No. 23-10362

IN THE 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 & 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

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INTRODUCTION AND SUMMARY

By plaintiffs' telling, the Nation's emergency rooms are overflowing with women injured by mifepristone. But Americans have been safely using mifepristone for over two decades. More than five million women in the United States have used mifepristone to terminate their pregnancies, as have millions of other women around the world. And study after study has shown that serious adverse events are exceedingly rare.

Plaintiffs lack standing to raise any of their challenges to FDA's regulation of mifepristone. Plaintiffs oppose abortion and therefore oppose mifepristone. But they do not face imminent future harm based on other individuals' independent decisions to prescribe or use that drug. Plaintiffs' own declarants have not even experienced the harms on which plaintiffs rest their standing arguments. The possibility that some women might at some point seek care from some plaintiff doctors for exceedingly rare adverse events is not a legally cognizable injury. And it is impossible to reconcile plaintiffs' probabilistic approach to standing with controlling Supreme Court precedent. Nor can plaintiffs shore up their standing by characterizing mifepristone as unsafe. Their

anecdotes and flawed studies do nothing to make their injuries less speculative, especially when weighed against the decades of scientific evidence on which FDA relied.

Plaintiffs' central claims are also time-barred. FDA approved mifepristone in 2000 and denied plaintiffs' citizen petition challenging that decision in 2016. Plaintiffs waited more than six years to seek judicial review of those decisions. Allowing plaintiffs to challenge mifepristone's approval at this late date, after the drug has been on the market for over two decades, would be profoundly disruptive.

Plaintiffs offer no basis to overturn any of FDA's decisions. Bedrock principles of administrative law do not allow courts to second-guess FDA's scientific judgments about the safety of a drug based on isolated and anecdotal allegations from a handful of plaintiffs. Congress assigned to FDA the role of applying its scientific expertise to determine whether a drug is safe and effective. FDA fulfilled that statutory responsibility here, relying on scientific evidence including dozens of studies involving tens of thousands of women, to support its conclusions that mifepristone is safe and effective under the approved conditions of use.

The equities independently foreclose preliminary relief. Hundreds of amici in this Court and the Supreme Court have explained the profound and irreparable harms that the district court's order would impose: Women who rely on mifepristone to safely terminate their pregnancies and manage their miscarriages would no longer have access to a vital treatment option. State and local governments would see their healthcare systems overburdened as women are unnecessarily diverted to surgical abortions. Drug development would be undermined, throwing the pharmaceutical industry into a state of uncertainty and stifling innovation. FDA would be unable to fulfill its statutory duty to approve safe and effective drugs. In contrast, plaintiffs would suffer no irreparable harm by maintaining the status quo that has been in place for over two decades.

ARGUMENT

I. Plaintiffs' Claims Are Not Judicially Reviewable

A. Plaintiffs Lack Article III Standing

1. a. Plaintiffs lack associational standing. Plaintiffs seem to agree (at 16) that doctors ordinarily do not suffer Article III injury when they treat patients. Treating patients is their chosen profession. Just

as lawyers are not injured when they represent clients and engineers are not injured when they build bridges, emergency room doctors are not injured when they treat patients for medical emergencies. Any other conclusion would enable emergency room doctors to sue anyone whose actions relate to health and safety. FDA Br. 23-24.

Plaintiffs attempt to reframe their injury, arguing (at 18-20) that mifepristone's availability causes them to treat patients harmed by mifepristone and thus prevents them from treating other patients. But the plaintiff doctors do not suffer Article III injury when they treat one type of patient rather than another. An emergency room doctor's chosen profession is to treat whichever patients arrive in need of care; while other types of doctors might pick and choose their patients based on various factors, emergency room doctors treat patients based on the urgency of their medical conditions. Plaintiffs similarly argue (at 18) that the plaintiff doctors suffer "mental and emotional stress" when they treat patients who took mifepristone, but "stress" is an unavoidable reality of their chosen profession—and it is not "fairly traceable" to FDA's approval of mifepristone, or to the other events in the long chains of causation that result in particular patients'

presenting in emergency rooms. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 180 (2000).

Plaintiffs' reframed injuries are also just as limitless as a rule that doctors generally are injured by treating patients. Many of their theories of injury do nothing to distinguish the plaintiff doctors from any other emergency room doctor treating any other emergency room patient. Doctors would have standing to sue gun manufacturers, tobacco companies, and fast-food restaurants, asserting that they feel stress when they treat patients suffering gunshot wounds or complications from heart disease or diabetes, or that they would prefer to treat different patients. Even their conscience-based theory would dramatically expand Article III standing; for example, surely some doctors have sincerely held religious objections to the consumption of alcohol or tobacco, and they too could sue alcohol or tobacco companies—or regulators who allow third parties to purchase and consume those items—if treating injured patients makes them feel complicit in their patients' consumption of alcohol or tobacco.

b. Plaintiffs also have not established standing to seek prospective relief because they rely on a smattering of alleged past

harms. Plaintiffs claim that FDA's actions have (1) caused them to participate in elective abortions, contrary to their consciences; (2) caused them to feel stress; (3) interfered with their medical practices; and (4) increased their exposure to liability. But even assuming these past harms were experienced by identified plaintiffs (which plaintiffs' declarants have not even alleged, *see infra* pp. 9-14), past injury "does not suffice" to establish standing to seek prospective injunctive relief. *Summers v. Earth Island Inst.*, 555 U.S. 488, 495-96 (2009). Mifepristone has been widely available for over two decades and used by millions of women. Plaintiffs allege only sporadic incidents of treating anyone for complications from mifepristone, despite claiming to have thousands of members practicing around the country. Such infrequent and scattered past events do not demonstrate certainly impending future harm to any particular plaintiff doctor. FDA Br. 21-23.

Plaintiffs argue (at 29) that *Summers* "did not allow an injury" from a "settled claim." But while that was one holding of the case, plaintiffs ignore that *Summers* rejected *multiple* theories of standing. The Court first held that the association lacked standing based on

affidavits about the activities of "organization member Ara Marderosian" because "the parties settled their differences on that score." *Summers*, 555 U.S. at 494. The Court then turned to the allegations of another member, "Jim Bensman," who asserted "that he had suffered injury in the past." *Id.* at 495. The Court concluded that Bensman's past injury did "not suffice" because "it relates to past injury rather than imminent future injury that is sought to be enjoined." *Id.*

Summers also rejected the theory that the organization had standing because, "accepting [its] self-description of the activities of its members, there is a statistical probability that some of those members are threatened with concrete injury." 555 U.S. at 497-98. The Court explained that such a probabilistic theory would "make a mockery" of its Article III precedents. *Id.* Plaintiffs argue (at 30-31) that their injuries are not probabilistic because a few of their members allege past injury and "expect[]" to be injured again, but *Summers* did not hold that a plaintiff's mere expectation of future injury confers standing.[1]

[1] Plaintiffs suggest (at 20, 31-32) that they have demonstrated standing based on a "substantial risk" that the harm will occur, quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014). "But to the extent that the 'substantial risk' standard is relevant and is distinct

Marderosian, whose settled claims may have supported standing, "had repeatedly visited" an affected location in the past and "had imminent plans to do so again." *Id.* at 494. By contrast, the expectation that, as a statistical matter, *other* members of the organization might be injured in the future did not suffice. *Id.* at 497-98. Plaintiffs here similarly have not shown that an identifiable individual member has "imminent plans" to provide emergency medical care to other providers' patients who may experience exceedingly rare serious adverse events related to mifepristone. The plaintiff doctors may have "imminent and ongoing plans to continue providing obstetric care," AHM Br. 30-31, but that is not the same thing.

