

No. 23-10362

**United States Court of Appeals
for the Fifth Circuit**

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

v.

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
CASE NO. 2:22-cv-00223

**BRIEF OF 240 MEMBERS OF CONGRESS AS *AMICUS CURIAE* IN
SUPPORT OF DEFENDANTS-APPELLANTS' EMERGENCY MOTION
FOR A STAY PENDING APPEAL**

William A. McConagha	Boris Bershteyn
Jennifer L. Bragg	One Manhattan West
Keyawna Griffith	New York, NY 10001
1414 New York Ave NW	(212) 735-3000
Washington, DC 20005	boris.bershteyn@probonolaw.com

Counsel for Amicus Curiae 240 Members of Congress

A complete list of the 50 U.S. Senators and the 190 Members of the U.S. House of Representatives participating as *amici curiae* is provided as an appendix to the brief. Among them are:

Sen. Charles E. Schumer	Rep. Hakeem Jeffries
Sen. Patty Murray	Rep. Katherine Clark
Sen. Bernard Sanders	Rep. Frank Pallone, Jr.
Sen. Richard J. Durbin	Rep. Jerrold Nadler
Sen. Richard Blumenthal	Rep. Diana DeGette
	Rep. Barbara Lee

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 2000

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 Drive
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

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

Grace X. Zhou
Assistant Attorney General
28 Liberty Street
New York, NY 10005

240 Members of Congress

Boris Bershteyn
One Manhattan West

New York, NY 10001
(212) 735-3000
boris.bershteyn@probonolaw.com

William A. McConagha
Jennifer L. Bragg
Keyawna Griffith
1414 New York Ave NW
Washington, DC 20005

Objector and Counsel:

News Media Coalition

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

Dated: April 11, 2023
New York, New York

s/ Boris Bershteyn
Boris Bershteyn
Counsel for Amici Curiae

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TABLE OF AUTHORITIES

Page(s)

CASES

Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc.,
462 U.S. 87 (1983).....6

Dobbs v. Jackson Women’s Health Organization,
142 S. Ct. 2228 (2022) xi, 2, 16, 18, 19, 23

MKB Management Corp. v. Burdick,
855 N.W.2d 31 (N.D. 2014).....7

National Mining Ass’n v. Secretary, U.S. Department of Labor,
812 F.3d 843 (11th Cir. 2016).....6, 16

Planned Parenthood of Southwest & Central Florida v. State,
No. 2022 CA 912, 2022 WL 2436704 (Fla. Cir. Ct. July 5, 2022),
rev’d on other grounds, 344 So. 3d 637 (Fla. Dist. Ct. App. 2022),
review granted, No. SC22-1050, 2023 WL 356196 (Fla. Jan. 23,
2023)7

Sabine River Authority v. U.S. Department of Interior,
951 F.2d 669 (5th Cir. 1992).....7

Schering Corp. v. FDA,
51 F.3d 390 (3d Cir. 1995).....5

STATUTES

5 U.S.C. § 7052

5 U.S.C. § 706(2)6

18 U.S.C. § 1461.....12

21 U.S.C. § 321(p)1, 4

21 U.S.C. § 3554, 9

21 U.S.C. § 355(a)1, 4

21 U.S.C. § 355(b)(1)5

21 U.S.C. § 355(b)(1)(A)(i)8, 10

21 U.S.C. § 355(d).....5

21 U.S.C. § 355(e)15

21 U.S.C. § 355(h).....5

21 U.S.C. § 355-112

21 U.S.C. § 355-1(a)(1)11

21 U.S.C. § 355-1(a)(1)(B)11

21 U.S.C. § 355-1(a)(1)(C)11

21 U.S.C. § 355-1(a)(1)(E)11

21 U.S.C. § 3719

21 U.S.C. § 371(a)5

21 U.S.C. § 393(b)(2)(B)4

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 to 399i1

Food and Drug Administration Amendments Act of 2007,
 Pub. L. No. 110-85, § 909(b)(1)(A), 121 Stat. 823, 95011

