries with "their provider." Danco.Br.25; FDA.Br.25. But if FDA had never approved mifepristone, surgical abortions would have remained the dominant method, with local abortion providers on hand for complications. Moreover, this argument ignores that, because FDA has now allowed for self-managed abortions without physician involvement, the non-physician providers are *incapable* of performing follow-up surgeries. This ensures that injured women will end up in emergency rooms all over the country, including those in which Plaintiff doctors work. As the stay panel held, FDA's continual deregulation of mifepristone leaves plaintiff physicians to deal with the aftermath of chemical abortion gone wrong. ROA.4389–90. 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.'" ROA.4390. (quoting ROA.1237, 1239, 1264, 1276).[4]

[4] The generic drug comes with all the same harms as does the name brand—so the district court's harm analysis applies fully to the 2019 ANDA approval.

2. *2016 Major Changes.* As noted, FDA removed nearly every meaningful safeguard in the 2016 Major Changes. "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." ROA.149. Those changes increased the harm to Plaintiffs in three ways.

First, more women will end up in emergency care because risks increase with gestational age. ROA.92, 154. Dr. Skop testified that unsupervised chemical abortion is dangerous because women may underestimate gestational age, elevating the chance of "complications due to the increased amount of tissue, leading to hemorrhage, infection and/or the need for surgeries or other emergency care." ROA.281.

In addition, 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*, Am. Coll. of Obstetrics & Gynecology Clinical Practice Bulletin (Oct. 2020), https://bit.ly/3VB36vK. As mentioned, the U.S. study on which FDA relied to approve mifepristone found that surgical intervention was needed for 17% of women at 50–56 days' gestation and 23% of women at 57–63 days' gestation—confirming that "the regimen is less effective and the incidence of adverse events is higher" for gestational ages over 49 days. Stay.Opp.App.2, 6. Even the systematic review that Danco touts, Danco.Br.45, showed a significant increase in the failure

rate as the baby's gestational age increases: 1.9% failed under 7 weeks, 3.3% failed between 7–8 weeks, 4.5% failed between 8–9 weeks, and 6.9% failed between 9–10 weeks. Melissa J. Chen and Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review*, U.C. Davis (July 2015), https://bit.ly/44wQ2vo.

Second, FDA's removal of follow-up care heightens the burden on Plaintiffs' medical practices and puts them "at an increased risk of being forced to violate their conscience rights." ROA.248. Under the 2016 REMS, "there is no follow-up or additional care provided to patients." ROA.295. "Instead, with no established relationship with a physician, patients are simply left to report to the emergency room when they experience adverse effects." *Id.* One doctor has been required to perform emergency surgeries to remove embryos, fetuses, and pregnancy tissue in a dozen different cases—many of which could have been avoided if FDA had not removed the follow-up exam. ROA.276–83.

Third, the 2016 Major Changes discontinued the requirement that *doctors* prescribe chemical abortion. As a result, "women who use this drug cannot possibly go back to their non-doctor-prescribers for surgical abortions [and] must instead seek 'emergency care' from a qualified physician." ROA.390. When emergencies occur—as the government concedes they will—it is plaintiff emergency room doctors and their colleagues "who must manage the aftermath." ROA.4395; ROA.278

("FDA's actions in 2016 and 2021 have increased the frequency of complications from chemical abortions.").

3. *2021 Mail-Order Changes.* As the stay panel explained, FDA's unlawful deregulation of mifepristone in 2021 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 perform the chemical abortion regimen at home." ROA.4394. The increase in mail-order or telemedicine abortions "means that more women will suffer complications from unsupervised use of mifepristone." ROA.288.

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." ROA.4394 (citing ROA.1264, 1275, 1285, 1936). One doctor testified: "Deregulated chemical abortion harms my practice because it increases the number of women who come to the emergency department with complications." ROA.282. This doctor attributed the increase in harm to FDA's authorization of mail-order abortions, removal of any in-person doctor evaluation, and elimination of in-person follow-up care. ROA.280–81. 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." ROA.938. And still another testified that the frequency of complications from chemical abortion increased when FDA stopped enforcing the in-person dispensing requirement. ROA.267. 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." ROA.836.

The risks are heightened in several specific situations. ROA.280. For women with ectopic pregnancies, "[t]he risks are greater under FDA's relaxed standards." ROA.4393. Ectopic pregnancies occur in about one out of every 50 pregnancies. ROA.4392. "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." ROA.4392–93. Delivering mifepristone through the mail "will cause some women to remain undiagnosed [for ectopic pregnancies] and at high risk for these adverse outcomes." ROA.4393.

As noted, risk also increases with gestational age, and women engaged in unsupervised chemical abortions may underestimate gestational age. If beyond ten weeks' gestation, women have higher "chances of complications due to the increased amount of tissue, leading to hemorrhage, infection and/or the need for surgeries of other emergency

care." ROA.288. Because FDA removed in-person prescribing, "many women are now being prescribed mifepristone … without a sonogram to verify the gestational age of the unborn child." ROA.288. Moreover, without in-person prescribing and dispensing, women can delay taking mifepristone until they are dangerously beyond the recommended gestational age. ROA.149–50, 281, 958–59. This risks women "present-[ing] to the emergency department with torrential bleeding." ROA.288. That in turn harms plaintiff doctors "by putting them in higher-risk situations with less critical information about patients, which increases their exposure to allegations of malpractice and potential liability." ROA.289.

The government points to the adverse events catalogued by FAERS as evidence that mifepristone—even without crucial safeguards—is safe. FDA.Br.54–55. But FDA admits that "FAERS data cannot be used to calculate the incidence of an adverse event … in the U.S. population." ROA.845. Those numbers are unreliable because FDA *eliminated* the prescriber adverse-event reporting requirement years before. It is nonsensical for FDA now to declare that "the absence of non-fatal adverse-event reports means mifepristone is 'safe.'" ROA.4412 (citing ROA.827–42). "This ostrich's-head-in-the-sand approach is deeply troubling—especially on a record that, according to [FDA's] own documents, necessitates a REMS program, a 'Patient Agreement Form,' and a 'Black Box' warning." ROA.4412.

FDA argues the sponsors are still required to report adverse events. FDA.Br.55. But no one is required to report events to Danco. And there were already "significant discrepancies" in the data when abortion providers *had* such a duty. ROA.1871–76. In a study of FAERS data from 2009 and 2010, for example, Planned Parenthood chemical abortions had resulted in 1,530 adverse events, including 1,158 continuing pregnancies. Meanwhile, the FAERS dashboard included only 664 adverse events and just 95 continuing pregnancies (less than 10% of those identified in the study) even though it purportedly covered all providers. *See* Christina A Cirucci et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 Health Servs. Rsch. & Managerial Epidemiology 1 (2021), ROA.801–06.

Defendants look to *Summers* to say all of Plaintiffs' harms are speculative. Not so. In *Summers*, the parties had settled the only "live dispute" over a "concrete application" of the challenged regulations. 555 U.S. at 490. The Supreme Court did not allow an injury from that settled claim to establish standing to challenge a different agency action, especially where the only other associational member's alleged injury was "not tied to application of the challenged regulations." *Id.* at 495. Here, Plaintiffs are injured by and directly challenge the FDA's unlawful actions.

The district court did *not* rely on a statistical-probability-of-injury-to-a-member theory. *Contra* FDA.Br.21–23. Rather, standing exists because Plaintiffs assert "specific allegations establishing that at least one identified member had suffered or would suffer harm." *Summers*, 555 U.S. at 498. In *Summers*, the government conceded that associational standing would exist where a member alleged injury to "interests in viewing the flora and fauna," affirmed that he "had repeatedly visited [a certain park]," and expected "to do so again." *Id.* at 494. Similarly here, individual Plaintiffs testified that they "often" treat patients suffering adverse complications from chemical abortions. Drs. Johnson, Frost-Clark, and Skop each testified to treating emergency medical conditions caused by mifepristone a dozen times or more. ROA.267–69, 277–82, 289–90, 296–97. Indeed, Dr. Skop has been required to perform emergency surgery to remove embryos, fetuses, and pregnancy tissue in a dozen different cases. ROA.278–83.

