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 AND DRUG ADMINISTRATION; ROBERT M. CALIFF, Commissioner of Food and Drugs; JANET WOODCOOK, 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,

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellant.

EMERGENCY MOTION UNDER CIRCUIT RULE 27.3 FOR A STAY PENDING APPEAL

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

LEIGHA SIMONTON
United States Attorney

SARAH E. HARRINGTON
Deputy Assistant Attorney General

MICHAEL S. RAAB
CYNTHIA A. BARMORE
Civil Division, Appellate Staff
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

CERTIFICATE OF INTERESTED PERSONS

Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.

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.

Plaintiffs-Appellees:

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.

Defendants-Appellants:

U.S. Food and Drug Administration

U.S. Department of Health and Human Services

Robert M. Califf, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration

Janet Woodcock, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration

Patrizia Cavazzoni, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Xavier Becerra, in his official capacity as Secretary, U.S. Department of Health and Human Services

Intervenor Defendant-Appellant:

Danco Laboratories LLC

Counsel:

For plaintiffs-appellees:

Erik Christopher Baptist
Alliance Defending Freedom
440 First Street NW
Washington, DC 20001

Christian D Stewart
Morgan Williamson LLP
701 S Taylor Suite 440 Lb 103
Amarillo, TX 79101

Denise Harle
Alliance Defending Freedom
1000 Hurricane Shoals Rd., NE Ste D1100
Lawrenceville, GA 30043

Erica Steinmiller-Perdomo
Alliance Defending Freedom
440 First Street NW Suite 600
Washington, DC 20001

Erin Morrow Hawley
Alliance Defending Freedom
440 First Street NW Suite 600
Washington, DC 20001

Julie Marie Blake
Alliance Defending Freedom
44180 Riverside Pkwy
Landsdowne, VA 20176

Matthew S Bowman
Alliance Defending Freedom
440 First Street NW Suite 600
Washington, DC 20001

For defendant-appellant:

Brian M. Boynton
Leigha Simonton
Sarah E. Harrington
Michael S. Raab
Cynthia A. Barmore
Noah T. Katzen
Christopher A. Eiswerth
Daniel Schwei
Emily B. Nestler
Julie Straus Harris
Kate Talmor

For intervenor defendant-appellant Danco Laboratories

Catherine Emily Stetson
Hogan Lovells US LLP
555 13th Street NW
Washington Dc, DC 20004

Jessica Lynn Ellsworth
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, DC 20004

Kaitlyn Golden
Hogan Lovells US LLP
555 13th St NW
Washington, DC 20004

Lynn Whipkey Mehler
Hogan Lovells US LLP
555 13th Street NW
District Of Columbia, DC 20004

Marlan Golden
Hogan Lovells US LLP
555 13th Street NW
Washington, DC 20004

Philip Katz
Hogan Lovells
555 Thirteenth Street NW
Washington, DC 20004

Ryan Patrick Brown
Ryan Brown Attorney at Law
1222 S Fillmore St
Amarillo, TX 79101

Amici and Counsel:

The Chattanooga National Memorial for the Unborn

Darald John Schaffer
Samples Jennings Clem & Fields PLLC
130 Jordan Avenue
Chattanooga, TN 37421

Michael S Jennings
Samples Jennings Clem & Fields PLLC
130 Jordan Drive
Chattanooga, TN 37421

Doctors for America

Christopher Morten
Columbia Law School
435 W 116th St (Jerome Greene Hall)
New York, NY 10027

Thomas S Leatherbury
Thomas S Leatherbury Law PLLC
1901 N Akard St
Dallas, TX 75201

American Center for Law and Justice

Edward Lawrence White , III
American Center for Law & Justice
3001 Plymouth Road Suite 203
Ann Arbor, MI 48105

State of Missouri

Joshua Divine
Office of The Missouri Attorney General
207 W High St Po Box 899
Jefferson City, MO 65102

Human Coalition

Elissa Michelle Graves
1907 Bonanza Drivce
Sachse, TX 75048

State of Mississippi, State of Alabama, State of Alaska, State of Arkansas, State of Florida, State of Georgia, State of Idaho, State of Indiana, State of Iowa, State of Kansas, State of Louisiana, State of Kentucky, State of Montana, State of Nebraska, State of Ohio, State of Oklahoma, State of South Carolina, State of South Dakota, State of Tennessee, State of Texas, State of Utah, State of Wyoming

Justin Lee Matheny
Mississippi Attorney General Office
550 High Street Suite 1200
Jackson, MS 39205

States of New York California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Washington, Wisconsin, Washington DC

Galen Sherwin
NYS Office of The Attorney General
Executive State Capital
Albany, NY 12224

Life Collective Inc

Darren L McCarty
McCarty Law PLLC
1410b W 51st Street
Austin, TX 78756

Family Research Council

Michael F Smith
The Smith Appellate Law Firm
1717 Pennsylvania Ave NW Suite 1025
Washington, DC 20006

Judicial Watch Inc

Meredith Di Liberto
Judicial Watch Inc
425 Third Street SW, Suite 800
Washington, DC 20024