REGULATIONS

21 C.F.R. § 314.500.....9, 20

Identification of Drug and Biological Products Deemed to Have Risk
 Evaluation and Mitigation Strategies for Purposes of the Food and
 Drug Administration Amendments Act of 2007,
 73 Fed. Reg. 16,313 (Mar. 27, 2008)12

New Drug, Antibiotic and Biological Drug Product Applications;
 Accelerated Approval,
 57 Fed. Reg. 13,234 (proposed Apr. 15, 1992).....10

New Drug, Antibiotic and Biological Drug Product Applications;
 Accelerated Approval,
 57 Fed. Reg. 58,942 (Dec. 11, 1992).....9, 10

OTHER AUTHORITIES

153 Cong. Rec. 10940 (May 2, 2007)12

153 Cong. Rec. 11668 (May 9, 2007)12

Affidavit of Dr. Sharon Liner in Support of Plaintiffs’ Motion, *Preterm-Cleveland v. Yost*, No. A2203203 (Ohio Ct. Com. Pl. filed Sept. 2, 2022)18

Jessica Beaman et al., *Medication to Manage Abortion and Miscarriage*, 35 J. Gen. Intern. Med. 2398 (2020)3

Chantel Boyens et al., *Access to Paid Leave Is Lowest Among Workers with the Greatest Needs*, Urban Inst. (July 2022), <https://www.urban.org/sites/default/files/2022-07/Access%20to%20Paid%20Leave%20Is%20Lowest%20among%20Workers%20with%20the%20Greatest%20Needs.pdf>21

Brief of *Amici Curiae* Medical and Public Health Societies in Opposition to Plaintiffs’ Motion for a Preliminary Injunction, *Alliance for Hippocratic Medicine v. U.S. Food & Drug Administration*, No. 2:22-cv-00223-Z (N. D. Tex. filed Feb. 14, 2023), Dkt. No. 1093

Brief of Amicus Curiae Doctors for America, *Alliance for Hippocratic Medicine v. U.S. Food & Drug Administration*, No. 2:22-cv-00223-Z (N. D. Tex. Feb. 13, 2023), Dkt. No. 9919

Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* (2021), <https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf>16

Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., Application No. 20-687, Medical Reviews (1999), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mi fepristone_medr_P1.pdf10

Ctr. for Drug Evaluation & Rsch. (CDER), *Drug and Biologic Restricted Distribution Approvals As of June 30, 2018*, FDA: U.S. Food & Drug Admin, <https://www.fda.gov/media/115040/download> (last visited Apr. 11, 2023).....10

Eugene Declercq et al., *The U.S. Maternal Health Divide: The Limited Maternal Health Services and Worse Outcomes of States Proposing New Abortion Restrictions*, Commonwealth Fund (Dec. 14, 2022), <https://www.commonwealthfund.org/publications/issue-briefs/2022/dec/us-maternal-health-divide-limited-services-worse-outcomes>.....21, 23

Ioannis T. Farmakis et al., *Maternal Mortality Related to Pulmonary Embolism in the United States, 2003-2020*, 5 Am. J. Obstetrics & Gynecology Maternal-Fetal Med. 100754 (2023)18

2 FDA Staff Medical Guides – Delegations of Authority, SMG 1410.10 (Feb. 22, 2023) (Delegations of Authority to the Commissioner of Food and Drugs), <https://www.fda.gov/media/81983/download>5

Diana Greene Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (2021)22

Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 Am. J. Pub. Health 407 (2018).....22

Karen Brooks Harper, *Wealth Will Now Largely Determine Which Texans Can Access Abortion*, Tex. Trib. (June 24, 2022), <https://www.texastribune.org/2022/06/24/texas-abortion-costs/>21

Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2020*, CDC (Feb. 23, 2022), <https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm>22

Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, CDC (Mar. 16, 2023), <https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm>22