Nor does *Department of Commerce v. New York*, 139 S. Ct. 2551 (2019), support plaintiffs' standing. That case concerned a challenged government action that would have had the "predictable effect" of "depress[ing] the census response rate." *Id.* at 2565-66. The plaintiff

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from the 'clearly impending' requirement," it does not permit plaintiffs to demonstrate standing based on an "attenuated chain of inferences." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013). And, unlike the plaintiffs in *Susan B. Anthony List*, plaintiffs here "challenge[] a government action regulating someone *other* than the plaintiffs themselves," making it "substantially more difficult" for them to establish standing. *E.T. v. Paxton*, 41 F.4th 709, 719 (5th Cir. 2022).

States proved that the result, although dependent on the actions of third parties, would directly harm the States by causing them to "lose out on federal funds that are distributed on the basis of state population." *Id.* Here, FDA's approval of mifepristone may predictably lead third parties to prescribe and use mifepristone. But that would not cause any direct harm to any plaintiff doctor. Plaintiffs cannot rely on population-level effects; they must show that a particular doctor will suffer the alleged harm. But it is highly speculative that any patient will seek out or present to the plaintiff doctors following an exceedingly rare serious adverse event related to mifepristone. FDA Br. 19-30. And it is wholly improbable that they will do so in ways that implicate plaintiffs' specific theories of injury, whether by interfering with their medical practices or otherwise.

c. In any event, for most of their theories of injury, plaintiffs do not even claim to have suffered any past harm, much less demonstrate certainly impending future harm.[2]

[2] While plaintiffs claim to have suffered stress from treating patients in the past, the stress inherent in their chosen profession is not a cognizable Article III injury. *See supra* pp. 4-5.

First, plaintiffs contend (at 20-21) that FDA's actions have exposed the plaintiff doctors to increased liability, citing their declarants' conclusory assertions. But plaintiffs do not identify any plaintiff doctor who has ever been sued, threatened with a lawsuit, or required to pay increased insurance premiums in any way connected to mifepristone. Nor do plaintiffs explain why any such harm is imminent. While plaintiffs' declarants hypothesize that some patients might lie to a plaintiff doctor about their medical history, *e.g.*, ROA.940, they offer no plausible explanation for how *a patient's* decision to provide an incomplete medical history would increase *the doctor's* liability exposure.

Second, plaintiffs argue (at 18-20) that FDA's actions have interfered with their medical practices, alleging that some plaintiff doctors have treated women harmed by mifepristone in the past. But they have not alleged a single example when a plaintiff doctor's medical practice was overwhelmed—or even burdened differently than by the typical triaging of patients in an emergency room—such that their treatment of a patient related to mifepristone resulted in anyone else being denied treatment. *E.g.*, ROA.1265 (declaration that Dr. Francis

once had "to call in an additional physician to help cover" other patient responsibilities); ROA.1279 (declaration that Dr. Skop "may not be immediately available" for other patients).

Finally, plaintiffs argue (at 15-18) that FDA's actions have forced the plaintiff doctors to treat patients contrary to their moral or religious beliefs. But FDA's approval of mifepristone does not require plaintiffs to do anything. And *none* of plaintiffs' declarants identified any example where institutional, professional, or legal obligations required them to provide care to which they object, let alone a likelihood that they would be compelled to do so in the future. Some described the experiences of their unidentified partners. ROA.1265-66 (declaration that Dr. Francis' "partner felt as though she was forced" to complete an abortion); ROA.1276 (declaration that Dr. Skop's "group practice" admitted women and, for one patient, "the doctors had to surgically finish the abortion"). Others described personally performing procedures other than abortions, but they did not explain whether they morally objected to performing those procedures or, if so, why they did not invoke federal or state conscience protections. ROA.1956 (declaration that Dr. Jester treated heavy bleeding and uterine

infection); ROA.1276 (declaration that Dr. Skop addressed pregnancy tissue in the uterus); ROA.1935 (declaration that Dr. Johnson provided a blood transfusion). Plaintiffs' other declarants simply expressed concern that FDA's actions might place the plaintiff doctors "at increased risk of being forced to violate their conscience rights." ROA.1245-46; ROA.1279-80 (declaration FDA's actions "could" or "may" force Dr. Skop to complete an abortion).

Federal conscience protections—such as the Church Amendments, 42 U.S.C. § 300a-7, the Weldon Amendment, Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. H., tit. V, §§ 506-507, and Section 245 of the Public Health Service Act, 42 U.S.C. § 238n—guard against the possibility that the plaintiff doctors will be forced by their employers to provide abortions against their consciences. This theory of injury thus relies on additional speculation that, even assuming women will seek treatment from a plaintiff doctor, he will morally object to providing the particular treatment, and, despite conscience protections and the likely presence of other, non-objecting doctors, he will be required to provide that treatment. The Department of Health and Human Services has emphasized that it "is not aware of

any instance" where a facility was unable to provide emergency care "because its entire staff objected to the service on religious or moral grounds." 73 Fed. Reg. 78,072, 78,087 (Dec. 19, 2008).

Contrary to plaintiffs' assertion (at 17), the government has not argued that federal conscience protections "*do not apply* when women come to hospitals injured by chemical abortion" or that the Emergency Medical Treatment and Active Labor Act (EMTALA) "requires doctors to perform emergency abortions" contrary to their sincerely held religious beliefs. Plaintiffs mischaracterize (at 17-18) the government's statements in recent briefing regarding hospitals' EMTALA obligations. The government explained that federal conscience provisions do not "override EMTALA, a separate statute," Defendants' Brief in Support of Motion to Dismiss at 27, *Texas v. Becerra*, No. 5:22-cv-00185-H (N.D. Tex. Aug. 15, 2022), in response to incorrect arguments that such provisions operated to exclude abortion care from EMTALA's definition of "stabilizing treatment," regardless of who was providing the care. The government did not argue that EMTALA would compel individual providers to perform abortions contrary to their sincerely held moral or religious beliefs; the government explicitly argued the opposite. *E.g.*, *id.*

at 40 (EMTALA "does not purport to displace [the Religious Freedom Restoration Act (RFRA)] or state that RFRA does not apply in this context"). Plaintiffs ignore that RFRA would inform EMTALA's application to individual doctors. *See Bostock v. Clayton County*, 140 S. Ct. 1731, 1754 (2020).