Advancing American Freedom

John Marc Wheat
Advancing American Freedom
801 Pennsylvania Ave NW Suite 930
Washington, DC 20004

Concerned Women for America

Mario Diaz
Concerned Women for America
Legal 1000 N Payne St
Alexandria, VA 22314

Greer Donley, R. Alta Charo, I. Glenn Cohen, Marsha Cohen, Nathan Cortez, Rebecca Eisenberg, Henry Greely, George Horvath, Peter Barton Hutt, Joan Krause, Holly Fernandez Lynch, Elizabeth McCuskey, Jennifer Oliva, Jordan Paradise, Christopher Robertson, Joanna Sax, Allison Whelan, Diana Winters, Patricia Zettler

Robert John Winson
Covington & Burling LLP
1999 Avenue Of The Stars
Los Angeles, CA 90067

Alysia Brianna Cordova
Mullin Hoard & Brown LLP
500 S Taylor Suite 800
Amarillo, TX 79101

Beth E Braiterman
Covington & Burling LLP
850 10th Street NW
Washington, DC 20001

Denise Esposito
Covington and Burling LLP
850 10th Street NW
Washington, DC 20001

Emile Katz
850 10th St NW
Washington, DC 20268

Guillaume Julian
Covington & Burling
850 Tenth Street NW
Washington, DC 20001

Julia F Post
Covington & Burling LLP
850 Tenth Street NW
Washington, DC 20001

Lewis A Grossman
Covington & Burling LLP
850 10th St., NW
Washington, DC 20268

Richard Biggs
Mullin Hoard & Brown LLP
500 S Taylor Suite 800
Amarillo, TX 79109

Robert A Long , Jr
Covington & Burling LLP
850 Tenth Street NW
Washington, DC 20001

American College of Obstetricians and Gynecologists

Molly A Meegan
ACOG
General Counsel's Office 409 12th Street SW Washington
Washington, DC 20024

Adam Bresler Aukland-Peck
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001

Matthew W Sherwood
McCarn & Weir
905 S. Fillmore Suite 530
Amarillo, TX 79101

Megan McGuiggan
Debevoise & Plimpton LLP
801 Pennsylvania Avenue NW Ste 500
Washington, DC 20004

Shannon Rose Selden
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001

Susan B. Anthony Pro-Life America, Catholic Health Care Leadership Alliance, The National Catholic Bioethics Center, Catholic Bar Association, Catholic Benefits Association, Christ Medicus Foundation

Murphy S Klasing
Weycer, Kaplan, Pulaski & Zuber, P.C.
11 Greenway Plaza Suite 1400
Houston, TX 77046

67 Members of Congress

Fernando M Bustos
Bustos Law Firm PC
P.O. Box 1980
Lubbock, TX 79408-1980

Carolyn McDonnell
Americans United for Life
1150 Connecticut Ave. NW Ste 500
Washington, DC 20036

American Medical Association, Society of Maternal and Fetal Medicine, American Academy of Family Physicians, American Gynecological & Obstetrical Society, American Society for Reproductive Medicine, Council of University Chairs of Obstetrics & Gynecology, North American Society for Pediatric and Adolescent Gynecology, Nurse Practitioners in Women's Health, Society of Family Planning, Society of Gynecologic Oncology, Society of OB/GYN Hospitalists

Adam Bresler Aukland-Peck
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001

Matthew W Sherwood
McCarn & Weir
905 S. Fillmore Suite 530
Amarillo, TX 79101

Megan McGuiggan
Debevoise & Plimpton LLP
801 Pennsylvania Avenue NW Ste 500
Washington, DC 20004

Shannon Rose Selden
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001

Ethics and Public Policy Center

M Edward Whelan
1730 M Street NW Suite 910
Washington, DC 20036

Charles W Fillmore
The Fillmore Law Firm LLP
201 Main Street Suite 801
Fort Worth, TX 76102

H Dustin Fillmore , III
The Fillmore Law Firm LLP
201 Main Street Suite 801
Fort Worth, TX 76102

Texas Business Leaders

John Clay Sullivan
S|L Law PLLC
610 Uptown Boulevard, Suite 2000
Cedar Hill, TX 75104

Charlotte Lozier Institute

Cristina Martinez Squiers
Schaerr | Jaffe LLP
1717 K Street NW Suite 900
Washington, DC 20006

Gene C Schaerr
Schaerr | Jaffe LLP
1717 K Street NW Suite 900
Washington, DC 20006

Coalition For Jewish Values Healthcare Council

Murphy S Klasing
Weycer, Kaplan, Pulaski & Zuber, P.C.
11 Greenway Plaza Suite 1400
Houston, TX 77046

State of Arizona

Joshua Bendor
Office of the Arizona Attorney General
2005 N Central Avenue
Phoenix, AZ 85004

Objector and Counsel:

News Media Coalition

Peter Blackmer Steffensen
SMU Dedman School of Law
P.O. Box 750116
Dallas, TX 75275-0116

/s/ Cynthia A. Barmore
Cynthia A. Barmore
Counsel for Appellants

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Regulations:

Legislative Material:

Other Authorities:

INTRODUCTION

More than two decades ago, the Food and Drug Administration (FDA) determined that mifepristone is safe and effective to terminate early pregnancies. FDA has consistently adhered to that judgment across five presidential administrations. During that time, more than five million Americans have chosen to end their pregnancies using mifepristone. Today, more than half of women who terminate their pregnancies rely on that drug. When mifepristone is used as FDA directs, serious adverse events are exceedingly rare, just as they are for many common drugs like ibuprofen.