Several doctors detail interference with their medical practice, increased liability and insurance risks, and the need to call in additional doctors to cover other patients while they treated emergency complications from mifepristone. ROA.267, 282, 288–91, 939–40, 953–54. And three doctors state that they were faced with emergency situations and forced to perform and participate in D&C or suction aspiration surgeries. ROA.267–70, 277–82, 959. Plaintiff doctors have "repeatedly" been harmed by chemical abortion and have imminent and

ongoing plans to continue providing obstetric care. *See Summers*, 555 U.S. at 494.

Defendants also overread *Clapper v. Amnesty International USA*, 568 U.S. 398 (2013), to suggest the Fifth Circuit erred in finding harm to be "certainly impending." FDA.Br.21; Danco.Br.24. As the district court held, *Clapper* is distinguishable because no plaintiff there had *ever* suffered an injury. ROA.4320–21. Further, recent cases reaffirm what *Clapper* stated in footnote five: that a material risk of future harm satisfies Article III so long as "there is a 'substantial risk' that the harm will occur." *SBA List*, 573 U.S. at 158 (cleaned up); *Massachusetts v. EPA*, 549 U.S. 497, 525 n.23 (2007). Plaintiff doctors need not wait until yet *another* woman is admitted to the ER—especially when so many women harmed by mifepristone regularly arrive at their doors.

Defendants are also wrong when they say Plaintiff doctors cannot be injured because other people are involved. *Cf.* FDA.Br.19–20. *Department of Commerce v. New York*, 139 S. Ct. 2551 (2019), refutes that argument. The Court there concluded that standing exists where evidence "established a sufficient likelihood that the reinstatement of a citizenship question would result in noncitizen households responding to the census at lower rates than other groups, which in turn would cause them to be undercounted and lead to many of respondents' asserted injuries." *Id.* at 2565. The Court rejected the government's claim that the harm was not traceable because it depended on the

action of third parties. *Id.* at 2566. Rather, plaintiffs had shown that "third parties will likely react in predictable ways to the citizenship question" based on the "historically" lower response rate that was likely due to a "reluctance" to answer a citizenship question. *Id.* This was not "mere speculation about the decisions of third parties; it relie[d] instead on the predictable effect of Government action on the decisions of third parties." *Id.* Because standing "requires no more than de facto causality," traceability was satisfied. *Id.* (cleaned up).

So too here. FDA's own numbers tell us about the predictable effect of FDA's action on the decisions of third parties. As the stay panel found, it is reasonably certain "that women will continue needing plaintiffs' 'emergency care.'" *See* ROA.278, 288, 940, 4394. FDA's mail-order abortion regimen creates "a 'substantial risk' that the harm will occur." *SBA List*, 573 U.S. at 158 (cleaned up).

Plaintiff doctors' and associations' claims are also redressable. Either halting mifepristone's approval or restoring crucial safeguards necessary to protect women will relieve Plaintiffs of at least some of the injuries caused by FDA's unlawful approval and deregulation of mifepristone. *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).

B. Third-party standing

The district court properly held that Plaintiffs can assert third-party standing because their 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 plaintiff doctors; and (3) are hindered from "protect[ing] their [own] interests." ROA.4315.[5]

"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. 2023). Indeed, 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. LLC v. Russo*, 140 S. Ct. 2103, 2118 (2020), *abrogated on other grounds by Dobbs*, 142 S. Ct. 2228.

Those 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); *Singleton v. Wulff*, 428 U.S. 106, 117 (1976). The "case for a close physician-patient relationship is even stronger here than in the

[5] FDA accuses the lower court of dispensing with the requirement that Plaintiffs suffer injury. FDA.Br.32–33. But the district court found both that Plaintiffs were injured and that they could assert the rights of their patients.

abortion context" because plaintiffs often spend hours treating post-abortive women, hospitalize them, and see them for several visits. ROA.4316–17. And "women who have *already* obtained an abortion may be *more* hindered than women who challenge restrictions on abortion" because they may experience post-abortive emotional harm. ROA.4317.

The stay panel declined to rule on third-party standing because of a footnote in *Dobbs*. ROA.4387–88 n.4. But *Dobbs* was a case brought by an abortion clinic and its doctor raising third-party harms, and the Supreme Court did not dismiss it for lack of standing. And unlike abortion provider cases, no conflict of interest between doctor and patient exists here. ROA.4316. 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 Plaintiffs can sue on behalf of their injured patients—as both seek protection from the harms of chemical abortion drugs.

C. Organizational standing

The district court appropriately held that plaintiff medical associations have organizational standing. ROA.4317–19. Such standing exists where, as here, an organization alleges that it has "diverted valuable resources away from [its] advocacy and educational efforts" to inform members, patients, and the public about the dangers of government action "to the detriment of other priorities and functions." ROA.4319; *accord Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379

(1982); *OCA-Greater Houston v. Texas*, 867 F.3d 604, 610–12 (5th Cir. 2017).

In response to FDA's actions, Plaintiff organizations have "calibrated [their] outreach efforts to spend extra time and money educating [their] members" about the dangers of mifepristone. *See OCA-Greater Houston*, 867 F.3d at 610. These organizations have been forced to divert "time, energy, and resources" away from their ordinary mission—educating the public "about the dangers of surgical abortion, the conscience rights of doctors, and the sanctity of life at all stages," ROA.164–66—and instead "conduct[] their own studies and analyses of the available data" to share accurate information on chemical abortions with member physicians, their patients, and the public. ROA.164. For instance, Plaintiffs expended "considerable time, energy, and resources" on their 92-page petition and 30-page response challenging FDA's 2000 Approval as well as their 26-page petition challenging the 2016 Major Changes. ROA.164–65.

Plaintiffs' ability to pursue their pro-life mission was "perceptibly impaired" by this resource diversion. *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." *Id.*; 13A Charles Alan Wright & Arthur R. Miller, Fed. Prac.

& Proc. § 3531.9.5 (3d ed. 2023) (standing where "organization has devoted specific effort and expense to combat the challenged activity.").

FDA lobs a broad-side attack on organizational standing, contending that a "diversion of resources" is insufficient. FDA.Br.31. But that contention is wildly out of step with the Supreme Court and circuit precedent cited above.

FDA next minimizes the injury here as mere changed "reporting requirements." FDA.Br.31. This short-changes the organizational harm—Plaintiffs "calibrated [their] outreach efforts to spend extra time and money educating its members about [the dangers of chemical abortion] and how to avoid their negative effects." *OCA-Greater Houston*, 867 F.3d at 610. Plus, omitting the reporting requirement is far from the only action undertaken by FDA to usher in an era of mail-order abortion that harms women and their doctors.

Danco complains that Plaintiffs cannot claim organizational standing because Plaintiffs oppose abortion. Danco.Br.30–31. 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.*, *OCA-Greater Houston*, 867 F.3d at 610; *Tex. State LULAC v. Elfant*, 52 F.4th 248 (5th Cir. 2022).

II. Plaintiffs' claims are timely.

The district court correctly found that Plaintiffs' claims are timely because the doctrines of reopening and equitable tolling apply. It likewise was correct in concluding that Plaintiffs satisfied any exhaustion requirement.