Hypertension, World Health Org., https://www.who.int/health-topics/hypertension#tab=tab_1 (last visited Apr. 11, 2023).....11

Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, FDA: U.S. Food & Drug Admin. (Mar. 23, 2023), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation>.....8

Irritable Bowel Syndrome (IBS), NHS Inform, <https://www.nhsinform.scot/illnesses-and-conditions/stomach-liver-and-gastrointestinal-tract/irritable-bowel-syndrome-ibs> (last visited Apr. 11, 2023)11

Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, Guttmacher Inst. (Feb. 24, 2022), <https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions>.....20

Marielle Kirstein et al., *100 Days Post-Roe: At Least 66 Clinics Across 15 US States Have Stopped Offering Abortion Care*, Guttmacher Inst. (Oct. 6, 2022), <https://www.guttmacher.org/2022/10/100-days-post-roe-least-66-clinics-across-15-us-states-have-stopped-offering-abortion-care>17

Jennifer Ko, *What the FDA Can Teach Us About Regulatory Excellence*, Regulatory Rev. (Jan. 16, 2018), <https://www.theregreview.org/2018/01/16/fda-teach-regulatory-excellence/>4

Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA Consumer: The Centennial Edition (Jan.-Feb. 2006), <https://www.fda.gov/files/Promoting-Safe-and-Effective-Drugs-for-100-Years-%28download%29.pdf>4

Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022, U.S. Food & Drug Admin., <https://www.fda.gov/media/164331/download> (last visited Apr. 11, 2023)14

Nat’l Acads. of Scis., Eng’g & Med., *The Safety and Quality of Abortion Care in the United States* (2018), <http://nap.edu/24950>.....7

Plaintiffs’ Original Petition for Declaratory Judgment and Application for Permanent Injunction, *Zurawski v. State*, No. D-1-GN-23-000968 (Tex. Dist. Ct. filed Mar. 6, 2023).....18

Rosalyn Schroeder et al., *Trends in Abortion Care in the United States, 2017-2021*, *Advancing New Standards in Reprod. Health*, U.C.S.F. (2022)21

Frances Stead Sellers & Fenit Nirappil, *Confusion Post-Roe Spurs Delays, Denials for Some Lifesaving Pregnancy Care*, *Wash. Post* (July 16, 2022), <https://www.washingtonpost.com/health/2022/07/16/abortion-miscarriage-ectopic-pregnancy-care/>.....18

U.S. Dep’t of Health & Hum. Servs., *Approved Drug Products with Therapeutic Equivalence Evaluations* (43rd ed. 2023), <https://www.fda.gov/media/71474/download>.....16

U.S. Dep’t of Just., Off. of Legal Counsel, *Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions* (Dec. 23, 2022), https://www.justice.gov/d9/opinions/attachments/2023/01/03/2022-12-23_-_comstock_act_1.pdf.....12

U.S. Gov’t Accountability Off., GAO-08-751, *Food and Drug Administration: Approval and Oversight of the Drug Mifeprex* (2008), <https://www.gao.gov/assets/gao-08-751.pdf>.....13

U.S. Gov’t Accountability Off., GAO-18-292, *Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* (2018), <https://www.gao.gov/assets/gao-18-292.pdf>14

Jessica Valenti, *I Write About Post-Roe America Every Day. It’s Worse Than You Think*, *N.Y. Times* (Nov. 5, 2022), <https://www.nytimes.com/2022/11/05/opinion/election-abortion-roe-women.html>19

Rosemary Westwood, *Bleeding and in Pain, She Couldn’t Get 2 Louisiana ERs to Answer: Is It a Miscarriage?*, *WGCU* (Dec. 29, 2022), <https://news.wgcu.org/2022-12-29/bleeding-and-in-pain-she-couldnt-get-2-louisiana-ers-to-answer-is-it-a-miscarriage>19