Rather than preserving the status quo, as preliminary relief is meant to do, the district court upended decades of reliance by blocking FDA's approval of mifepristone and depriving patients of access to this safe and effective treatment, based on the court's own misguided assessment of the drug's safety. The district court took this extraordinary step despite the fact that plaintiffs did not seek relief for many years after mifepristone's original approval, waited nearly a year after the most recent FDA actions they seek to challenge, and then

asked the court to defer any relief until after a final resolution of the case.

The district court's extraordinary and unprecedented order should be stayed pending appeal. Plaintiffs lack standing to challenge FDA's approval of a drug they neither take nor prescribe; their challenge to FDA actions dating back to 2000 is manifestly untimely; and they have provided no basis for second-guessing FDA's scientific judgment. Those defects foreclose plaintiffs' claims, and the court flouted fundamental principles of Article III and administrative law in holding otherwise. Indeed, no precedent, from any court, endorses plaintiffs' standing, timeliness, or merits theories.

The court's sweeping nationwide relief was especially unwarranted given the balance of harms: If allowed to take effect, the court's order would thwart FDA's scientific judgment and severely harm women, particularly those for whom mifepristone is a medical or practical necessity. This harm would be felt throughout the country, given that mifepristone has lawful uses in every State. The order would undermine healthcare systems and the reliance interests of businesses and medical providers. In contrast, plaintiffs present no evidence that

they will be injured at all, much less irreparably harmed, by maintaining the status quo they left unchallenged for years.

The district court granted a seven-day administrative stay. This Court should extend the administrative stay pending resolution of stay proceedings in this Court and, if necessary, the Supreme Court. The Court should then stay the district court's order pending appeal. The government requests that this Court enter an administrative stay or grant a stay pending appeal by noon on April 13, to enable the government to seek relief in the Supreme Court if necessary. Plaintiffs oppose a stay pending appeal and an administrative stay, while Intervenor consents.

STATEMENT

1. In 2000, FDA approved mifepristone as safe and effective to terminate pregnancy through the first seven weeks of gestation. Add.181. FDA placed restrictions on the drug's distribution, known today as a risk evaluation and mitigation strategy (REMS), to ensure its safe use. Add.186-91. FDA comprehensively reviewed the scientific evidence and concluded that, with those restrictions in place, the benefits of mifepristone outweighed its risks. Add.181-88. In 2002, two

of the plaintiffs in this case petitioned FDA to withdraw the approval, and FDA denied that petition in March 2016. Add.804-36.

Also in March 2016, FDA modified mifepristone's approved conditions of use, including the REMS, in light of evidence showing the drug's safety and effectiveness under those modified conditions of use. Add.768, 777-802. For example, FDA increased the gestational age limit from seven to ten weeks. *Id.* In 2019, two of the plaintiffs filed a petition challenging the 2016 modification. That petition did not ask FDA to revisit the 2000 approval; instead, it asked FDA to "restore" the 2000 conditions and "retain" a requirement that mifepristone be dispensed to patients in person. Add.192. In 2021, FDA denied that petition in relevant part, Add.843-76, and, in 2023, removed the in-person dispensing requirement, *REMS Single Shared System for Mifepristone 200 mg* (Jan. 2023), https://perma.cc/MJT5-35LF.

2. Plaintiffs are physicians and organizations representing physicians. They sought an injunction ordering FDA to withdraw its 2000 approval of mifepristone, or, alternatively, roll back the 2016 changes and require in-person dispensing. Add.177-78.

On April 7, the court ruled in favor of plaintiffs and issued a stay under 5 U.S.C. § 705, suspending FDA's approvals of mifepristone and thereby effectively prohibiting the sponsors from introducing mifepristone into interstate commerce. The court rejected the government's arguments that plaintiffs lack standing, Add.6-17, and that many of their claims are untimely, Add.18-25. On the merits, the court held that FDA's actions were arbitrary and capricious, largely based on the court's own interpretation of extra-record publications submitted by plaintiffs. Add.49-60. The court also held that FDA's 2000 approval of mifepristone improperly relied on the agency's Subpart H regulations, Add.39-48, and that statutory provisions derived from the 1873 Comstock Act prohibited FDA from removing the in-person dispensing requirement, Add.32-38; *see* 18 U.S.C. §§ 1461, 1462. Finally, the court determined that the equities and public interest favored relief. Add.61-65. The court denied the government's request for a stay pending appeal. Add.67, 374.[1]

[1] Shortly after the district court issued its order, another court enjoined FDA from "altering the status quo" with respect to mifepristone's availability in certain States. *Washington v. FDA*, No. 23-3026 (E.D. Wash. Apr. 7, 2023). FDA has moved to clarify that injunction in light of the district court's order in this case.