A. Reopening

This Court has adopted "the well-established reopening doctrine." *Texas v. Biden*, 20 F.4th 928, 951–55 (5th Cir. 2021), *rev'd in part on other grounds*, 142 S. Ct. 2528 (2022). The doctrine "create[s] an exception to statutory limits on the time for seeking review of an agency's decision," *Nat'l Ass'n of Reversionary Prop. Owners v. Surface Transp. Bd.*, 158 F.3d 135, 141 (D.C. Cir. 1998) (cleaned up), and "allows an otherwise untimely challenge to proceed where an agency has—either explicitly or implicitly—undertaken to reexamine its former choice," *Nat'l Biodiesel Bd. v. EPA*, 843 F.3d 1010, 1017 (D.C. Cir. 2016) (cleaned up). Indeed, "the time for seeking review starts anew where the agency reopens an issue." *Sierra Club v. EPA*, 551 F.3d 1019, 1024 (D.C. Cir. 2008). As the district court noted, "[t]he reopening doctrine has been applied in the adjudication context where an agency undertakes a serious, substantive reconsideration of a prior administrative decision." ROA.4326 (cleaned up).

A court "must look to the entire context … to determine whether an issue was in fact reopened." *Pub. Citizen v. Nuclear Regul. Comm'n*,

901 F.2d 147, 150 (D.C. Cir. 1990). If an agency "altered its original decision," it "reopened the proceeding." *Sendra Corp. v. Magaw*, 111 F.3d 162, 167 (D.C. Cir. 1997); *see also Nat'l Biodiesel Bd.*, 843 F.3d at 1017 (asking whether "the basic regulatory scheme remains unchanged"). That includes agency actions that later "removed … necessary safeguards." *Sierra Club*, 551 F.3d at 1025.

Both the 2016 Major Changes and the 2021 Petition Response reopened the 2000 Approval, each time resetting the six-year statute of limitations to sue FDA over the 2000 Approval. And the 2016 Major Changes became a final agency action only upon issuance of the 2021 Petition Response. *See* 21 C.F.R. § 10.45(b).

1. Reopening under the 2016 Major Changes

In response to Danco's sNDA, FDA completely revised the predicate terms and conditions that served as the basis for the 2000 Approval. ROA.172–73, 175. The 2016 Major Changes involved at least nine significant changes to the regimen, gutting the safeguards that FDA determined were necessary to approve mifepristone. *See supra* at 8–9.

The 2016 Major Change's "entire context" show that FDA expressly considered whether to revoke its 2000 Approval. For 14 years, FDA "carefully considered" the 2002 Citizen Petition's request to revoke the 2000 Approval. ROA.635. FDA ultimately decided to deny the 2002 Citizen Petition *on the same day* the agency issued its 2016 Major

Changes. *Id*. Those same-day decisions demonstrate that the FDA considered the 2000 Approval in tandem with the 2016 Major Changes and substantively reopened the 2000 approval. *See Growth Energy v. EPA*, 5 F.4th 1, 21 (D.C. Cir. 2021).

Because the 2016 Major Changes dramatically altered the "basic regulatory scheme" by removing "necessary safeguards," the agency also constructively reopened the 2000 Approval. *See Nat'l Biodiesel Bd.*, 843 F.3d at 1017; *Sierra Club*, 551 F.3d at 1025. Put another way, FDA "reopen[ed its 2000 Approval when] it remove[d] essential safeguards that had previously limited or contained the impact of" that Approval. ROA.4405. The 2016 Major Changes were nothing short of a "sea change" in the chemical abortion regimen. *See Nat'l Biodiesel Bd.*, 843 F.3d at 1017.

2. Reopening under 2021 Petition Response

The 2021 Petition Response reflected the FDA's final determination to remove the in-person dispensing requirement for mifepristone—effectively authorizing mail-order chemical abortions. This action reduced the prescriber's ability to confirm gestational age and diagnose ectopic pregnancies.

The district court rightly highlighted that "FDA's response to the 2019 Petition *explicitly* states FDA undertook a *full review* of the Mifepristone REMS Program in 2021." ROA.4328 (cleaned up). A "full review" under that program "necessarily considers the possibility that a

drug is too dangerous to be on the market, any mitigation strategy notwithstanding." ROA.4328–29. And that "full review"—another actual reopening of the 2000 Approval—is not surprising given that the 2019 Citizen Petition challenged multiple aspects of the 2000 Approval, in addition to requesting FDA "not further erode patient protections" by removing the in-person dispensing requirement.[6]

As with the 2016 Major Changes, FDA also constructively "reopen[ed its 2000 Approval when] it remove[d an] essential safeguard[ ] that had previously limited or contained the impact of" that Approval. ROA.4405. Removing this "necessary safeguard[]" restarted the statute of limitations. *Sierra Club*, 551 F.3d at 1025–26.

The district court correctly held that FDA reopened the 2000 Approval because (1) "FDA repeatedly altered its original decision by removing safeguards and changing the regulatory scheme for chemical abortion drugs," and (2) FDA's "full review" in 2021 "reaffirmed its prior actions after undertaking a substantive reconsideration of those actions." ROA.4328–29.

[6] In its time-sensitive review, the stay panel understandably missed that the 2019 Citizen Petition asked FDA to "strengthen" the conditions of the 2000 Approval and "retain" the remaining REMS. *Contra* ROA.4403 (stating that "plaintiffs only asked FDA to restore the pre-2016 status quo ante").

B. Equitable tolling

The district court also correctly held that equitable tolling was appropriate given FDA's decades-long pattern of delay and obfuscation. ROA.4330–31. A litigant is entitled to equitable tolling where two factors are established: "(1) that he has been pursuing his rights diligently, and (2) that some extraordinary circumstance stood in his way and prevented timely filing." *Menominee Indian Tribe of Wis. v. United States*, 577 U.S. 250, 255 (2016) (cleaned up).

FDA's delay-and-dodge strategy in responding to Plaintiffs' 2002 Citizen Petition and 2019 Citizen Petitions merit equitable tolling. *See WildEarth Guardians v. U.S. Dep't of Just.*, 181 F. Supp. 3d 651, 670 (D. Ariz. 2015) (finding that "the statute of limitations, pursuant to 28 U.S.C. § 2401(a), is subject to equitable tolling in the context of an APA claim for judicial review"). FDA "moved the goalposts [in its 2016 Major Changes] … on the *same day* it issued its [2016 Petition Denial]" and then took an additional "2 years, 8 months, and 17 days to respond to the 2019 Petition which challenged those changes," only to remove the regimen's final safeguard. *See* ROA.4330.

C. Exhaustion

The APA's plain text directs parties to exhaust administrative remedies only where an agency rule "provides that the action … is inoperative" during the administrative challenge. 5 U.S.C. § 704; *see also Darby v. Cisneros*, 509 U.S. 137, 154 (1993) (exhaustion needed

"*only* when expressly required by statute or when an agency rule requires appeal before review and the administrative action is made inoperative pending that review." (emphasis in original)). And exhaustion is not an "absolute" requirement. *Myron v. Martin*, 670 F.2d 49, 52 (5th Cir. 1982); *Wash. Ass'n for Television & Child. v. FCC*, 712 F.2d 677, 680 (D.C. Cir. 1983). Courts retain "discretion to waive exhaustion" when (1) exhaustion is futile, (2) an agency abuses the administrative process, or (3) an agency's action is "patently in excess" of its authority. *Wash. Ass'n*, 712 F.2d at 681–82. All three exceptions apply here.