What Are the Risks of Preeclampsia & Eclampsia to the Mother?, Nat’l Insts. of Health, <https://www.nichd.nih.gov/health/topics/preeclampsia/conditioninfo/risk-mother> (last updated Nov. 19, 2018)18

Katherine O’Connell White, *POV: Overturning Roe v. Wade Will Worsen Health Inequities in All Reproductive Care*, BU Today (June 24, 2022), <https://www.bu.edu/articles/2022/overturning-roe-v-wade-will-worsen-health-inequities/>21

**STATEMENT OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 29**

All parties have consented to the filing of this brief of up to 5,200 words in length. No counsel for a party authored any part of this brief. No party, party's counsel or any person other than the amicus curiae, its members, or its counsel contributed money that was intended to finance the preparation or submission of this brief.

INTEREST OF AMICI CURIAE

Amici curiae are 240 Members of Congress—50 Senators and 190 Members of the House of Representatives. (See Appendix for List of *Amici*.) *Amici* have a special interest in both upholding the Constitution’s separation of powers—among other things, by ensuring that federal administrative agencies are able to faithfully exercise the authorities Congress delegated to them by statute without undue judicial interference—and protecting the physical health and safety of their constituents.

Amici believe that the district court’s stay of FDA’s September 28, 2000 Approval of mifepristone and other challenged agency actions has no basis in law, threatens the Congressionally mandated drug approval process, and poses a serious health risk to pregnant individuals by making abortion more difficult to access—when access has already been seriously eroded in the aftermath of *Dobbs v. Jackson Women’s Health Organization*. Accordingly, *Amici* respectfully urge this Court to grant emergency relief from the district court’s stay.

SUMMARY OF ARGUMENT

For the last century, a statutory scheme designed by Congress has assured the safety and effectiveness of the drugs available in the United States. At its core resides the application of scientific standards by agency experts. In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act (“FDCA”), which established the foundations for the modern regulation of our drug supply. *See* 21 U.S.C. §§ 321(p), 355(a). Congress designated the U.S. Food and Drug Administration (“FDA”) as the expert federal agency with authority to review and approve drug applications, including subsequent changes to those applications. While Congress permitted some judicial review of FDA’s approval decisions, it did not invite federal courts to substitute their judgment for the expert conclusions of FDA’s scientists.

Here, FDA’s determination that mifepristone is safe and effective is based on a thorough and comprehensive review process prescribed and overseen by the legislative branch. Since mifepristone’s initial approval in 2000, FDA has repeatedly and consistently affirmed that the medication is safe and effective for its approved conditions of use. FDA’s process and conclusions have been validated by both Congress and the Government Accountability Office—and by the lived experience of over 5 million patients who have used the drug in the United States.

And, as with all drugs, FDA continued to closely monitor the post-marketing safety data on mifepristone.

By staying FDA's two-decade old approval of mifepristone, the district court has disrupted the longstanding statutory framework and erroneously awarded an extraordinary remedy. Decades after FDA's initial approval—yet somehow in an emergency posture—the district court intruded into FDA's drug approval process, casting a shadow of uncertainty over its decisions. The perils of this unwarranted judicial intervention into science-based determinations can hardly be overstated. Researchers, health care providers, and patients suffering from a range of medical conditions rely on the integrity and stability of the rigorous science-based drug approval process. The specter of precipitous judicial meddling therefore threatens access to life-improving and lifesaving drugs.

More immediately, the district court's misguided stay under Section 705 of the Administrative Procedure Act ("APA") will reduce access to abortion, exacerbating an already significant reproductive health crisis. Although the district court styled its relief as "less drastic," it is not apparent that its consequences are less disruptive than those of a mandatory injunction. Since the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, abortion has become inaccessible in much of the United States. The resulting delays and denials of care have already had baleful effect on the health of pregnant individuals, for some of

whom pregnancy is a life-threatening condition, regardless of their desire to carry their fetus to term. The district court’s order would exacerbate these adverse health outcomes by eliminating access to the most common method of early abortion—a two drug regimen of mifepristone and misoprostol. Moreover, eliminating access to mifepristone—also used in combination with misoprostol for the management of early miscarriage¹—will mean fewer options for treating early pregnancy loss,² which includes a spontaneous abortion, missed abortion, incomplete abortion, or inevitable abortion—conditions that can be life-threatening, including posing a risk of sepsis or loss of future pregnancy capacity if not treated quickly.³