ARGUMENT

I. Plaintiffs Lack Standing And Their Central Claims Are Time-Barred

The merits of plaintiffs' claims are not properly before any court.

A. The district court erred in holding that plaintiffs have standing. Their asserted injuries rest on a "highly attenuated chain of possibilities" that falls far short of demonstrating injury-in-fact. *Louisiana v. Biden*, 2023 WL 2780821, *4 (5th Cir. 2023) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 (2013)). Plaintiffs do not prescribe mifepristone. Instead, they speculate that *other* doctors will prescribe mifepristone; that those doctors' patients will experience exceedingly rare serious adverse events; that those patients will then seek out plaintiffs—doctors who oppose mifepristone and abortion—for care; and that they will do so in sufficient numbers to burden plaintiffs' medical practices. Such "'allegations of *possible* future injury' are not sufficient" because a "threatened injury must be *certainly impending* to constitute injury in fact." *Clapper*, 568 U.S. at 409. That is especially so here, because plaintiffs' speculative claims of injury "depend[] on the unfettered choices made by independent actors." *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992).

The court concluded that the plaintiff organizations have standing to sue on behalf of their members "because they allege adverse events from chemical abortion drugs can overwhelm the medical system." Add.7. But plaintiffs rely on only a handful of alleged incidents over two decades, none of which meaningfully interfered with a member's medical practice. Under the court's approach, doctors would have standing to challenge FDA approval of any drug; they would likewise have standing to challenge any other federal action that might injure third parties. An association of doctors could, for example, challenge the licensing of federal firearms dealers, or allegedly inadequate highway safety standards, on the theory that some individuals may be injured and seek treatment from the association's members.

Neither plaintiffs nor the district court cited any precedent for that extravagant position. To the contrary, Supreme Court precedent forecloses plaintiffs' attempt to rely on a "statistical probability" that some member might treat a patient for mifepristone complications—even if particular members have done so on rare occasions in the past. *Summers v. Earth Island Inst.*, 555 U.S. 488, 497-99 (2009). Standing cannot be based on "past injury rather than imminent future injury

that is sought to be enjoined." *Id.* at 495. Isolated past incidents plainly do not show "*certainly impending*" future harm to plaintiffs' medical practices. *See Clapper*, 568 U.S. at 409.

The court also concluded that the associations have organizational injury because they have spent money "to respond to FDA's actions." Add.13. But plaintiffs "cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending." *Clapper*, 568 U.S. at 416. The court's reasoning would entitle any organization to challenge any governmental policy that it advocates against.[2]

Finally, the court erred in holding that plaintiffs may assert the interests of women who might take mifepristone in the future. Add.9-11. Doctors who are not regulated by a challenged law cannot assert third-party standing on behalf of hypothetical future patients who

[2] The court also concluded that lack of information on adverse events undermined plaintiffs' ability to obtain informed consent to prescribe mifepristone. Add.8-9. But plaintiffs have no intention of prescribing mifepristone. Relatedly, the court found organizational standing based on FDA's requirements for adverse event reporting. Add.12-13. But these claimed injuries at most would enable plaintiffs to challenge FDA's reporting requirements, not the drug approval. *See* Add.856 (explaining adverse event reporting changes).

might someday want their services. *See Kowalski v. Tesmer*, 543 U.S. 125, 130-31 (2004) (no third-party standing based on "future attorney-client relationship with as yet unascertained Michigan criminal defendants"). Plaintiffs' interests are also not aligned with their hypothetical future patients. *See Canfield Aviation, Inc. v. NTSB*, 854 F.2d 745, 748 (5th Cir. 1988). In fact, they are diametrically opposed: Plaintiffs seek to block access to mifepristone, but the hypothetical patients they posit are, by definition, women who wish to use the drug.

The court reasoned that if abortion providers have standing to challenge laws restricting abortion, so too must plaintiffs have standing here. Add.10. But unlike physicians who regularly provide abortions and thus have or will have patients harmed by an abortion restriction, it is wholly speculative that plaintiffs will have patients harmed by mifepristone. And unlike providers whose conduct is directly regulated by the challenged restriction, plaintiffs face no "'threatened imposition of governmental sanctions' for noncompliance" with any agency action related to mifepristone. *See June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2118-19 (2020).

B. The court also erred by holding that plaintiffs' claims are timely. As the court recognized, Add.19, each claim has a six-year statute of limitations. 28 U.S.C. § 2401(a). FDA approved mifepristone in 2000. Add.181. In 2002, plaintiffs filed a petition challenging certain safety findings and the agency's use of its Subpart H authority, and FDA denied that petition in March 2016. Add.804-36. Those actions occurred more than six years before plaintiffs filed suit. Add.179. Plaintiffs' claims challenging the 2000 approval and the 2016 petition denial are thus time-barred.

The court erred in concluding that FDA reopened those decisions and thereby restarted the statute of limitations. Add.19-23. The reopening doctrine does not apply here, where FDA did not undertake "a serious, substantive reconsideration" of its 2000 approval of mifepristone. *See Texas v. Biden*, 20 F.4th 928, 951-52 (5th Cir. 2021), *rev'd on other grounds*, 142 S. Ct. 2528 (2022).