In any event, these alleged injuries are not within the zone of interests of the Federal Food, Drug, and Cosmetic Act (FDCA) and provide no basis to invalidate FDA's approval of mifepristone. No provision of the FDCA aims to protect doctors based on their conscience-related objections to FDA-approved drugs. The federal statutes that *do* include religious or conscience protections create a system of exemptions that allows individuals, in appropriate circumstances, to decline to participate in activities they find objectionable. *See supra* pp. 12-14. Those statutes do not provide a sword to prevent *other* people from voluntarily engaging in conduct that *they* do *not* find objectionable. Plaintiffs cite no authority that would allow them to seek the wholesale suspension of FDA's approval of mifepristone—or any other generally applicable government action—based on their personal objections to performing an abortion.

2. Plaintiffs' remaining standing theories likewise fail. They assert (at 35-36) that the plaintiff organizations have standing based on their diversion of resources, but they again offer no limiting principle. Under that theory, the organization in *Summers* would have had standing to challenge the government actions that it opposed. Any organization could manufacture standing to challenge any action simply by advocating against it. That is not the law. FDA Br. 30-31.

Plaintiffs also contend (at 33-34) that they have third-party standing to assert the interests of women who, by definition, want to use mifepristone. But they cite no precedent allowing a plaintiff to invoke third-party standing to cure its own lack of injury. They do not engage with FDA's analysis refuting the district court's conclusions about women's interests. FDA Br. 32-34. And they continue to ignore the agency of women who are best positioned to decide, in consultation with their medical providers, whether using mifepristone is in their interests. *Id.*

B. Plaintiffs' Safety Arguments Do Not Demonstrate Their Standing

Plaintiffs attempt to support their standing arguments by asserting that mifepristone is unsafe, such that some plaintiff doctor

inevitably will provide emergency care related to the drug's use. As discussed, *Summers* forecloses that statistical approach. FDA Br. 22-23. Regardless, more than two decades of heavily studied experience conclusively demonstrates that mifepristone is safe under the approved conditions of use. Serious adverse events are "exceedingly rare," and the rate of emergency room presentation is very low. FDA Br. 24-26. Plaintiffs' purported evidence provides no basis to conclude otherwise. Moreover, while plaintiffs recognize (at 22) that standing is not dispensed in gross, they fail to establish injury tied to each of FDA's challenged actions. FDA Br. 27-30.

1. 2000 approval. Plaintiffs rely (at 22-23) on paragraph 6 of the Patient Agreement Form to argue that women inevitably will seek emergency treatment from the plaintiff doctors. Paragraph 6 addresses unsuccessful medication abortions, indicating that mifepristone "will not work" for a certain percentage of women. ROA.4389. It does not address medical emergencies, which, as discussed, are far rarer.[3] Unsuccessful medication abortions generally do not present

[3] Emergencies are addressed in paragraph 4, which directs patients to contact their "provider" or another person their "provider has told [them] … to call" in the event of an emergency. ROA.4389.

emergencies requiring immediate attention; instead, the Patient Agreement Form indicates that women should "talk with [their] provider" about follow-up treatment. ROA.4389. Plaintiffs have not shown that women will instead go to a plaintiff doctor's emergency room, much less under circumstances that injure plaintiffs. It is highly speculative that any woman would seek out a plaintiff doctor for help completing her abortion, when the plaintiff doctors do not provide abortions. FDA Br. 24-26.

Turning to actual adverse events, plaintiffs do not dispute (at 28) that the data provide no support for their claims. Instead, they argue that the true rate of adverse events is higher than the data show, relying on FDA's changes to the REMS reporting requirements in 2016. But Article III does not allow plaintiffs to rely on speculation to demonstrate their harms. *Summers*, 555 U.S. at 498. Plaintiffs thus cannot rely on those changes to excuse their lack of evidence that serious adverse events are anything other than exceedingly rare. Indeed, FDA changed those requirements only after *15 years* of adverse event data showed "known risks occurring rarely." ROA.822; *infra* pp. 35-36.

Plaintiffs attempt (at 20-22) to overcome their lack of data by relying on the speculative and anecdotal observations of their declarants. *E.g.*, ROA.278 (declaration that, "[g]iven [her] experience," Dr. Skop "expect[s] to see and treat more patients"). Those conclusory assertions do nothing to undermine decades of scientific evidence amassed by FDA showing that serious adverse events are "exceedingly rare" and will remain so under the revised conditions of use. ROA.2189; FDA Br. 24-30, 39-42, 47-51, 54-56.

Plaintiffs also reference (at 67) a handful of studies, but none concludes that mifepristone is unsafe. They rely on a 2009 study by Niinimaki purportedly showing that mifepristone has a higher rate of adverse events than surgical abortion, but that study found both methods "are generally safe" with low overall rates of serious adverse events. ROA.839.[4] Plaintiffs also rely on several outdated studies from the 1990s, but those have minimal relevance in light of more recent and

[4] A coauthor stated in an interview that plaintiffs and the district court "were purposely misunderstanding his work and overemphasizing 'adverse events' despite overwhelming scientific evidence of the drug's safety and the study itself noting the rarity of serious complications." Lauren Weber et al., *Unpacking the Flawed Science Cited in the Texas Abortion Pill Ruling*, Wash. Post, Apr. 13, 2023.

comprehensive studies and decades of clinical experience. ROA.1637 (addressing myriad limitations of 1999 Jensen study); *e.g.*, ROA.839-40 (discussing 2015 study that identified "no difference in major adverse events" between mifepristone and surgical abortion).

Nor do plaintiffs' extra-record studies demonstrate that mifepristone is dangerous. For example, they rely on a 2021 study by Studnicki that found a higher rate of emergency room visits following medication versus surgical abortion, but the overall rate for both methods was low. ROA.1483. In any event, that study was based on Medicaid claims data that were subject to inconsistencies, ROA.1488, and others have found lower rates of emergency room visits, *e.g.*, ROA.2197-98 (discussing study that reported 0.1% of women experienced a "major complication," defined to include "emergency department presentation" or "hospitalization," among other things). Furthermore, a 2022 study by Studnicki found that "[w]omen experiencing chemical abortion and a subsequent emergency room (ER) visit within 30 days were *less likely* … to be hospitalized for any reason in that same time period than women who had experienced surgical abortion." ROA.1501 (emphasis added).

Plaintiffs also argue (at 67) that mifepristone causes psychological harms to some women, citing the district court's reliance on anonymous blog posts. But plaintiffs do not assert that women will seek treatment from the plaintiff doctors for psychological harms or that those doctors would be injured in that event. Any such harms are thus irrelevant to plaintiffs' standing. Regardless, plaintiffs' assertions are meritless, and their reliance on anonymous blog posts is misplaced. FDA Br. 34.