Plaintiffs' efforts to exhaust would have been "futile because the administrative agency [would have] clearly reject[ed] the claim." *Gulf Restoration Network v. Salazar*, 683 F.3d 158, 176 (5th Cir. 2012); *Carr v. Saul*, 141 S. Ct. 1352, 1361 (2021) ("[T]his Court has consistently recognized a futility exception to exhaustion requirements."). Despite federal regulations requiring FDA to respond to petitions within "180 days," 21 C.F.R. § 10.30(e)(2), FDA ignored Plaintiffs' original challenge to the 2000 Approval *for 14 years* before denying it while *simultaneously* removing further safeguards. It would have been "clearly useless" to challenge the 2000 Approval again in the 2019 Petition. *Tesoro Refin. & Mktg. Co. v. Fed. Energy Regul. Comm'n*, 552 F.3d 868, 874 (D.C. Cir. 2009). It's preposterous for Danco to argue that FDA's position on the 2000 Approval might have changed if Plaintiffs renewed their challenge

in the 2019 Petition. (And given that the 2019 Generic Approval relied on the same flawed data challenged in the 2000 Approval, that, too, would have been futile to challenge.)

What's more, Plaintiffs *did* renew some of those challenges, and Danco is wrong to suggest otherwise. As in the 2002 Petition, Plaintiffs' 2019 Petition pressed FDA to require ultrasounds—the safety precaution present in nearly every study on which FDA relied for its various decisions but did *not* include on mifepristone's label—and mandate meaningful adverse event reporting. ROA.745, 751. FDA's rejection of these renewed challenges shows the futility of re-challenging the 2000 Approval wholesale.

In addition to futility, FDA's abuse of the administrative process excuses exhaustion. There's nothing "novel," Danco.Br.39, about Plaintiffs seeking judicial review after an agency twice fails to timely meet its regulatory deadlines. And badly at that—taking 4,971 days to adjudicate a petition on a 180-day deadline is a "plain miscarriage of justice." *Hormel v. Helvering*, 312 U.S. 552, 558 (1941). Nor did FDA learn anything from its dilatory behavior, taking 994 days to resolve Plaintiffs' second petition.

Moreover, FDA's abuses frustrate the purposes behind exhaustion. FDA was given *plenty* of time—16 years in total—to "correct its own mistakes." *Woodford v. Ngo*, 548 U.S. 81, 89 (2006). Its belated petition responses undermine the efficiency exhaustion is supposed to promote.

Danco suggests Plaintiffs should have filed suit to compel FDA to act on their petitions and that failing to do so was somehow itself an "abuse[ ] of process." Danco.Br.40. But the entire point of the process is to *avoid* federal litigation. Danco would have Plaintiffs ping-pong between an agency dragging its feet and a federal court that Danco *also* insists shouldn't be involved.

Regarding Plaintiffs' Comstock Act claims, exhaustion was not required because, as the district court concluded, FDA's actions were "in excess of" its authority, "contrary to an important public policy extending beyond the rights of the individual litigants," and "inadequate." ROA.4333–37 (quoting *Myron*, 670 F.2d at 52 and *Coit Indep. Joint Venture v. Fed. Sav. & Loan Ins. Corp.*, 439 U.S. 561, 587 (1989)). Further, any petition on the issue would have been futile. Since *Dobbs*, the Biden Administration has consistently promoted mail-order abortion, ROA.4336–37, and since Plaintiffs filed this lawsuit, the FDA and Department of Justice have both considered and rejected Plaintiffs' position. ROA.2339-59, 4229.

III. Plaintiffs are likely to succeed on the merits.

A. FDA violated Subpart H's plain language.

FDA impermissibly used its accelerated authority under Subpart H to approve mifepristone. This pathway applies only to "certain new drug products that … treat[ ] serious or life-threatening *illnesses* and

that provide *meaningful therapeutic benefit to patients over existing treatments*." 21. C.F.R. § 314.500 (emphasis added). FDA's 2000 Approval violated Subpart H's plain language.

First, the plain language of Subpart H applies only to new drugs that treat "illnesses." Yet pregnancy is *not* an illness. ROA.4346. Whereas an illness refers to "sickness," an "unhealthy condition," or "a particular *abnormal* condition," pregnancy is the *opposite*: a "natural process" that "most women experience." ROA.4346, 4349. That pregnancies may cause serious medical conditions in some women "is materially different than classifying pregnancy *itself* as a serious or life-threatening illness *per se*." ROA.4347. "Even the Population Council argued to FDA that the imposition of Subpart H is unlawful because the plain meaning of these terms does not comprehend normal, everyday occurrences such as pregnancy and unwanted pregnancy." ROA.4348 (cleaned up). FDA's contrary-to-unambiguous-text interpretation deserves no deference. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) ("If uncertainty does not exist, there is no plausible reason for deference.").

In fact, Defendants admit "pregnancy is not an 'illness'" and argue instead that the preamble to the Subpart H final rule expanded the term "illness" to encompass "conditions." FDA.Br.46; Danco.Br.51. "But the Final Rule says no such thing." ROA.4346. And a preamble cannot override clear regulatory text. *Cuomo v. Clearing House Ass'n, LLC*, 557 U.S. 519, 533 (2009).

Second, chemical abortion drugs do not provide a "meaningful therapeutic benefit … over existing treatments." 21. C.F.R. § 314.500. The studies FDA relied on did not even "compare chemical abortion with surgical abortion to find such a benefit." ROA.4350–51.

Defendants instead argue that the "benefit" of a successful chemical abortion is the avoidance of surgery and anesthesia. FDA.Br.46; Danco.Br.51. But the avoidance of the existing treatment cannot itself be the benefit. ROA.4351 ("By defining the 'therapeutic benefit' solely as the avoidance of" surgery, FDA improperly guaranteed that it would satisfy prong two of Subpart H). Further, "chemical abortions are over fifty percent more likely than surgical abortion to result in an emergency room visit within thirty days." *Id.*

Importantly, the FDAAA did not affect whether mifepristone "was properly approved or authorized under Subpart H in the first place." ROA.4354. The FDAAA's grandfathering clause was a stopgap measure that did not approve any drug but merely eased the regulatory transition. As the district court explained, "Congress's *general* reiteration that dangerous drugs should carry a REMS did not codify FDA's *specific* approval of the mifepristone NDA." ROA.4354.

B. FDA's 2000 Approval, 2016 Major Changes, 2019 ANDA Approval, and 2021 Actions violated the FDCA and APA.

As discussed, *see supra* pp. 2–9, the FDCA requires that substantial evidence, adequate tests, and sufficient information show the safety and effectiveness of a drug "for use under the conditions prescribed … *in the proposed labeling*." 21 U.S.C. § 355(d) (emphasis added); *see also* 21 C.F.R. § 312.21(c) (pre-approval trials must "provide an adequate basis for physician labeling"). FDA focuses on only one of these requirements—21 U.S.C. § 355(d)(4)—when discussing its review of a new drug application. FDA.Br.43. But the other requirements also apply. 21 U.S.C. §§ 355(d)(1), (d)(2), (d)(5). FDA has no discretion to ignore its statutory obligations.

Under the APA, FDA "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (cleaned up). A court must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (cleaned up). In short, a court "must set aside any action premised on reasoning that fails to account for relevant factors or evinces a clear error of judgment." *Univ. of Tex. M.D. Anderson Cancer Ctr. v. HHS*, 985 F.3d 472, 475 (5th Cir. 2021)

(cleaned up). Those relevant factors include the FDCA's statutory requirements.

1. 2000 Approval

FDA's 2000 Approval relied on one U.S. trial and two French studies that all included safeguards not incorporated into the approved labeling. *See supra* at 3–5. FDA failed to offer any evidence, testing, or information—each required under the FDCA—to show the safety and effectiveness of mifepristone without these safeguards. This fails the APA's basic tenets. *See* 21 U.S.C. § 355(d); ROA.4356, 4362.