Therefore, emergency relief from the order is necessary to mitigate the imminent harm facing members of the public, many of whom rely on the availability of mifepristone for reproductive care—and many more of whom rely on the integrity of FDA’s drug approval process for continued access to life-

¹ Jessica Beaman et al., *Medication to Manage Abortion and Miscarriage*, 35 J. Gen. Intern. Med. 2398, 2398 (2020) (“Thus, for both medication abortion and medical management of early miscarriage, the standard of care is to provide oral mifepristone followed by misoprostol tablets.”).

² *Id.* at 2400 (“Up to one-third of all pregnancies end in miscarriage.”).

³ Brief of *Amici Curiae* Medical and Public Health Societies in Opposition to Plaintiffs’ Motion for a Preliminary Injunction at 5, *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-cv-00223-Z (N. D. Tex. Feb. 14, 2023), Dkt. No. 109.

improving and lifesaving drugs. Congress intended to—and did—vest authority in FDA to evaluate and ensure the safety and efficacy of drugs in the United States, and *Amici* call on this Court to give due weight to that intent.

ARGUMENT

I. CONGRESS CHARGED EXPERTS AT FDA WITH EVALUATING THE SAFETY AND EFFECTIVENESS OF DRUGS—SUBJECT ONLY TO CIRCUMSCRIBED JUDICIAL REVIEW

Congress has designed a system for assuring the safety and effectiveness of the drugs available in the United States—a system that became the envy of the world.⁴ At the core of that system is the expert application of scientific standards. In 1938, Congress enacted a landmark statute, the FDCA, which established the foundations for the modern regulation of our drug supply. *See* 21 U.S.C. §§ 321(p), 355(a). Since 1962, Congress has required that drugs be shown to be safe and effective for their approved conditions of use before they can be sold in the United States. *See* 21 U.S.C. § 355; *see also id.* § 393(b)(2)(B).

⁴ *See* Jennifer Ko, *What the FDA Can Teach Us About Regulatory Excellence*, *Regulatory Rev.* (Jan. 16, 2018), <https://www.theregreview.org/2018/01/16/fda-teach-regulatory-excellence/>; *see also* Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, *FDA Consumer: The Centennial Edition* (Jan.-Feb. 2006).

FDA is the expert agency charged by Congress with reviewing and approving drug applications and any subsequent changes to those applications.⁵ In accordance with congressional design, a team of physicians, statisticians, chemists, pharmacologists, and other scientific experts reviews each New Drug Application (“NDA”) submitted to the agency and assesses all relevant data in light of the proposed labeling and intended use of the drug.⁶ The agency must approve an application if, among other requirements, it has concluded that the drug is safe and effective under the conditions of use prescribed, recommended or suggested in the proposed labeling.⁷

FDCA’s review provisions do not invite the courts to substitute their judgment for the expert assessment of FDA scientists, but to treat their “findings . . . as to the facts, if supported by substantial evidence,” as “conclusive.” 21 U.S.C. § 355(h); *see also Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir.

⁵ *See* 21 U.S.C. § 371(a) (“The authority to promulgate regulations for the efficient enforcement of this chapter [21 U.S. Code ch. 9 (the FDCA)] . . . is vested in the Secretary [of Health and Human Services].”). The Secretary of Health and Human Services (“the Secretary”) has in turn delegated all functions vested in the Secretary under the FDCA to the Commissioner. *See* 2 FDA Staff Medical Guides – Delegations of Authority, SMG 1410.10, para. 1(A)(1) (Feb. 22, 2023) (Delegations of Authority to the Commissioner of Food and Drugs), <https://www.fda.gov/media/81983/download>.