Finally, plaintiffs emphasize (at 28, 67) risks from using mifepristone in ways that FDA has *not* approved. They claim that women have been harmed by using mifepristone to abort viable fetuses, and they rely on studies that found adverse events associated with using mifepristone during the second trimester. *E.g.*, ROA.2216-17 (discussing 2011 Niinimaki study, which studied use of mifepristone up to 20 weeks' gestation); ROA.1264-65 (declaration about a patient who obtained an abortion drug online "from India"); ROA.1286-87 (declaration about a patient who took mifepristone even though the drug "was contraindicated"). FDA has approved mifepristone as safe and effective for use only through 10 weeks' gestation. Any injury related to using mifepristone for unapproved uses is not attributable to

FDA's approval. Any drug might be unsafe when used not in accordance with its labeling. On plaintiffs' theory, they would have standing to challenge any drug's approval on the ground that someone could be harmed by using the drug in unapproved ways.

2. 2016 changes. Plaintiffs challenge multiple decisions made by FDA in 2016, but they fail to show any cognizable injury attributable to those decisions.

First, plaintiffs assert (at 24-25) that increasing the gestational age to 10 weeks has increased the number of women seeking care from them. But FDA thoroughly evaluated the scientific evidence and found that mifepristone "is safe and effective" through 10 weeks' gestation with "rare" serious adverse events. ROA.809; *infra* pp. 33-34. Plaintiffs have not shown otherwise based on the conclusory assertion of a single declarant and one study from over two decades ago.[5] Moreover, it is

[5] Plaintiffs also mischaracterize (at 25) the success rate reported in a 2015 systematic review. The data reported over a 10-year period showed that no follow-up surgical intervention was needed in 96.6% of cases through 70 days' gestation, with medication abortion "highly effective" through 63 days' gestation. Melissa J. Chen, et al., *Mifepristone with Buccal Misoprostol for Medical Abortion: A Systematic Review*, 126 Obstetrics & Gynecology 12, 17, 19 (2015). The 332 patients between 64 and 70 days' gestation (1% of the studied

highly speculative that the plaintiff doctors (who do not provide abortions) would be forced to provide any follow-up surgical abortions, even if the gestational age change marginally decreased mifepristone's efficacy. *See supra* pp. 16-17.

Second, plaintiffs argue (at 25) that FDA's "removal of follow-up care" increases the risk that their medical practices will be burdened and that the plaintiff doctors will be forced to violate their consciences. But FDA did not remove the directive that patients follow up with their providers; it simply removed the directive that patients complete that follow up *in person*. ROA.1697 (follow-up is "still needed"). Based on studies involving "almost 2,400 subjects," FDA concluded that "alternatives to in-clinic follow-up are effective and safe, detecting most of the ongoing pregnancies so that women can get needed treatment." ROA.2208; *infra* p. 34. Plaintiffs offer no basis to second-guess FDA's conclusions.

Third, plaintiffs assert (at 23, 25-26) that FDA's decision to allow certain non-physicians to prescribe mifepristone "ensures that injured

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population) reported an even higher success rate (93.1%) than the studies supporting FDA's 2000 approval. *Id.* at 13, 19.

women will end up in emergency rooms all over the country" because women will be unable to return to their providers for follow-up care. That is highly speculative. FDA Br. 25-26, 29-30. Some women may require follow-up care by someone other than their prescribing providers, but there is no reason to think that women will seek treatment from the plaintiff doctors. For both unsuccessful medication abortions and medical emergencies alike, the Patient Agreement Form directs women to contact their original provider or follow plans put in place by that provider. *See supra* pp. 16-17 & n.3. Moreover, an unsuccessful medication abortion does not invariably require intervention by a doctor, much less an emergency room doctor. Non-doctors routinely provide aspiration abortions in many States. Amicus Br. of National Association of Nurse Practitioners in Women's Health, et al., 8, 12-14; Nicole Dube, *States Allowing Non-Physicians to Provide Abortion Services*, Conn. Office of Leg. Research (July 29, 2022), https://perma.cc/UKE5-K9Z7. And non-surgical options are available, such as repeat doses of misoprostol. ROA.2175.

Finally, plaintiffs make no attempt to explain how they are injured by FDA's decisions not to require a second in-person visit

(thereby allowing at-home administration of misoprostol) or to change the adverse event reporting requirements. They thus plainly lack standing to challenge those decisions.

3. <u>In-person dispensing</u>. Plaintiffs assert (at 26-28) that FDA's removal of the in-person dispensing requirement increases the risk of serious adverse events related to ectopic or misdated pregnancies. But the conclusory and anecdotal assertions of their declarants cannot supplant FDA's considered judgments. FDA relied on REMS assessment reports, adverse event data, numerous studies involving thousands of patients, and other evidence to conclude that "mifepristone will remain safe and effective for medical abortion if the in-person dispensing requirement is removed." FDA Br. 54-56; *infra* pp. 37-38. Moreover, even if there were a marginal increase in such adverse events, it is highly speculative that plaintiffs would be injured when just 0.005% of women who take mifepristone have an ectopic pregnancy. FDA Br. 29-30. Plaintiffs do not assert that any plaintiff doctor has ever treated a woman with an ectopic rupture after taking mifepristone or that he would be required to do so over his moral objection.

Plaintiffs also improperly conflate an in-person dispensing requirement with an ultrasound requirement. Plaintiffs assert (at 28) that, "[b]ecause FDA removed in-person prescribing, 'many women are now being prescribed mifepristone … without a sonogram,'" but FDA *never* required providers to perform ultrasounds. Instead, FDA always deferred to providers, recognizing that there are multiple ways to date pregnancies and diagnose ectopic pregnancies, many of which do not require an ultrasound or other in-person exam. *See infra* pp. 28-30. Indeed, the rarity of ectopic pregnancies in women who take mifepristone suggests that providers have diagnosed ectopic pregnancies successfully even without an ultrasound requirement. It is therefore speculative that removing the in-person dispensing requirement results in any fewer ultrasounds being performed, much less an increase in adverse events that would injure plaintiffs.

C. Plaintiffs' Central Claims Are Time-Barred

Plaintiffs' central claims are also barred by the six-year statute of limitations. FDA Br. 35-38. Plaintiffs argue (at 37-41) that FDA restarted the limitations period in 2016 and 2021, but nothing in those decisions reflected an intention to reopen mifepristone's 2000 approval.

FDA Br. 35-38. Plaintiffs identify no case that ever applied the reopening rationale under similar circumstances. They rely on *Sierra Club v. EPA*, 551 F.3d 1019 (D.C. Cir. 2008), but that framework applies only where the agency's original decision "may not have been worth challenging" on its own. *Id.* at 1025-26. Plaintiffs did challenge FDA's original approval. While plaintiffs note (at 38-39) that FDA denied that challenge on the same day that it issued the 2016 changes, those were separate decisions that addressed separate issues. Plaintiffs do not dispute that they failed to seek timely review of the relevant agency decision.