First, FDA did nothing to reconsider its approval of mifepristone when it modified the conditions of use, including the REMS, in 2016. At that time, FDA relaxed specific REMS conditions. FDA had already found in 2000 that mifepristone was safe and effective *with* those

conditions; the question in 2016 was whether mifepristone would remain safe and effective *without* them. FDA thus evaluated new evidence bearing on whether certain conditions were too restrictive. And FDA did not even mention Subpart H, much less reopen its analysis of that issue. Nor would FDA have needed to revisit these issues when it modified the conditions of use, including the REMS, given that, on the same day, FDA issued a separate decision denying plaintiffs' petition raising these arguments. Plaintiffs did not timely seek review of that decision. They cannot circumvent the statute of limitations by seeking judicial review of a different agency decision predicated on the understanding that mifepristone was properly approved.

Second, FDA did not reopen the approval when it denied plaintiffs' second petition in 2021. An agency does not "trigger the reopening doctrine" when it denies a petition and "respond[s] to assertions in the petition." *National Mining Ass'n v. U.S. Dep't of Interior*, 70 F.3d 1345, 1352 (D.C. Cir. 1995). To the contrary, when an agency refuses to rescind a prior decision, judicial review is strictly "limited to the '*narrow issues as defined by the denial of the petition*'" and does not

reach "the agency's original action." *NLRB Union v. FLRA*, 834 F.2d 191, 196 (D.C. Cir. 1987). Here, FDA simply responded to plaintiffs' assertions related to in-person dispensing and the 2016 changes. Revoking the underlying approval was not at issue. Indeed, plaintiffs themselves took that approval for granted, affirmatively urging FDA to "restore" the restrictions "approved in 2000" and "retain" the mifepristone REMS. Add.192.

The court's reliance on *Sierra Club v. EPA*, 551 F.3d 1019 (D.C. Cir. 2008), was misplaced. *Sierra Club* held that an agency constructively reopened a rule by "significantly alter[ing] the stakes of judicial review" when the original rule "may not have been worth challenging" on its own. *Id.* at 1025-26. Here, plaintiffs *did* challenge mifepristone's original approval on its own (by filing a citizen petition in 2002); they simply failed to timely seek review of FDA's denial of that challenge. In any event, FDA did not effect a "sea change" to mifepristone's "basic regulatory scheme" in 2016 and thus did not constructively reopen the approval even under the *Sierra Club* framework. *See National Biodiesel Bd. v. EPA*, 843 F.3d 1010, 1017 (D.C. Cir. 2016).

The court alternatively concluded that plaintiffs were entitled to equitable tolling. Add.23-25. But plaintiffs *never even asked* for equitable tolling, because they have no plausible claim to it. As the court acknowledged, equitable tolling is available "only if [a plaintiff] shows '(1) that he has been pursuing his rights diligently, and (2) that some extraordinary circumstance stood in his way' and prevented timely filing." *Holland v. Florida*, 560 U.S. 631, 649 (2010). The court did not find, and could not plausibly have found, that either requirement was satisfied. 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 of that decision and identify no extraordinary circumstance that prevented them from filing sooner. Nor is there any merit to the court's suggestion that FDA's delay in responding to plaintiffs' petition somehow erases the statute of limitations that Congress established. If anything, that delay extended the deadline for plaintiffs to bring suit. And if plaintiffs were dissatisfied with the delay, they could have sued to compel agency action. But nothing that happened *before* FDA's 2016 decision denying plaintiffs' petition

justifies their failure to sue within the generous six-year statute of limitations *after* FDA's action.

II. Plaintiffs' Claims Lack Merit

Even were plaintiffs' claims properly before the court, they would be unlikely to succeed.

A. FDA's approval of mifepristone and subsequent modifications of the REMS were wholly reasonable. The FDCA requires FDA to determine whether a drug "is safe for use" under the proposed conditions of use. 21 U.S.C. § 355(d). That is what FDA did with mifepristone. *See* Add.181-88, 778-802, 806-35, 842-76. The Government Accountability Office confirmed that FDA's 2000 and 2016 decisions followed the agency's standard processes. Add.377, 432.

The court repeatedly characterizes mifepristone as unsafe. But over the last two decades, the available evidence conclusively demonstrates that mifepristone is safe under the approved conditions of use. More than five million women have used mifepristone to terminate their pregnancies in the United States. Add.658. Mifepristone is also approved in dozens of other countries. Add.759 (62 countries as of 2015). The literature reflects "exceedingly rare" rates of serious adverse

events. Add.707. The mifepristone labeling indicates, for example, sepsis and hemorrhage are each 0.2% or less and transfusions and hospitalization related to medical abortion are each 0.7% or less. *See Mifepristone Labeling* 8, https://perma.cc/PU3Y-7TSK. All drugs can cause adverse events, including mifepristone. Even ibuprofen, which is commonly used for pain relief, can infrequently cause serious adverse events. Add.467. The FDCA does not require FDA to approve drugs only when they are without risk—no drug is—but to consider a drug's risks in relation to its benefits. That is what FDA did here.