⁶ *See* 21 U.S.C. § 355(b)(1).

⁷ *See* 21 U.S.C. § 355(d).

1995) (“[J]udgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of FDA’s expertise and merit deference from us.”); 5 U.S.C. § 706(2) (limiting scope of review to certain circumscribed grounds); *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983) (“When examining [an expert agency’s] scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.”); *Nat’l Mining Ass’n v. Sec’y, U.S. Dep’t of Lab.*, 812 F.3d 843, 866 (11th Cir. 2016) (it is appropriate for reviewing courts to “‘give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise’”; “[t]o do otherwise puts [a] court in the unenviable—and legally untenable—position of making for itself judgments entrusted by Congress to [the expert agency]” (citation omitted)). Indeed, the district court’s order appears to be the very first time in FDA’s history that a court has stayed the approval of a widely marketed drug over the agency’s objection.

Here, rather than affording any deference to FDA, the district court appears to have second-guessed FDA’s expert determinations with cherry-picked anecdotes and studies, and on that basis, imposed a remedy that could significantly upend the status quo. Appellants’ Exhibits in Supp. of Mot. for Stay at Add. 44-45, Dkt. No. 27 (hereinafter, “Add.”) (asserting that “chemical abortion drugs do not provide a meaningful therapeutic benefit over surgical abortion.”); *id.* at 48 (claiming that

surgical abortion is a far safer procedure); *id.* at 52 (relying on “myriad stories and studies brought to the Court’s attention”); *id.* at 57-58 (admitting the court does not have exact numbers and is relying on compounding assumptions). The National Academies of Sciences, Engineering and Medicine have concluded that much of the published literature on the supposed negative effects of abortion (such as that relied upon by the district court) “fails to meet scientific standards for rigorous, unbiased research.”⁸ Numerous courts have rejected the expert testimony of the physicians whose submissions the district court accepted at face value.⁹ Even when “conflicting evidence is before the agency”—which was not the case here—“the agency and not the reviewing court has the discretion to accept or reject from the several sources of evidence.” *Sabine River Auth. v. U.S. Dep’t of Interior*, 951 F.2d 669, 678 (5th Cir. 1992).

⁸ Nat’l Acads. of Scis., Eng’g & Med., *The Safety and Quality of Abortion Care in the United States* 152 (2018), <http://nap.edu/24950>.

⁹ *See, e.g., MKB Mgmt. Corp. v. Burdick*, 855 N.W.2d 31, 68 (N.D. 2014) (per curiam) (rejecting testimony of Dr. Harrison as lacking “scientific support”); *Planned Parenthood of Sw. & Cent. Fla. v. State*, No. 2022 CA 912, 2022 WL 2436704, at *13 (Fla. Cir. Ct. July 5, 2022) (rejecting testimony of Dr. Skop, who “provided no credible scientific basis for her disagreement with recognized high-level medical organizations in the United States”), *rev’d on other grounds*, 344 So. 3d 637 (Fla. Dist. Ct. App. 2022).

For decades, the federal judiciary has respected Congress’s delegation of the drug approval process to FDA’s scientists and experts. While courts have, on occasion, held against FDA on issues related to the market exclusivity that is afforded to a drug sponsor by the statute, it is an extraordinary and unprecedented step for the district court to invalidate on substantive grounds—and over FDA’s objection—a longstanding approval for a drug with a history of safe and effective use. This Court should stay that aberrant decision pending appellate review.

II. FDA’S DETERMINATION THAT MIFEPRISTONE IS SAFE AND EFFECTIVE FOLLOWED A THOROUGH AND COMPREHENSIVE PROCESS PRESCRIBED AND OVERSEEN BY THE LEGISLATIVE BRANCH

More than twenty years ago, FDA approved mifepristone, determining that it is safe and effective for the medical termination of intrauterine pregnancy under the conditions set forth in the FDA-approved prescribing information. Add. 181 (Approval of NDA for mifepristone, Sept. 28, 2000); *see also* 21 U.S.C. § 355(b)(1)(A)(i), (c)(1)(A), (d). Since then, FDA has repeatedly and consistently affirmed that mifepristone is safe and effective for its approved conditions of use.¹⁰

¹⁰ *See Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA: U.S. Food & Drug Admin. (Mar. 23, 2023), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation>.