Plaintiffs also do not identify (at 39-40) any way in which FDA's "full review" of the mifepristone REMS in 2021 revisited the drug's approval from 2000. FDA did not, for example, reevaluate the strength of the three clinical trials underlying the original approval or address Subpart H at all. Instead, in its 2021 decision, FDA evaluated the REMS for the purpose of responding to plaintiffs' specific arguments in their 2019 petition; as the stay panel correctly stated, that petition "only asked FDA to restore the pre-2016 status quo ante." ROA.4403; *see* ROA.741. Judicial review of an agency's denial of a petition is

strictly limited to the "narrow issues" raised by that petition and decided by the agency. *See, e.g.*, *NLRB Union v. FLRA*, 834 F.2d 191, 196 (D.C. Cir. 1987).

Plaintiffs argue (at 41-42) that they are entitled to equitable tolling, but they identify no barrier that "prevented timely filing." *Menominee Indian Tribe of Wis. v. United States*, 577 U.S. 250, 255 (2016). FDA's letter to plaintiffs denying their petition in 2016 plainly notified them that FDA had denied their petition. Plaintiffs offer no reason why they waited more than six years to seek judicial review. While they emphasize FDA's delay in responding to their petition, that delay did not erase the statute of limitations. Nothing that happened *before* FDA's 2016 decision justifies their failure to sue within the generous six-year statute of limitations *after* that decision. If plaintiffs were dissatisfied with the delay, they could have sued to compel agency action.

II. FDA's Challenged Actions With Respect To Mifepristone Were Lawful

A. FDA Lawfully Approved Mifepristone In 2000

1. Plaintiffs have not shown that FDA's approval of mifepristone in 2000 was arbitrary and capricious. FDA relied on multiple clinical

trials involving thousands of patients demonstrating the drug's safety. The agency thoroughly explained that decision in 2000, ROA.591-98, and, in 2016, responded to all of plaintiffs' arguments challenging that decision, ROA.635-67. Study after study over the past two decades confirms the soundness of FDA's decision. FDA Br. 40-44.

Plaintiffs do not identify any relevant evidence that FDA ignored. Instead, plaintiffs assert (at 48-49) that FDA erred by not imposing an ultrasound requirement, which they argue is the most accurate way to date pregnancies and diagnose ectopic pregnancies. Even on its own terms, that argument at most would justify remanding for FDA to impose an ultrasound requirement, not invalidating the drug's approval.

FDA reasonably declined to impose that requirement. As FDA explained in 2000, "[t]he role of ultrasound was carefully considered," but "other clinical methods" are also effective and FDA reasonably left the decision to "the medical judgment of the physician." ROA.595. When FDA denied plaintiffs' citizen petition in 2016, it again thoroughly explained why an ultrasound requirement was unnecessary. ROA.651-53 (discussing alternative methods); ROA.652-53 (noting that,

among women with reported ectopic pregnancies who took mifepristone and received ultrasounds, more than half of the ultrasounds failed to detect the ectopic pregnancy). Plaintiffs suggest (at 50) that these are "post hoc" explanations, but FDA properly engaged with plaintiffs' own arguments in refusing to rescind its approval of mifepristone or impose an unnecessary ultrasound requirement.

Relatedly, plaintiffs argue (at 48-50) that, because the trials underlying the 2000 approval included an ultrasound requirement, it was arbitrary and capricious not to include that requirement in the drug's approved conditions. But this "study match" requirement finds no support in the FDCA, administrative law, or science. FDA Br. 42-44. Agencies often lack "perfect empirical or statistical data," and yet agencies reasonably make "predictive judgment[s] based on the evidence" they have. *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1160 (2021). Regardless, plaintiffs mischaracterize the French trials underlying FDA's approval, which did *not* include an ultrasound requirement. ROA.652 n.47. And plaintiffs do not explain (at 50-51) why FDA could not have relied on the French trials, which involved about 1800 women, to approve mifepristone without the U.S. trial.

ROA.591. Nor do plaintiffs explain (at 50-51) why it is relevant how many physicians in the French trials chose to perform ultrasounds. The question for FDA was whether to *require* ultrasounds; the French trials provided evidence that mifepristone was safe and effective without such a requirement, in part because providers are well positioned to determine whether an ultrasound is necessary for their patients. ROA.595; ROA.652-53.

Plaintiffs repeat (at 51-52) the district court's erroneous assertion that FDA found mifepristone to be dangerous but later caved to political pressure. FDA determined in February 2000 that there was insufficient evidence to show that mifepristone would be safe and effective *without* distribution restrictions, which were "needed to assure safe use of this product." ROA.587; FDA Br. 44 n.7. The sponsor thus proposed additional restrictions, and seven months later FDA concluded that "adequate information has been presented to approve" mifepristone *with* those restrictions. ROA.600. That decision was supported by extensive scientific evidence.

2. Plaintiffs also argue (at 45-47) that FDA's approval was invalid under Subpart H, but plaintiffs do not explain why any such error in

2000 would justify suspending FDA's approval today. Congress incorporated mifepristone into the statutory REMS framework when it enacted the Food and Drug Amendments Act of 2007 (FDAAA). FDA Br. 60-61. Even if the FDAAA were, as plaintiffs assert (at 46), simply a "stopgap measure," plaintiffs ignore that FDA itself has directly regulated mifepristone under the REMS framework since 2011. Any error in relying on Subpart H thus was superseded by subsequent events. FDA Br. 45.

Regardless, FDA properly invoked Subpart H. FDA Br. 46. The fact that pregnancy is a "natural process," AHM Br. 45, does not prevent it from also being a serious medical condition for some women. And while plaintiffs assert (at 46) that "the avoidance of the existing treatment cannot itself be the benefit," they offer no reason why, when the existing treatment is surgery and the alternative treatment would avoid known risks associated with that existing treatment.

Finally, even if this Court holds that FDA's reliance on Subpart H renders the approval invalid, the proper remedy would be remand without vacatur. *See Texas v. United States*, 50 F.4th 498, 529 (5th Cir. 2022). Vacatur would have extremely "disruptive consequences." *Id.*

FDA could readily resolve any deficiency by approving the drug and imposing the same distribution restrictions under the statutory REMS authority, which expressly applies to drugs intended to treat "a disease or condition." 21 U.S.C. § 355-1(a)(1).

B. FDA Lawfully Changed The Conditions Of Use In 2016

In 2016, FDA lawfully increased the gestational age limit from seven to 10 weeks, reduced the number of required clinical visits from three to one, and allowed certain non-physicians to prescribe mifepristone. FDA based those changes on an exhaustive review of data gathered over two decades and dozens of major studies involving thousands of women. *See* ROA.698-724; ROA.2142-2241; FDA Br. 46-50. FDA also thoroughly responded to plaintiffs' arguments challenging the 2016 changes and asking the agency to reinstate the 2000 conditions of use. ROA.803-42.