Even where a drug may be associated with an adverse event, it may not have caused that event. Among the more than five million women who have taken mifepristone since 2000, as of June 30, 2022, only 28 deaths were reported and some of those deaths were associated with obvious alternative causes—including homicide, drug overdose, and other factors entirely unrelated to their use of mifepristone. *See Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022*, https://perma.cc/LAM4-KVDZ. In addition, pregnancy itself entails a significantly higher risk of serious adverse events,

including a death rate 14 times higher than that associated with legal abortion. Add.807.

This Court's role is to "simply ensur[e] that the agency has acted within a zone of reasonableness." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). The court erred by overriding FDA's eminently reasonable scientific judgments based on the court's own interpretation of articles and studies, including many submitted by plaintiffs or their amici to the court but not to FDA. For example, in concluding that *no* women should have access to mifepristone because it is harmful to them, the court relied on an article that was based entirely on fewer than 100 anonymous blog posts submitted to a website titled *Abortion Changes You*, Add.46; the study itself conceded that "the population of women who write an anonymous post about their abortion experience may be different from those who do not." Katherine A. Rafferty & Tessa Longbons, *#AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives*, 36 Health Comm. 1485, 1492 (2021), https://perma.cc/K69Y-FJXQ.

The court criticized FDA for relying on studies with somewhat different protocols than the conditions of use approved by the agency, *e.g.*, Add.49, 59, but an obligation to approve drugs only with conditions of use identical to the study protocols in supporting clinical trials finds no support in the FDCA. Congress directed FDA to evaluate drug safety based on "the information submitted … as part of the application" and "any other information" before the agency. 21 U.S.C. § 355(d). No provision requires FDA to limit approved conditions of use to the precise protocols in clinical trials. Had Congress wanted to impose such a requirement, it would have said so, but it instead granted wide discretion to FDA.

Nor is there any scientific reason to require drug sponsors to rerun costly clinical trials without the safeguards that proved unnecessary in previous trials. As FDA explained, "[m]any clinical trial designs are more restrictive … than will be necessary or recommended in post[-]approval clinical use; this additional level of caution is exercised until the safety and efficacy of the product is demonstrated." Add.831. FDA thus routinely approves drugs with conditions of use that differ from clinical trial protocols. For example, routine biopsies

were performed in trials for menopause hormonal therapy drugs to establish their safety, but FDA did not require biopsies in those drugs' approved conditions of use. Add.831, 470-73, 517-18; *see also, e.g.*, Add.530, 563 (for Aveed, liver function tests required in clinical trials but not approved conditions of use); Add.599, 632 (for Cialis, same for electrocardiograms); Add.634, 654 (for Lipitor, same for routine measurement of creatinine kinase levels). Similarly, here, FDA thoroughly explained why particular "safeguards" were unnecessary to include in mifepristone's approved conditions of use, Add.184-85, 821-24, and relied on abundant evidence that the court did not address.

The court also faulted FDA for deferring to medical providers on the appropriate method for dating pregnancies and diagnosing ectopic pregnancies. Add.51-59. The agency respects that doctors are usually best positioned to make clinical decisions for their patients, and there are a variety of ways to date pregnancies and diagnose ectopic pregnancies. Add.821. FDA's deference to the doctor-patient relationship is hardly arbitrary and capricious.[3]

[3] The court also mistakenly described FDA as having concluded that mifepristone was *not* safe and effective under the approved

B. The court also erred by holding that FDA's approval of mifepristone was invalid under Subpart H of its regulations. Add.39-48.

The court fundamentally misunderstood FDA's Subpart H authority. Those regulations apply to drugs that treat "serious or life-threatening illnesses" and provide meaningful therapeutic benefits over existing treatments. 21 C.F.R. § 314.500. FDA may restrict the drug's distribution under Subpart H, as it did for mifepristone. *See id.* § 314.520. But the drug *approval* is based on FDA's statutory authority under 21 U.S.C. § 355, not Subpart H. And in 2007, Congress created the new REMS framework and incorporated mifepristone's restrictions into that framework. Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, 121 Stat. 823, tit. IX. FDA has regulated mifepristone under that framework ever since, including by approving a REMS for mifepristone in 2011 under the new statutory authority. The FDAAA and FDA's actions under it supersede and

---

conditions. Add.50, 55. That was FDA's evaluation of mifepristone in February 2000 *without* distribution restrictions, but seven months later FDA concluded that "adequate information has been presented to approve" mifepristone *with* those restrictions. Add.189.

render irrelevant any issues concerning FDA's reliance on Subpart H in approving mifepristone in 2000. Any error from relying on Subpart H to impose those restrictions was therefore harmless.

In any event, FDA properly invoked Subpart H. FDA found that pregnancy "can be a serious medical condition in some women," and mifepristone avoided a surgical procedure for 92% of patients. Add.186, 806-10. The court reasoned that pregnancy is not an "illness," but the preamble to FDA's final rule explained that Subpart H was available for drugs that treat serious or life-threatening conditions. Add.807; 57 Fed. Reg. 58,942, 58,946-48 (Dec. 11, 1992). Congress ratified this understanding by authorizing FDA to impose similar restrictions under the REMS framework on drugs intended to treat a "disease or condition." 21 U.S.C. § 355-1(a)(1). And while the court disagreed that avoiding a surgical procedure is a "meaningful therapeutic benefit," FDA reasonably determined that it is for many patients. Add.808.