For example, even though the studies all included ultrasounds to confirm gestational age and diagnose ectopic pregnancies, the 2000 Approval failed to require one on mifepristone's label. ROA.4357–64.[7] Without any evidence, testing, or information, FDA deferred to abortion providers on whether to perform an ultrasound. *See supra* at 5. But "[t]he mere fact that other clinical methods can be used to date pregnancies does not support the view that it should be the provider's decision to decide which method—if any—is used to make this determination." ROA.4357–58. Indeed, "FDA has never denied that an ultrasound is the *most accurate* method to determine gestational age

[7] The district court also noted that FDA "'entirely failed to consider an important aspect of the problem' by omitting any evaluation of the psychological effects of the drug or an evaluation of the long-term medical consequences of the drug." ROA.4357 (citing *State Farm*, 463 U.S. at 43).

and identify ectopic pregnancies." ROA.4358. "[T]he fact that other clinical methods can be used does not mean that all such methods are equal in their accuracy and reliability." *Id.* FDA's refusal to require ultrasounds ignored "the relevant data" and failed to "articulate a satisfactory explanation for its action." *State Farm*, 463 U.S. at 43.

FDA also argues that clinical trials are sometimes "more restrictive" than the approved regimen because "this additional level of caution is exercised until the safety and efficacy of the product is demonstrated." FDA.Br.43. That may be true for preliminary studies, but not for the studies FDA uses to approve a new drug. In these pivotal trials, a 1-for-1 match may be unnecessary, but the FDCA still requires substantial evidence, sufficient information, and adequate tests supporting the safety and effectiveness of "the drug … used the way it would be administered when marketed." ROA.4355 (emphasis omitted).[8] Otherwise, FDA would be allowed to conduct real-world experiments on unsuspecting women in the general population. The FDCA demands more.

FDA's references to biopsies, liver function tests, and other measurements in studies are inapposite. FDA.Br.43–44. Those metrics evaluate adverse outcomes by screening for conditions before and after treatment (e.g., whether a drug causes cancer or liver abnormalities).

[8] *Glossary*, Weill Cornell Medicine, https://bit.ly/3NQUNtM (last visited May 5, 2023).

When no adverse condition is present post-treatment, FDA can find that the drug is safe and no longer measure for this non-existent adverse outcome. But the U.S. and French studies employed ultrasounds to screen for *actual* conditions that would exclude women from taking mifepristone. FDA had no evidence, testing, or information to justify omitting this crucial safeguard from mifepristone's label.

So Defendants resort to post-hoc rationalizations. ROA.1449–50; Danco.Br.44. For example, in 2016, FDA's Petition Denial "rel[ied] on a [later] study showing that clinicians rarely underestimate gestational age." ROA.1449–50. In addition, Danco now argues for the first time that the French studies modeled the approved regimen by deferring to the investigators' discretion whether to perform an ultrasound. Danco.Br.43–44. But FDA's 2000 Approval offered no such rationales. It is a "foundational principle of administrative law that a court may uphold agency action only on the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015).

Besides, FDA's post-hoc study "does nothing to support" FDA's approach to diagnosing ectopic pregnancies. ROA.4358–60. FDA also needed the U.S. study to "confirm[] the effectiveness and safety of [mifepristone]." ROA.591. And to Plaintiffs' knowledge, the French trials neither included the total number of women who received ultrasounds nor differentiated the outcomes for these differently

situated women. FDA thus could draw no conclusions from these studies on whether to exclude ultrasounds from the approved regimen.

The 2000 Approval also failed to comply with the FDCA's requirement for a risk-benefit assessment. 21 U.S.C. § 355(d). FDA offered only the purported "benefit" of "avoidance of surgical procedure." ROA.595. But as discussed above, *supra* at 47–48, this benefit is illusory. And FDA's post-hoc justification that pregnancy has a "death rate 14 times higher" than abortion, FDA.Br.42, is inaccurate. ROA.298–311, 4226, 4278–94.

The district court also highlighted how FDA initially had its own reservations about the safety of mifepristone. ROA.4357. In February 2000, for example, FDA determined that it lacked "adequate information" to demonstrate the safety and effectiveness of mifepristone. ROA.4361. In June 2000, FDA sent a list of requirements to Danco that it considered necessary to treat post-abortion complications along with the requirement that prescribing physicians be able to accurately assess gestational age via ultrasound. ROA.405. But when that list was publicly leaked, FDA bowed to political pressure and approved mifepristone just three months later without *any* ultrasound requirement or *any* of its recommended post-abortion complication safeguards. *Id.*

The district court was correct to conclude that "FDA acquiesced on its legitimate safety concerns—in violation of its statutory duty—based

on plainly unsound reasoning and studies that did not support its conclusions." ROA.4363. The 2000 Approval was not "the product of reasoned decisionmaking" and "[t]o hold otherwise would be 'tantamount to abdicating the judiciary's responsibility under the [APA].'" ROA.4364 (quoting *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995)). The 2000 Approval violated the APA because it was not in accordance with the FDCA and was arbitrary and capricious.

2. 2016 Major Changes

In 2016, FDA agreed to Danco's request to make "major," "interrelated" changes to the mifepristone regimen. ROA.4230–46. But *none* of the studies on which FDA relied evaluated the interrelated 2016 Major Changes *as a whole* or under the conditions prescribed in the proposed labeling. *Id*. And FDA never explained how a piecemeal approach to studying these major, interrelated changes satisfied the FDCA's requirements. *Id*. Defendants do not dispute these facts.

Though Defendants point to a few studies that evaluated "multiple changes," they are ultimately left arguing that FDA did not need to study the changes as a whole—precisely because no study did. FDA.Br.48–50; Danco.Br.45–46. This matters. For example, Plaintiffs challenged FDA's decision to increase the maximum gestational age while switching to buccal administration of misoprostol because it would increase complications, especially at gestational ages greater

than 49 days. ROA.743–44.[9] Recognizing this fundamental flaw, FDA cites two studies that allegedly "closely mirrored the 2016 conditions." *Id.* But these studies incorporated crucial safeguards that FDA either never required or removed in 2016: ultrasounds to determine gestational age (and identify ectopic pregnancies) and follow-up exams to identify and treat complications (including surgery to remove "persistent non-viable pregnancy or substantial debris"). *See supra* at 7–9.

The district court thus correctly concluded that the 2016 Major Changes violated the APA "[f]or similar reasons as the 2000 Approval." ROA.4365. FDA "rel[ied] on studies that included the very conditions that FDA refused to adopt"—including ultrasounds and in-person follow-up exams. *Id.* "FDA built on its already-suspect 2000 Approval by removing *even more* restrictions related to chemical abortion drugs that were present during the final phase of the investigation." *Id.*

The stay panel agreed that the 2016 Major Changes violated the APA. ROA.4412. Even though "FDA studied the safety consequences of eliminating one or two of the 2000 Approval's REMS in *isolation*," the FDA "relied on zero studies that evaluated the safety-and-effectiveness

[9] FDA claims it "changed other conditions of use that plaintiffs have not challenged." FDA.Br.50–51. That is incorrect. *See* ROA.743–44, 747–48 (expressing concerns with FDA's decision to change the dosages, expand the window to take misoprostol, switch to buccal administration, and allow ingestion of misoprostol without medical supervision).

consequences of the 2016 Major [ ] Changes *as a whole*." *Id.* "This deficiency shows that FDA failed to consider 'an important aspect of the problem' when it made the 2016 Major [ ] Changes." *Id.* (quoting *Michigan v. EPA*, 576 U.S. at 752).