Plaintiffs identify no evidence that FDA ignored in making any of the 2016 changes, instead arguing (at 52-55) that FDA's decision was not supported by a study that examined every change together. As discussed, however, the FDCA imposes no such "study match" requirement. *See supra* p. 29. And plaintiffs acknowledge (at 52) that

FDA *did* consider "studies that evaluated 'multiple changes.'" Plaintiffs' only response (at 53) is to assert that two of the studies cited by FDA were insufficiently similar because they used ultrasounds and follow-up exams. FDA Br. 50. But FDA extensively explained why an ultrasound requirement is unnecessary, and patients are still directed to follow up with their providers. *See supra* pp. 22, 28-30; *infra* p. 34. Moreover, studies may impose ultrasound requirements "to ensure proper data collection," ROA.595—not as a necessary safety precaution.

At bottom, plaintiffs fail to engage with the extensive evidence underlying FDA's decisions. When FDA increased the gestational age limit, FDA evaluated nearly two dozen studies. FDA Br. 47; ROA.2171-80; ROA.712-13. The literature showed that mifepristone's efficacy at later stages was "comparable to (and in several studies, greater than) the success rates for medical abortion in the initial 2000 decision." ROA.2180. For example, FDA relied on "[f]our studies and one systematic review" that "evaluated the exact proposed dosing regimen through 70 days gestation." ROA.704. The systematic review "covered 20 studies including over 30,000 women," reporting success rates "in the range of 97-98%." ROA.704. FDA also thoroughly responded to

plaintiffs' submission challenging the change, concluding that mifepristone "is safe and effective" through 10 weeks' gestation with "rare" serious adverse events. ROA.809.

FDA likewise relied on extensive evidence in deciding to reduce the number of required clinic visits, which allows misoprostol to be taken at home and follow-up to be conducted remotely. FDA Br. 47-48; ROA.2180-83; ROA.2203-09; ROA.713-14. FDA also thoroughly rejected plaintiffs' arguments challenging this change. ROA.814-21. For example, based on nearly a dozen studies involving "large numbers of women in the U.S." and abroad, FDA concluded that taking misoprostol at home was "associated with exceedingly low rates of serious adverse events, and with rates of common adverse events comparable to those in the studies of clinic administration of misoprostol that supported the initial approval in 2000." ROA.713; ROA.2181; ROA.2190. FDA similarly concluded, based on studies involving "almost 2,400 subjects," that "alternatives to in-clinic follow-up are effective and safe, detecting most of the ongoing pregnancies so that women can get needed treatment." ROA.2208; ROA.714; ROA.1703-04; ROA.1711; ROA.2186.

FDA also relied on extensive evidence to allow certain non-physicians to prescribe mifepristone, just as they prescribe other drugs. FDA Br. 47-48. The agency found that "it is safe for midlevel providers to administer medical abortion." ROA.2221. For example, multiple studies involving thousands of patients showed "no differences in efficacy, serious adverse events, ongoing pregnancy or incomplete abortion" depending on whether a physician versus a nurse or nurse midwife provided the drug. ROA.2221; ROA.707. FDA also thoroughly rejected plaintiffs' submission challenging this change. ROA.811-14. That decision reflects the reality that advanced practice clinicians "are vital participants in the U.S. health care system and are licensed to provide a broad range of health services consistent with their heightened educational standards and rigorous certification and continuing education requirements." Amicus Br. of National Association of Nurse Practitioners in Women's Health et al., 4, 8-25.

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

FDA also lawfully changed the prior requirement that prescribers agree to report certain serious adverse events, such as hospitalizations and blood transfusions, to the drug's sponsor. FDA Br. 52-53. FDA

thereby relaxed reporting requirements that applied above and beyond FDA's standard reporting requirements for all approved prescription drugs. Plaintiffs argue (at 52-55) that FDA lacked any basis to change these requirements, but, as FDA explained at the time, "after 15 years of reporting serious adverse events, the safety profile of Mifeprex [was] essentially unchanged." ROA.724. FDA also thoroughly addressed and refuted plaintiffs' arguments to reverse that change. ROA.822-23 (citing mifepristone's "well-characterized safety profile" and the fact that "known risks occur[] rarely").

Plaintiffs suggest (at 54-55) that FDA could not change the reporting requirements at the same time that it changed the conditions of use. But plaintiffs do not engage at all with the extensive scientific evidence supporting the safety of those changes. *See supra* pp. 32-35. It was not arbitrary and capricious for FDA to change the reporting requirements when 15 years of heightened reporting requirements confirmed mifepristone's safety profile, and extensive scientific evidence indicated that mifepristone would remain safe under the approved conditions of use.

D. FDA Lawfully Determined That The In-Person Dispensing Requirement Should Be Removed

1. Plaintiffs contend (at 56-58) that FDA's 2021 decision to remove the in-person dispensing requirement was arbitrary and capricious, but extensive evidence supported that decision. FDA Br. 54-56. Plaintiffs identify no evidence that FDA failed to consider. They paint FDA's reliance on adverse event data as unreliable, but mifepristone remains subject to *more* reporting requirements than apply to nearly all approved prescription drugs. In any event, FDA relied on multiple other sources of evidence, including extensive published literature, to conclude that "mifepristone may be safely used without in-person dispensing." ROA.829-38; *see* FDA, *REMS Modification Rationale Review* 19-42 (2021), https://perma.cc/W4U3-L38P.

Plaintiffs note (at 56) FDA's acknowledgement that certain studies "on their own" did not establish the safety of dispensing mifepristone by mail. But FDA explained that "the safety and efficacy outcomes reported in these studies remain within the ranges labeled for the approved mifepristone products." ROA.837. FDA thus evaluated these studies against the backdrop of a significant body of literature

that firmly established mifepristone's safety and efficacy under the approved conditions. Plaintiffs further argue that it was insufficient for FDA to rely on REMS assessment reports and its solicitation of "additional information from the [drug sponsors] to provide for more comprehensive assessment of the REMS." ROA.827. But plaintiffs cite no authority for that objection, which would overturn FDA's decision as arbitrary and capricious despite the agency's making every effort to find and consider all relevant data.

2. Plaintiffs further err in arguing (at 57-63) that FDA's 2021 decision was contrary to law based on statutory provisions derived from the 1873 Comstock Act. FDA Br. 56-61; Amicus Br. of Former DOJ Officials 4-28.

Regardless of how plaintiffs believe the Comstock Act should be understood, that Act provides no basis to invalidate FDA's decision. FDA Br. 56-57. The FDCA does not require FDA to address other laws that may restrict a drug's distribution or use when it approves or regulates drugs under that statute. Plaintiffs assert (at 62) that the Administrative Procedure Act requires FDA to "abide by" any law, but FDA's removal of the in-person dispensing requirement does not itself

violate the Comstock Act. Nor does FDA's action cause any other individual to violate the Comstock Act. By their terms, 18 U.S.C. §§ 1461 and 1462 prohibit distribution only by the U.S. Postal Service and by a "common carrier" "in interstate or foreign commerce." Those provisions do not prohibit other types of distribution, such as by private carrier. FDA's removal of the in-person dispensing requirement thus does not require distribution by prohibited methods even under plaintiffs' interpretation.