Finally, even if the Subpart H argument had merit, the proper remedy would be a remand to the agency without vacatur, because setting aside the 2000 approval would be severely disruptive and FDA could readily address the concern by re-evaluating the drug under the

current statutory REMS framework. *See Central & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000).

C. The court also concluded that FDA erred in 2021 in electing not to enforce and then deciding to remove the in-person dispensing requirement because of statutory provisions derived from the Comstock Act, which restrict the importation, mailing, or interstate distribution by common carrier of drugs "intended for producing abortion," among other items. 18 U.S.C. §§ 1461, 1462; Add.32-38. The court did not suggest that the Comstock Act had any bearing on FDA's original approval of mifepristone; its holding would at most justify relief related to in-person dispensing. And the court's reliance on the Comstock Act was doubly flawed: The Comstock Act is not relevant to FDA's exercise of its authority under the FDCA, and the court misinterpreted the Act in any event.

1. The FDCA requires FDA to assess safety and effectiveness when it approves a drug or imposes a REMS. *See* 21 U.S.C. §§ 355(d), 355-1. Nothing in the FDCA requires FDA to address in those decisions the Comstock Act or any of the many other laws that may restrict the drug's distribution or use. Instead, the FDCA properly leaves

enforcement of those laws to the agencies charged with their administration. For example, the Controlled Substances Act restricts distribution of fentanyl, but FDA has not incorporated those restrictions in the approval or REMS for certain fentanyl products. *Transmucosal Immediate Release Fentanyl Shared System REMS Program* (Dec. 2022), https://perma.cc/JK6T-S99C; 21 U.S.C. §§ 841-843.

2. Regardless, the district court misinterpreted the Comstock Act. The statute originally prohibited selling drugs for "causing unlawful abortion" (among other items) in federal territories, Act of Mar. 3, 1873, ch. 258, § 1, 17 Stat. 598, 598-99; mailing drugs for "procuring of abortion," *id.* § 2; and importing the "hereinbefore-mentioned articles," *id.* § 3. The next year, Congress clarified that the importation restriction, like the federal territory restriction, was limited to drugs for "causing *unlawful* abortion." Rev. Stat. § 2491 (1st ed. 1875), 18 Stat. pt. 1, at 460 (emphasis added). Despite "slight distinctions in expression," the Act's restrictions were part of a unified scheme, and courts and the Postal Service interpreted all of the restrictions as limited to articles used unlawfully. *See, e.g.*, *United States v. One Package*, 86 F.2d 737, 740 (2d Cir. 1936) (Learned Hand, J.,

concurring); Add.262-73. And, by 1965, FDA had approved at least seven oral contraceptives, even though contraceptives were still among the Act's enumerated items. *See* Lara Marks, *Sexual Chemistry: A History of the Contraceptive Pill* 77-78 (2001). Congress ratified this understanding by repeatedly amending the Comstock Act and the FDCA without material change. *See, e.g.*, Add.269-72.

The court ignored this history, emphasizing the Act's "plain text." Add.34-35. But reading the words "in their context and with a view to their place in the overall statutory scheme," the Act never prohibited the distribution of abortion drugs for lawful uses. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). At most, the text is ambiguous: The statute does not specify whether it applies to drugs for "any" or only "unlawful" abortion. 18 U.S.C. §§ 1461, 1462. Various provisions used "abortion" and "unlawful abortion" interchangeably. And the reference to "indecent or immoral" uses suggests it does not target legitimate medical uses. Thus, at a minimum, the Act does not speak "clearly" enough to have "significantly changed the federal-state balance" by applying to drugs used lawfully. *See United States v. Bass*, 404 U.S. 336, 349 (1971).

In any event, whatever the Act's application to other abortion drugs, it cannot criminalize mifepristone's distribution system, because Congress affirmatively directed that distribution system to continue by enacting the FDAAA in 2007. Congress therein "deemed" drugs like mifepristone to have an enforceable REMS containing "any" existing conditions. FDAAA § 909(b), 121 Stat. at 950-51; Add.810. The FDAAA thereby superseded any application of the Comstock Act to mifepristone. Since mifepristone's approval in 2000, the drug has been imported and distributed interstate. *See* Add.220; *e.g.*, Add.186 (requiring "[s]ecure shipping procedures"). The "plain import" of Congress's decision to direct mifepristone's existing distribution system to continue is that the Comstock Act does not bar those same activities. *See Dorsey v. United States*, 567 U.S. 260, 274-75 (2012). Thus, although the court declared that "[r]epeals by implication" are disfavored, Add.36-37, plaintiffs' reading of the Comstock Act cannot be reconciled with Congress's 2007 action, which carried forward the existing distribution system for mifepristone.