Defendants argue that courts should defer to FDA's "scientific expertise." FDA.Br.38; Danco.Br.48. But an agency's "experience and expertise … do not substitute for" reasoned decisionmaking. *CS Wind Viet. Co., Ltd. v. United States*, 832 F.3d 1367, 1377 (Fed. Cir. 2016). FDA does not "have unfettered discretion to approve dangerous drugs under substantially different conditions than the tests, trials, and studies cited." ROA.4365–66. Under the APA, FDA "must cogently explain why it has exercised its discretion in a given manner, and that explanation must be sufficient to enable [the Court] to conclude that the [agency's action] was the product of reasoned decisionmaking." ROA.4366 (quoting *A.L. Pharma*, 62 F.3d at 1491 (quotations omitted)). "Defendants have not done so here." *Id.*

In addition to changing the mifepristone regimen, the 2016 Major Changes eliminated the requirement for prescribers to report non-fatal adverse events. ROA.724. FDA justified this decision by asserting that "after 15 years of reporting serious adverse events, the safety profile of Mifeprex is essentially unchanged." *Id*. But FDA did not explain how it could remove this requirement considering the major, interrelated changes the agency was simultaneously making to the regimen.

Defendants post-hoc contention that the two drug sponsors remain obligated to report adverse events (FDA.Br.47, Danco.Br.47) belies the reality that these sponsors lack any meaningful ability to track complications. Nowhere near America's emergency rooms, these companies rely entirely on others to report, and those "others" have no reporting obligation. FDA's decision to eliminate this reporting requirement was arbitrary and capricious. ROA.4365, 4412.

3. 2019 ANDA Approval

Under the FDCA, FDA may approve a generic version of an approved drug if (1) the proposed labeling matches the approved labeling, and (2) the drugs are chemically the same—allowing the generic sponsor to rely on FDA's previous findings of safety and effectiveness for the approved drug. 21 U.S.C. § 355(j); 21 C.F.R. § 314.94. If FDA withdraws the listed drug on which the ANDA-approved generic is based, FDA is generally required to withdraw the generic drug as well. 21 U.S.C. § 355(j)(6); 21 C.F.R. § 314.151.

Because the 2019 ANDA Approval relied on the unlawful 2000 Approval and the unlawful 2016 Major Changes, the 2019 ANDA Approval is also unlawful.[10] The district court agreed that the 2019 ANDA Approval is unlawful because "Plaintiffs have a substantial

[10] Defendants failed to respond to the merits of this challenge in the district court and thus waived any objection. ROA.4224.

likelihood of success in their challenges to the 2000 and 2016 Actions." ROA.4366. This Court should do the same.

4. 2021 Actions to remove in-person dispensing

FDA's 2021 actions to remove the in-person dispensing requirement relied on fatally flawed datasets. ROA.787–88, 827–28.

First, FDA relied on FAERS data "despite the agency's 2016 decision to eliminate the requirement for abortionists to report non-fatal 'adverse events,'" ROA.4344–45, *and* despite FDA's admonition that "FAERS data cannot be used to calculate the incidence of an adverse event … in the U.S.," among other limitations. ROA.144, 845. Defendants again hide behind the cover of "scientific" deference. FDA.Br.54; Danco.Br.48. But "it is circular and self-serving to practically eliminate an 'adverse event' reporting requirement and then point to a low number of 'adverse events' as a justification for removing even *more* restrictions than were already omitted in 2000 and 2016." ROA.4345. It's also "unreasonable." ROA.4412.

Second, by its own admissions, *see supra* at 7–9, FDA relied on studies that were "not adequate on their own to establish safety of the model of dispensing mifepristone by mail." ROA.837. Even more troubling, FDA's reliance on these studies had its obligations upside-down. It said that "[d]espite the limitations of the studies … the outcomes of these studies *are not inconsistent with our conclusion* that

… mifepristone will remain safe." ROA.830 (emphasis added). But it is FDA's burden to show that the studies *establish* safety.

Third, Defendants also rely on "data from the drug's sponsors." FDA.Br.55. FDA asked mifepristone's manufacturers for "additional information" to "better understand whether there was any impact on safety or non-compliance" during the time when in-person dispensing was not enforced per court order (May 2020 to January 2021). ROA.827–28. Not surprisingly, Danco and GenBioPro reported the same adverse events that were already in FAERS. But again, *no one* is required to report adverse events to these companies. *See* ROA.4344–45; ROA.4412 (FAERS unreliable because FDA "practically eliminate[d] an 'adverse event' reporting requirement"). Doubling down on the same unsound data doesn't make it *more* reliable.

To rely on such flawed data and reasoning is the epitome of arbitrary and capricious action. It certainly does not come close to the substantial evidence, adequate testing, and sufficient information the FDCA requires. Therefore, the district court correctly held that the 2021 Non-Enforcement Decision and 2021 Petition Response were unlawful. ROA.4345.

C. FDA's actions violate the Comstock Act

The Comstock Act prohibits the mailing or delivery of "[e]very article or thing designed, adapted, or intended for producing abortion." 18 U.S.C. §§ 1461–62. The Act's plain text explicitly forbids what FDA

approved in 2021—namely, mailing abortion drugs.[11] That should end the analysis. *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004) (statutory interpretation "begins with the statutory text, and ends there as well if the text is unambiguous"). By permitting mail-order abortion, FDA did not act "in accordance with law." 5 U.S.C. § 706(2)(A).

Defendants cannot muddy these clear waters with extratextual references to the Act's context or historical understandings. When interpreting a statute, the text is paramount, "always the alpha" and "the omega," *In re DeBerry*, 945 F.3d 943, 947 (5th Cir. 2019); it alone "offers a fixed standard" for what Congress enacted into law, *Dobbs*, 142 S. Ct. at 2245. And though context and history can play important roles in understanding that text, they cannot be used to frustrate the text's clear, original meaning. *N.Y. State Rifle & Pistol Ass'n v. Bruen*, 142 S. Ct. 2111, 2137 (2022). When that statutory language is "plain," the courts' job to interpret it "is at an end." *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1749 (2020).

FDA gets the Act's context and history wrong. Start with the statutory context. FDA looks at three different provisions within the Comstock Act—one that originally modified the word abortion with

[11] The FDA's 2000 Approval also required and approved a distribution plan for the delivery of chemical abortion drugs by mail, express company, or common carrier. ROA.113.

"unlawful," one that did not, and one that was later amended to say "unlawful abortion"—and argues that they all mean the same thing. But this context shows the *opposite*. Congress knew when to use the word "unlawful." *Cargill v. Garland*, 57 F.4th 447, 460 (5th Cir. 2023) (en banc). It also knew how to amend the Act to include the word unlawful when it "intend[ed] [it] to apply." *See Jama v. ICE*, 543 U.S. 335, 341 (2005). That Congress chose not to include the word "unlawful" in the mailing provision or later amendment shows that Congress *did not want to use that word*.

FDA's interpretation badly mars the Comstock Act's original meaning. Even if Congress intended the mailing provision to prohibit drugs used only for "unlawful abortions," that phrase must be given its original, not modern, meaning. *Bostock*, 140 S. Ct. at 1738. When in 1873 Congress enacted the Act, "abortion had long been a *crime* in every single State" and "was regarded as unlawful." *Dobbs*, 142 S. Ct. at 2248. Whatever morays developed about abortion later, in 1873—the operative time to understand the Act's original meaning—this broad prohibition reflected "the attitude of a large segment of public opinion on this matter." *Poe v. Ullman*, 367 U.S. 497, 546 n.12 (1961) (Harlan, J., dissenting). Nearly every abortion was "unlawful."