Moreover, plaintiffs misinterpret the Comstock Act. FDA Br. 57-60. Reading the words "in their context and with a view to their place in the overall statutory scheme," it is clear that the Act never prohibited the distribution of abortion drugs used for lawful purposes. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Plaintiffs emphasize (at 58-59) that certain provisions lack the "unlawful" qualifier found in other provisions, but the Supreme Court has recognized that "different words used in different parts of the same statute" can "mean roughly the same thing." *See Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. 519, 540 (2013). It was "of considerable importance that the law as to importations should be the same as that

as to the mails." *United States v. One Package*, 86 F.2d 737, 740 (2d Cir. 1936) (Learned Hand, J., concurring). Plaintiffs offer no reason that Congress would have authorized criminal prosecution for the mailing or importation of any abortion drug, 18 U.S.C. §§ 1461, 1462, while allowing customs officials to seize those drugs only if they are intended for unlawful uses, 19 U.S.C. § 1305(a). The more natural reading is that Congress intended these provisions to apply consistently to the same set of articles.

Nor is it atextual to rely on statutory context, particularly here, where a Note has been included in the U.S. Code since 1948 explaining that these provisions do not apply to drugs intended for lawful uses. FDA Br. 58; 18 U.S.C. § 1461 note (describing, *e.g.*, *United States v. Nicholas*, 97 F.2d 510, 512 (2d Cir. 1938), as holding that mailing "is not forbidden absolutely, but only when such articles or publications are unlawfully employed").[6] Congress repeatedly amended the Comstock

[6] Plaintiffs rely (at 60-61) on *Davis v. United States*, 62 F.2d 473, 474 (6th Cir. 1933), and *One Package*, 86 F.2d at 739, but Congress understood those cases to limit the Comstock Act to drugs mailed for unlawful uses. *See* 18 U.S.C. § 1461 note (describing *Davis* as holding that the Act applied only if the sender intended "that the article described therein should be used for condemned purposes"); *id.* (citing

Act with that understanding. Plaintiffs also ignore the "many instances in which Congress affirmed FDA's authority to approve new drugs for introduction into interstate commerce and regulate their distribution, irrespective of the prohibitions in the Comstock Act." Amicus Br. of Food and Drug Law Scholars 25-28.

Even if the Comstock Act's prohibitions applied to drugs used for "unlawful abortions," plaintiffs argue (at 59-60), the quoted language means *all* abortions because abortion was unlawful in every State in 1873. In fact, many States allowed abortion under various circumstances, such as to save the life of the woman, to preserve her health, or before quickening. *See Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2285-2300 (2022). More fundamentally, however,

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One Package); *One Package*, 86 F.2d at 739 ("The word 'unlawful' would make this clear as to articles for producing abortion, and the courts have read an exemption into the act covering such articles even where the word 'unlawful' is not used."). Plaintiffs also cite *Bours v. United States*, 229 F. 960 (7th Cir. 1915), but the relevant question is how Congress understood the legal landscape against which it was legislating, and the Note did not mention *Bours*. Nor could *Bours* have undermined the settled construction of every subsequent court. Regardless, because *Bours* held that an indictment was defective because the Act did not apply to abortions "to save [the] life" of the woman, *id.* at 964-66, it was immaterial whether other types of lawful abortions also fall outside the Act's scope.

plaintiffs offer no basis for their assumption that Congress intended the Comstock Act to turn on the state of the law in 1873: The longstanding interpretation ratified through repeated congressional amendments is that the Act prohibits only the mailing of drugs intended for use in abortions that are unlawful *at the time of the mailing*—not in 1873.

Moreover, Congress ratified the existing distribution system for mifepristone in 2007. FDA Br. 60-61. Plaintiffs contend (at 62) that the FDAAA "says nothing about the specific approval for chemical abortion drugs," but Congress "was well aware that mifepristone would be included under [the REMS] provision when it took this action, and it made no exception for it." Amicus Br. of 253 Members of Congress 11-12; FDA Br. 60-61.[7]

[7] While none of FDA's actions should be suspended, this Court should limit any adverse decision to the relief sought by plaintiffs. FDA made various changes to the conditions of use in 2016, such as the approved dosing regimen. FDA Br. 50-51. While plaintiffs claim (at 53 n.9) to have "express[ed] concerns" with these changes, they do not argue that they were unlawful and did not challenge them in their 2019 citizen petition. Plaintiffs also do not dispute that their challenge to generic mifepristone rises and falls with their challenge to branded mifepristone, FDA Br. 53-54, or that their challenge to FDA's exercise of enforcement discretion is moot, FDA Br. 61-62.

III. The District Court Abused Its Discretion In Awarding Preliminary Relief

1. Preliminary relief is unwarranted here where it upends the status quo that has been in effect for over two decades. FDA Br. 63.[8] Plaintiffs suggest (at 63 n.12) that the status quo should be deemed to be the one that existed in 2000, but the "status quo" in 2023 cannot refer to the world as it existed in 2000. The purpose of preliminary relief is "to preserve" the existing positions of the parties and the existing legal regime, and thereby "prevent irreparable harm" before the merits are determined. *City of Dallas v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017). The status quo today plainly includes mifepristone, which millions of women have relied on to end their pregnancies and manage their miscarriages. Upending the status quo would impose vast irreparable harm on women, the Nation's healthcare

[8] The court erroneously invoked 5 U.S.C. § 705 to stay the effective date of agency action. FDA Br. 62-63. Plaintiffs contend (at 70) that nothing in § 705 requires a stay to be contemporaneous with agency action, but that is the plain import of the text; it is impossible to "postpone" actions that took effect years earlier. And the court's order did not "preserve" any existing "status or rights" of plaintiffs, who have no status or rights under the FDCA; it upended a decades-long status quo.

system, FDA, the sponsors, and the public interest generally. FDA Br. 63-67.

Amici describe the vast practical consequences of the court's decision. If allowed to stand, it will "impose a severe, almost unimaginable, cost on pregnant patients. Even temporary lack of access to mifepristone will cause patients to suffer serious physical harm and even death. And because mifepristone has many uses outside of medication abortion, enjoining its use will also cause irreparable harm to patients who are prescribed the drug for miscarriage management and other conditions." Amicus Br. of American College of Obstetricians and Gynecologists et al., 21-26; Amicus Br. of Physicians for Reproductive Health 18-27; Amicus Br. of Over 200 Reproductive Health, Rights, and Justice Organizations 14-25; Amicus Br. of Doctors for America et al., 14-23; Amicus Br. of Advocates for Survivors of Intimate Partner Violence 18-26.