III. The Government's Interests And The Public Interest Overwhelmingly Favor A Stay

The purpose of preliminary relief "is to preserve the status quo and thus prevent irreparable harm" before the merits are decided. *See City of Dallas v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017). "[M]aintenance of the status quo" is likewise "an important consideration in granting a stay." *Barber v. Bryant*, 833 F.3d 510, 511 (5th Cir. 2016). The court upended the status quo with its abrupt and sweeping nationwide order. If allowed to take effect, that order will irreparably harm patients, healthcare systems, and businesses.

Congress empowered FDA to ensure that drugs are safe and effective. FDA has done so with respect to mifepristone, both in 2000 and in carefully assessing its distribution conditions in recent years. The court's order arrogates that power to the detriment of women across the country. For many patients, mifepristone is the best method to lawfully terminate their pregnancies. Add.321-23, 330-37, 350-51. Surgical abortion can entail greater health risks for some patients, such as patients allergic to anesthesia. Add.184-86, 808, 319-20, 330, 333, 342, 349-50. Surgical abortion is also often unavailable for practical reasons even when abortion is lawful, and travel costs could place

abortion entirely out of reach for some patients. Add.334-37 (explaining that 1 of 18 Maine Family Planning clinics offers surgical abortion). Deprivation of "necessary medical care" imposes irreparable harm. *Jones v. Texas Dep't of Criminal Justice*, 880 F.3d 756, 759-60 (5th Cir. 2018) (per curiam). The order also harms patients, their families, and providers by overburdening healthcare systems, leading to long waits for care in a system with limited resources. Add.294-303.

Moreover, in every State abortion is lawful under circumstances where mifepristone may be the best treatment option. *See* Add.274-77. The government also understands that mifepristone is used for non-abortion purposes, including miscarriage management, a reality that underscores the larger potential effects of the court's order. For example, while Wyoming recently passed a law to prohibit mifepristone's use in many circumstances, it sought to preserve access to mifepristone for miscarriage management. SF109, § 1, 67th Leg., 2023 Gen. Sess. (Wyo. 2023). The order thus deprives residents in all States of a treatment option that may best serve their needs.

IV. Plaintiffs Will Not Suffer Irreparable Harm

In contrast, plaintiffs have not shown that a stay would "substantially injure" their interests. *Nken v. Holder*, 556 U.S. 418, 426 (2009). The court reasoned that plaintiffs would be irreparably harmed by having to treat patients suffering adverse events from mifepristone. Add.61. As discussed above, however, serious adverse events are "exceedingly rare." Add.707. And plaintiffs' claims of irreparable harm—like their standing allegations—rely on speculation that hypothetical patients suffering rare adverse events will seek plaintiffs' care. Yet plaintiffs' own experiences confirm mifepristone's safety profile: Despite mifepristone's widespread use for decades, plaintiffs describe only a handful of times they or their members ever treated a patient for alleged complications from mifepristone. *See supra* pp. 6-8. It is wholly implausible that their practices will be materially affected by such cases in the future, particularly for plaintiffs in States where abortion is largely banned.

In addition, the course of plaintiffs' litigation vividly demonstrates the lack of equity in blocking the distribution of a drug that has been found safe and effective by FDA and available to millions of patients for

more than two decades. In 2016, FDA denied plaintiffs' petition challenging the drug approval, and plaintiffs waited more than six years to seek judicial review. Their "unnecessary, years-long delay in asking for preliminary injunctive relief weigh[s] against their request." *Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018) (per curiam). Even the most recent action plaintiffs challenge occurred eleven months before they filed suit. Plaintiffs also encouraged the court to consolidate their preliminary injunction motion with a bench trial, confirming their interests would not be prejudiced by forgoing preliminary relief and waiting months for trial. *See* Add.362. Plaintiffs' conduct confirms that there is no basis for extraordinary nationwide relief that would upend a decades-long status quo and inflict grave harm on women, the medical system, and the public.

CONCLUSION

The Court should immediately extend the administrative stay and then stay the district court's order pending appeal.

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

LEIGHA SIMONTON
United States Attorney

SARAH E. HARRINGTON
Deputy Assistant Attorney General

MICHAEL S. RAAB

/s/ Cynthia A. Barmore
CYNTHIA A. BARMORE
Civil Division, Appellate Staff
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530
(202) 305-1754

APRIL 2023

CERTIFICATE OF SERVICE

I hereby certify that, on April 10, 2023, I electronically filed the foregoing motion 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.

/s/ Cynthia A. Barmore
Cynthia A. Barmore
Counsel for Appellants

CERTIFICATE OF COMPLIANCE

I hereby certify that this motion complies with the requirements of Federal Rule of Appellate Procedure 27(d) because it has been prepared in 14-point Century Schoolbook, a proportionally spaced font. I further certify that this motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2) because it contains 5,192 words according to the count of Microsoft Word. I further certify that this emergency motion complies with the requirements of 5th Cir. R. 27.3 because it was preceded by a telephone call to the Clerk's Office on April 10, 2023, and email to opposing counsel on April 10, 2023, advising of the intent to file this emergency motion. I further certify that the facts supporting emergency consideration of this motion are true and complete. I further certify under 5th Cir. R. 27.4 that appellees oppose this motion and plan to file a response in opposition.

/s/ Cynthia A. Barmore
Cynthia A. Barmore
Counsel for Appellants