Given this context and history, even FDA admits that the Act's original language flatly prohibited mailing abortion-related drugs. FDA.Br.57. Yet Defendants persist with another contention: when FDA

acted, "multiple courts of appeals and OLC … interpreted the statute to restrict only the sending of items intended for *unlawful* abortions," so FDA was justified to read the Act that way, too. Danco.Br.56. But reading the word "unlawful" into the Act only gets Defendants halfway to their proposed solution; they also have to show that mifepristone would not cause an "unlawful abortion," as that phrase would have been understood *in 1873*. And yet the cases Defendants rely on all interpreted the Comstock Act in accordance with its original meaning. *Bours v. United States*, 229 F. 960, 964 (7th Cir. 1915) (holding that "the word 'abortion' in the national statute must be taken in its general medical sense … indicat[ing] a national policy of discountenancing abortion as inimical to the national life," with exceptions only "in the interest of national life"); *Davis v. United States*, 62 F.2d 473, 474 (6th Cir. 1933) (Comstock Act does not prohibit devices that could be used for abortion but are instead prescribed for "proper medical purposes"); *United States v. One Package*, 86 F.2d 737, 739 (1936) (reading the statute to "embrace[ ] only such articles as Congress would have denounced as immoral if it had understood all the conditions under which they were to be used," including "articles for producing abortion[s]").

Alternatively, FDA suggests that Congress silently ratified these courts' interpretation when it "repeatedly amend[ed] the Comstock Act without material change *after* that construction had been called to the

attention of Congress." FDA.Br.58 (cleaned up). Yet "the most obvious way for Congress to have ratified the supposed 'consensus interpretation' would have been to add the word unlawful to section 1461." ROA.4180 (Ethics and Public Policy Center Amicus Br.). Indeed, Congress unsuccessfully tried that in 1978. *Id.* In any event, "the reenactment canon does not override clear statutory language." *Oklahoma v. Castro-Huerta*, 142 S. Ct. 2486, 2498 (2022). This is especially true when the contrary construction was based on a smattering of old court of appeals opinions. And the cases FDA relies upon for the supposed consensus do not show that "unlawful" meant anything different than it would have in 1873.

The only way Defendants equate "unlawful" with something less than its original meaning is to point to *Roe v. Wade*, 410 U.S. 113 (1973), *overruled by Dobbs*, 142 S. Ct. at 2242. Defendants insist that FDA could ignore the Comstock Act because, when FDA acted, "*Roe v. Wade* was governing law." Danco.Br.55. But as the district court correctly noted, *Roe* "did not prohibit *all* restrictions on abortion." ROA.4344. The *Roe*/*Casey* regime prohibited only "undue burdens" on abortion. Defendants identify no court that held the Comstock Act unlawful, nor do they argue that prohibiting mail-order abortion constitutes an undue burden (a hard argument to make, given the availability of surgical abortion). FDA cannot use *Roe* as a shield for its unlawful actions.

Nor can FDA use the FDAAA as an excuse to ignore federal law. The agency contends that Congress "superseded any application of the Comstock Act to mifepristone." FDA.Br.61. Not so. The FDAAA created a new regulatory framework for dangerous drugs. To help ease the regulatory transition, Congress "deemed" prior safeguards for dangerous drugs generally adequate—but only until FDA could comply with the new regulatory guidelines. This grace period says nothing about the specific approval for chemical abortion drugs. *Environmental Integrity Project v. EPA*, 969 F.3d 529, 545 (5th Cir. 2020) (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001)) (Congress does not "alter the fundamental details of a regulatory scheme in vague terms or ancillary provision").

Finally, FDA does not get to ignore the Comstock Act merely because the FDCA doesn't mention it. The APA requires that FDA abide by "*any* law, and not merely those laws that the agency itself is charged with administering." *FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003) (emphasis in original).

IV. The equities favor Plaintiffs

Defendants' equities analyses assume that they are correct on the merits and about mifepristone's safety. Given that Plaintiffs are likely to prevail on the merits, and the district court did not commit clear

error in concluding that mifepristone is and has always been dangerous to women and girls, the equities weigh decisively in Plaintiffs' favor.[12]

A. Neither FDA nor Danco can show irreparable injury.

FDA did not claim any irreparable harm to itself either before the district court or before this Court in requesting an emergency injunction on appeal. ROA.4413 ("FDA does not articulate any irreparable harm that *FDA* will suffer absent a stay."). But FDA now changes course and articulates two supposed harms: (1) blocking the agency "from fulfilling its statutory responsibilities consistent with its scientific judgment," FDA.Br.66, and (2) imposing "costs [to make necessary adjustments to the regulatory scheme] that would be incurred again if the [district] court's conclusions are ultimately reversed," *id.* at 66–67.

The first alleged harm is entirely derivative of the merits. The district court held that FDA did *not* fulfill its statutory responsibilities, did not exercise scientific judgment, and instead acted in arbitrary and capricious ways. ROA.4339–41; Argument § III, *supra*. Requiring FDA to comply with the law is not an irreparable harm but an ordinary exercise of the judicial function.

[12] The district court's § 705 order is not a "disfavored" mandatory injunction. *Contra* Danco.Br.56. Every drug's "status quo" is a presumption of illegality until FDA approves it through a lawful procedure. The fact that FDA stonewalled judicial review does not make FDA's unlawful approval the status quo.

Nor is a government agency's expenditure of bureaucratic time and money an irreparable injury. *Al Otro Lado v. Wolf*, 952 F.3d 999, 1008 (9th Cir. 2020). At best, a diversion of an agency's "time, resources, and personnel from other pressing" projects is a "minimal" harm. *Hernandez v. Sessions*, 872 F.3d 976, 995 (9th Cir. 2017).

As for Danco, it claims economic harm if it cannot distribute mifepristone. Danco.Br.56–57. But 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. ROA.3382–88. Danco then lobbied FDA to remove several crucial safeguards and completely revise the regimen in the 2016 Major Changes. ROA.698–725. And Danco continues to distribute chemical abortion drugs in violation of the Comstock Act. 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.

If this Court enjoins only the 2016 or 2021 actions, Danco then complains that "[d]istributing a misbranded product will expose Danco to severe civil or criminal penalties," and that procuring FDA approval for a new label would take too much time. Danco.Br.57.[13] But the

[13] In support, Danco cites a declaration from Janet Woodcock, Danco.Br.57, but the district court never saw that declaration because it was first filed with the United States Supreme Court. Further, Ms. Woodcock is hardly a disinterested bureaucrat. She is a named Defendant who served as (1) Director of FDA's Center for Drug

consequences of failing to comply with applicable federal law cannot count as irreparable harm. Further, if this Court leaves FDA's 2000 Approval in place, staying only later FDA actions that unlawfully removed protections designed to keep women safe, then the operable standards are the 2011 REMS. Labels and documents that comply with those REMS have already been approved and could be speedily deployed.

B. The district court's order prevents irreparable harm to Plaintiffs.

As explained in section I, *supra*, Plaintiffs face imminent irreparable harm from the 2000 Approval and FDA's elimination of mifepristone's safety standards. The number of women harmed is *not* a "tiny number." Danco.Br.61. Moreover, "the time, energy and resources that Plaintiff medical associations expend in response to FDA's actions on chemical abortion drugs cannot be recovered." ROA.4367–68. And an unlawful agency action under the APA "almost always produces [ ] irreparable harm." *Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016).

Defendants' delay criticisms are ironic given that FDA waited a combined 16 years to respond to Plaintiffs' petitions. FDA.Br.68–69; Danco.Br.62. Those criticisms miss the mark in any event. It was

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Evaluation and Research during the 2000 Approval and 2016 Major Changes and (2) FDA Acting Commissioner during the challenged 2021 actions.

eminently sensible for Plaintiffs to request the modest additional time that would have allowed the district court to efficiently rule on the merits. Such a course would have resulted in a final judgment rather than an interlocutory order. As Plaintiffs explained in their proposal, "prompt[ ]" consolidation of the preliminary injunction hearing, "swift" production of the administrative record, and "expedit[ion]" of the case for trial would result in a merits ruling "without introducing further delay—delay which will result in continued harm to women and girls." ROA.3243. It was also sensible to expeditiously gather evidence before filing suit. Plaintiffs should not be punished for encouraging speedy and efficient resolution to prevent more harm.