Nor are these harms limited to the most severe aspects of the court's decision. Even if the 2000 approval of mifepristone is left in place, reverting to the conditions of use then in effect would erect unnecessary barriers to a woman's considered choice to take the drug.

Women who are delayed or prevented from accessing mifepristone would be irreparably harmed. *See, e.g.*, Amicus Br. of Honeybee Health 20-24 (explaining why "eliminating patients' access to mail-order mifepristone … increases patients' health risks").

The court's order also undermines the healthcare systems of state and local governments. Dozens of state and local governments explain that "disrupting access to mifepristone in States where abortion remains lawful would place a potentially unbearable strain on already overburdened health care systems and cause broad repercussions, worsening pregnancy-related morbidity and mortality, impeding delivery of other essential medical care, and deepening entrenched health disparities." Amicus Br. of New York et al., 4; Amicus Br. of Local Governments 24-26; Amicus Br. of the City of New York et al., 8-31; Amicus Br. of Medical Students for Choice 3-22 (describing adverse impacts on medical training).

The pharmaceutical industry likewise warns that the court's order threatens the complex system of drug regulation and undermines future drug development. The most direct harms of course would be felt by companies that sell and distribute mifepristone. But the court's

approach and reasoning would have serious adverse consequences well beyond this case. "Far from being limited to a single drug, the district court's logic would create chaos for the drug-approval process" and thereby "chill crucial research and development, undermine the viability of investments in this important sector, and wreak havoc on drug development and approval generally—all of which would irreparably harm patients, providers, and the entire pharmaceutical industry." Amicus Br. of Pharmaceutical Companies, Executives, and Investors 3-4; Amicus Br. of Pharmaceutical Research and Manufacturers of America et al., 22-26; Amicus Br. of Patient and Provider Advocacy Organizations 9-20. Plaintiffs speculate (at 69) that these harms will not occur because "[t]he district court meticulously reviewed the science," but the court did not engage with FDA's scientific analysis *at all*—nor did it even wait for the full administrative record.

Plaintiffs do not dispute these realities, apart from reiterating their baseless assertions that mifepristone is unsafe. Instead, plaintiffs focus (at 63-64) on FDA and argue that the court's order does not harm the government. But they do not contest that, in this context, the interests of the government and the public "merge." *Nken v. Holder*,

556 U.S. 418, 435 (2009). Regardless, plaintiffs are incorrect that FDA suffers no irreparable harm. This Court has recognized that a government agency is irreparably harmed when an order "interferes with [the agency's] ability to perform its statutory duties." *Valentine v. Collier*, 978 F.3d 154, 165 (5th Cir. 2020). "FDA is the expert agency charged by Congress with reviewing and approving drug applications," but the court "second-guessed FDA's expert determinations with cherry-picked anecdotes and studies." Amicus Br. of 253 Members of Congress 5-6; Amicus Br. of Former Commissioners of FDA 16-25; Amicus Br. of Former FDA Officials 26-30; Amicus Br. of Public Citizen 4-24. Additionally, preliminary relief risks the "inevitable disruption that would arise from a lack of continuity and stability in [an] important area of law." *Campaign for S. Equality v. Bryant*, 773 F.3d 55, 58 (5th Cir. 2014). If FDA ultimately prevails on the merits but not on preliminary relief, it twice will incur substantial costs "in terms of time, expense, and administrative red tape" to implement changes and then revert to the prior regulatory conditions. *Ruiz v. Estelle*, 650 F.2d 555, 569-71 (5th Cir. Unit A June 1981) (per curiam).

2. In contrast, plaintiffs' alleged harms are attenuated and speculative. FDA Br. 67-69. Plaintiffs largely blame FDA for the delay in judicial review. But the question is not whether FDA responded to plaintiffs' petitions in a timely manner at the administrative level—which plaintiffs never sought to hasten by seeking to compel FDA to act under 5 U.S.C. § 706. The question is whether plaintiffs proceeded to court with the necessary urgency after FDA denied their petitions to demonstrate that they will be irreparably harmed without emergency preliminary relief. Plaintiffs do not contest that they chose not to seek judicial review for *more than six years* after FDA's 2016 denial of their petition asking the agency to withdraw mifepristone's approval. Nor do they contest that they waited years or months to challenge FDA's subsequent actions. Plaintiffs' "unnecessary, years-long delay in asking for preliminary injunctive relief" belies any sense of urgency. *Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018) (per curiam).

Plaintiffs argue (at 69-70) that federalism and the separation of powers weigh in their favor. But mifepristone has lawful uses in every State, whether to terminate pregnancies or to help women manage their miscarriages. FDA Br. 64-65. Plaintiffs argue that mifepristone might

be used illegally, but the same is true of many drugs. All States have an interest in their citizens having access to FDA-approved drugs for lawful purposes.[9]

Furthermore, overriding FDA's expert scientific judgments would disserve the separation of powers. Plaintiffs have been attempting for decades to block American women's access to mifepristone, and the political branches have repeatedly rejected those efforts. *See, e.g.*, 144 Cong. Rec. H5089-5100 (daily ed. June 24, 1998) (proposed amendment to appropriations bill); ROA.348 (2006 congressional hearing); FDA Br. 60-61 (other unsuccessful legislative efforts). Having failed to accomplish their goals through the democratic process, plaintiffs have

[9] There is no basis for plaintiffs' suggestion (at 2) that the federal government is encouraging violations of state law. The Administration announced steps to support "patients, providers, and pharmacies who wish to *legally* access, prescribe, or provide mifepristone—no matter where they live." The White House, *Fact Sheet: President Biden to Sign Presidential Memorandum on Ensuring Safe Access to Medication Abortion* (Jan. 22, 2023), https://perma.cc/YC3P-LYLP (emphasis added). And the Administration's monitoring efforts are explicitly directed at legislation "that threaten[s] to infringe on Federal legal protections." The White House, *Memorandum on Further Efforts to Protect Access to Reproductive Healthcare Services* (Jan. 22, 2023), https://perma.cc/Y5NJ-BYFJ.

now turned to the courts. But the relief they seek would improperly arrogate responsibilities that Congress entrusted to FDA.

CONCLUSION

The district court's order should be reversed.

Respectfully submitted,

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MAY 2023

CERTIFICATE OF SERVICE

I hereby certify that, on May 12, 2023, I electronically filed the foregoing brief with the Clerk of the Court by using the appellate CM/ECF system. I further certify that the participants in the case are CM/ECF users and that service will be accomplished by using the appellate CM/ECF system.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) and the Court's Order dated May 2, 2023, expanding the word limit because it contains 9,499 words according to the count of Microsoft Word. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it was prepared in Century Schoolbook 14-point font, a proportionally spaced typeface.

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No. 23-10362 Alliance Hippocratic Medicine v. FDA
USDC No. 2:22-CV-223

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Sincerely,

LYLE W. CAYCE, Clerk

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