A. The District Court’s Focus On 21 C.F.R. Part 314, Subpart H, Is Misplaced Because FDA’s Authority To Authorize Mifepristone Is Derived From Statutory Authority Under the FDCA, And Any Alleged Defect In The 2000 Approval of Mifepristone Has Been Cured By Subsequent Congressional Action

The district court’s focus on 21 C.F.R. Part 314, Subpart H, ignores FDA’s longstanding interpretation of that regulation. In 1992, FDA lawfully promulgated Subpart H, in accordance with the APA, to help assure the safety and effectiveness of products for use in the United States. *See* 57 Fed. Reg. 58,942, 58,958 (Dec. 11, 1992) (promulgating Subpart H). Subpart H applies to federal regulations for certain new drugs “studied for their safety and effectiveness in treating serious or life-threatening illnesses” that “provide meaningful therapeutic benefit to patients over existing treatments.” 21 C.F.R. § 314.500. This was an entirely appropriate and proper exercise of authority, consistent with Section 701 of the FDCA, 21 U.S.C. § 371, which expressly authorizes FDA to promulgate regulations for the efficient enforcement of the FDCA.¹¹

However, FDA’s authority to approve mifepristone stemmed from Section 505 of the FDCA, 21 U.S.C. § 355, not from 21 C.F.R. Part 314, Subpart H. Prior to marketing a new drug, a sponsor must file an NDA pursuant to

¹¹ *See supra* note 5.

Section 505(b) of the FDCA, and must demonstrate that the drug is safe and effective for the proposed indication. 21 U.S.C. § 355(b)(1)(A)(i).

When FDA approved mifepristone in 2000, it reviewed data from two “prospective, open-label, multicenter clinical trials” in the United States involving over two thousand patients,¹² as well as expert advice from members of the FDA Reproductive Health Drugs Advisory Committee.¹³ Moreover, the agency’s determination was consistent with its long-standing construction of the scope of these regulations and similar regulatory programs to cover drugs designed for “conditions” as well as illnesses and diseases. In the final rule, FDA explained that Subpart H was available for serious or life-threatening “conditions,” whether or not they were understood colloquially to be “illnesses.” 57 Fed. Reg. 58,942, 58,946 (Dec. 11, 1992) (explaining that “FDA’s reference to depression and psychoses” in its preamble to the proposed rule “was intended to give examples of conditions or diseases that can be serious for certain populations or in some or all of their phases”); *see also* 57 Fed. Reg. 13,234, 13,235 (proposed Apr. 15, 1992) (preamble).¹⁴

¹² *See* Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., Application No. 20-687, Medical Reviews 6-20 (1999).

¹³ *See id.* at 21.

¹⁴ *See also* Ctr. for Drug Evaluation & Rsch. (CDER), *Drug and Biologic Restricted Distribution Approvals as of June 30, 2018*, FDA: U.S. Food & Drug (cont'd)

Moreover, any alleged defect in the original approval of mifepristone in 2000 was cured in 2007, when Congress gave FDA the authority to require a risk evaluation and mitigation strategy (“REMS”) in circumstances when FDA determined that such a strategy is “necessary to ensure that the benefits of the drug outweigh the risks.”¹⁵ 21 U.S.C. § 355-1(a)(1). When Congress codified the restricted use and distribution provisions of Subpart H in 2007 through the REMS program, it applied the new REMS framework to drugs for a “disease or *condition*.”¹⁶ When Congress enacted this REMS provision, it “deemed” drugs with restrictions of distribution under Subpart H, including mifepristone, to have an effective REMS. Pub. L. No. 110-85, § 909(b)(1)(A). Congress was well