C. The district court's order prevents irreparable harm to women, girls, and 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. HHS*, 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) (cleaned up). And "the public interest weighs strongly in favor of preventing unsafe drugs from entering the market." *Hill Dermaceuticals, Inc. v. FDA*, 524 F. Supp. 2d 5, 12 (D.D.C. 2007).

To counter this point, Defendants say the district court's order harms women who seek mifepristone. FDA.Br.63–65; Danco.Br.58–59.

But they "are not stay applicants in this case." ROA.4413. And far more important, the evidence shows that the harm runs the opposite way. *See Deerfield Med. Ctr. v. City of Deerfield Beach*, 661 F.2d 328, 338 (5th Cir. 1981) (finding irreparable harm to third-party pregnant women). As the district court found, chemical abortions "are over fifty percent more likely than surgical abortion to result in an emergency room visit within thirty days," and chemical abortions produce "far higher rates of hemorrhaging, incomplete abortion, unplanned surgical evacuation," "pain, nausea, vomiting and diarrhea." ROA.4351–53; *accord* ROA.3911–15 (collecting studies).

There are also serious mental health impacts. ROA.4352. Unlike surgical abortions, "a mother sees the remains of her aborted child … which add[s] to the psychological pain that is unique to medication abortion," a pain compounded by the reality that "women are often alone when they experience the effects of the medication abortion," isolated even "from in-person physician interaction." ROA.3731–34 (Human Coalition Amicus Br.) (citing medical studies and collecting women's stories when, following a chemical abortion, they saw their intact, fully formed babies dead and covered in blood). And it is well documented that human sex traffickers use chemical abortions to coerce and force women to have abortions. ROA.3734–37.

This harm is not limited to FDA's 2000 Approval. *Just since the 2016 Major Changes*, the rate of women and girls suffering

complications due to chemical abortion and requiring critical medical treatment has and will continue to increase. ROA.232, 244, 267, 288, 295, 938, 953–54, 961. As explained above, FDA's decision to expand the gestational age for mifepristone use while eliminating in-person dispensing and follow-up visit requirements is dangerous and harmful. ROA.287, 958–59. It is not irreparable harm to protect women from a dangerous drug. *Contra* FDA.Br.64.

In sum, FDA has eliminated all safeguards that gave abortion providers the opportunity to rule out ectopic pregnancies, verify gestational age, and identify any contraindications to prescribing mifepristone. It also eliminated the follow-up care that once allowed doctors to identify complications like sepsis, hemorrhaging, or 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 nearest hospital. ROA.254, 277–79, 281, 296, 945–46, 958–59, 961. The public interest weighs conclusively in favor of Plaintiffs.

While dismissing Plaintiffs' standing, FDA claims that limiting mifepristone would harm abortion providers by causing many of the same injuries to their medical practice and the healthcare system as those alleged by Plaintiffs. FDA.Br.65. But it is FDA's burden to make that showing on appeal, and it offers no evidence to show why restricting or limiting mifepristone's availability will be a greater

burden on the healthcare system than providing emergency and follow-up treatment to women who take mifepristone.

Defendants further assert that the district court's stay jeopardizes "medical innovation" in the biopharmaceutical industry, since the stay shows that courts "can overturn drug approvals without regard for science or evidence." FDA.Br.65–66; Danco.Br.59. But that is the exact opposite of what happened here. The district court meticulously reviewed the science and evidence and reasonably concluded that women and girls are being harmed. ROA.4351–53. The public does not benefit from medical innovation that disregards red flags in drug studies.

Finally, Danco claims that vacating the district court's stay order promotes federalism and the separation of powers. Danco.Br.60–61. Not so. FDA has imposed a mail-order elective-abortion policy on the country, violating the promise of *Dobbs*. As the amici states have explained, FDA's actions cast aside the "considered judgments by elected [state] representatives on how to address the health interests at stake." ROA.3842 (Mississippi Amicus Br.). Given chemical abortion risks, states have required in-person examinations, physician administration, and follow-up care. ROA.3843–44. Others prohibit chemical abortion entirely. *Id.* Yet FDA's mail-order abortion scheme renders all these protections for life, health, and safety meaningless. *See* Alice Miranda Ollstein & Lauren Gardner, *Retail Pharmacies Can*

Now Offer Abortion Pill, FDA Says, Politico (Jan. 3, 2023), http://bit.ly/3wCPl3V ("Telemedicine and mail delivery of the pills has allowed patients to circumvent state bans."). Evading state law is *not* a public interest. ROA.3845–48. It also conflicts with the Comstock Act. The public interest strongly weighs against FDA.

D. The district court issued an appropriate remedy.

FDA argues that the district court erred in granting a stay under § 705 because Plaintiffs did not first request a stay from FDA itself. FDA.Br.62. This argument fails for the same reasons FDA's other exhaustion defenses fail. "Requiring Plaintiffs to exhaust their administrative remedies may equate to another decade-plus of waiting for the agency to give them the time of day." ROA.4336. In addition, any such request would "be futile because [FDA] will clearly reject the [request]." ROA.4336–37 (citation omitted).

Alternatively, FDA asserts, with no case citation, that a § 705 stay "must be contemporaneous with the challenged action, not years or decades later." FDA.Br.62–63. Nothing in 5 U.S.C. § 705 says that. To the contrary, the statute authorizes a reviewing court to "issue all necessary and appropriate process," which is precisely what the district court did.

Finally, FDA says § 705 relief "is intended to preserve the status quo pending judicial review, not, as here, dramatically upend it." FDA.Br.63. But the relevant statutory language authorizes a reviewing

court to issue all necessary relief "to postpone the effective date of an agency action *or* to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705 (emphasis added). Here, the district court entered a stay to postpone the effective date of FDA's mifepristone approval and subsequent decisions removing virtually all safety restrictions, precisely as § 705 authorizes. And the court did so to preserve Plaintiffs' rights pending a merits ruling. There is nothing improper about such relief.

Danco, but not FDA, argues that the only appropriate remedy if Plaintiffs prevail is remand to the agency without vacatur. Danco.Br.61 (citing *Cent. & S. W. Servs. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000)). But "unsupported 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). And FDA agrees with that principle. *See* Defs.' Resp. in Opp'n to Mot. Prelim. Inj. at 32, *Washington v. FDA*, No. 1:23-cv-3026-TOR (E.D. Wash. Mar. 17, 2023) (FDA arguing that "when a party prevails on its APA challenge, the proper remedy—even in the context of a preliminary injunction [request]—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 do 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)). Remand without vacatur "invites agency indifference." *In re Core Commc'ns, Inc.*, 531 F.3d 849, 862 (D.C. Cir. 2008) (Griffith, J., concurring). If FDA had data to substantiate its decision and rebut Plaintiffs' medical evidence, it would have proffered it below. Because FDA didn't produce the necessary data, Danco wrongly asserts that the district court awarded "more relief than would be available on the merits." Danco.Br.61. *E.g.*, *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891 (2020) (affirming judgment awarding plaintiffs vacatur of arbitrary and capricious agency decision).

CONCLUSION

The district court should be affirmed in all respects.

Respectfully submitted,

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This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and Circuit Rule 32 and the Court's Order dated May 2, 2023 expanding word limit because it contains 15,821 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), as determined by the word counting feature of Microsoft Office 365.

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Dated: May 8, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on May 8, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the CM/ECF system, which will accomplish service on counsel for all parties through the Court's electronic filing system.

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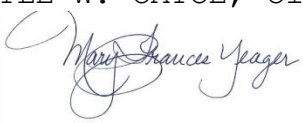

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