Admin, <https://www.fda.gov/media/115040/download> (last visited Apr. 11, 2023) (listing drugs which treat, *inter alia*, pulmonary hypertension and Irritable Bowel Syndrome (IBS)). Both hypertension and IBS are colloquially known as “conditions.” See *Irritable Bowel Syndrome (IBS)*, NHS Inform, <https://www.nhsinform.scot/illnesses-and-conditions/stomach-liver-and-gastrointestinal-tract/irritable-bowel-syndrome-ibs> (last visited Apr. 11, 2023); *Hypertension*, World Health Org., https://www.who.int/health-topics/hypertension#tab=tab_1 (last visited Apr. 11, 2023).

¹⁵ Where FDA has determined that a REMS is necessary, the sponsor must submit an application along with a proposed REMS. In making a determination of whether the benefits of the drug outweigh its risks with REMS, FDA shall consider factors including the “seriousness of the disease or condition” to be treated and the “seriousness of any known or potential adverse events that may be related to the drug.” 21 U.S.C. § 355-1(a)(1)(B), (E). Through this process, mifepristone has been subjected to exacting scrutiny and review.

¹⁶ 21 U.S.C. § 355-1(a)(1)(B), (C) (emphasis added).

aware that mifepristone would be included under that provision when it took this action, and it made no exception for it.¹⁷

In 2011, FDA took the step of implementing the REMS for mifepristone under express statutory authority in section 505-1 of the FDCA, 21 U.S.C. § 355-1. FDA had announced several years earlier that mifepristone would require submission of a REMS application. *See* Identification of Drug and Biological Products, 73 Fed. Reg. 16,313, 16,314 tbl. 1 (Mar. 27, 2008). Subsequently, a REMS application for mifepristone was submitted on September 17, 2008, and FDA approved the application on June 8, 2011. Add. 769. By virtue of FDA's approval of REMS for mifepristone under its express statutory authority, any alleged defect in the prior approval process for mifepristone was affirmatively cured.¹⁸

¹⁷ *See* 153 Cong. Rec. 11668 (May 9, 2007) (statement of Sen. Coburn); 153 Cong. Rec. 10940 (May 2, 2007) (statement of Sen. DeMint).

¹⁸ The district court also misapplied the Comstock Act, 18 U.S.C. § 1461, erroneously ignoring the Department of Justice's well-reasoned opinion. *See generally* U.S. Dep't of Just., Off. of Legal Counsel, *Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions* 46 Op. O.L.C. ___ (Dec. 23, 2022) (concluding that Congress's repeated actions ratified the well-established judicial construction that the statute did not prohibit the mailing of items designed to produce abortion unless the sender intended them to be used unlawfully). That opinion correctly notes that, in enacting the REMS provision in 2007, Congress acted "in a manner consistent with the understanding that the Comstock Act does not categorically prohibit" the distribution of drugs intended to induce abortions by mail or common carrier. *Id.* at 14.

B. The Integrity of FDA’s Approval Process Of Mifepristone Has Been Examined and Validated

The integrity of FDA’s approval process for mifepristone has been examined before—and found to be sound. In 2008, the U.S. Government Accountability Office (GAO), an independent, non-partisan agency, conducted an extensive audit of mifepristone’s 2000 approval, concluding it was “generally consistent with the approval processes for the other . . . Subpart H restricted drugs.” GAO-08-751, *Approval and Oversight of the Drug Mifeprex* at 6 (2008).¹⁹ The GAO also noted that, when it came to post-market oversight of mifepristone, “FDA has routinely reviewed the available information on reported adverse events” from a range of sources and then, “working with the drug’s sponsor, has taken a variety of steps to address safety concerns.”²⁰ Notably, in conducting its study, the GAO “interviewed FDA officials and external stakeholders who had access to technical information or had conducted analyses” concerning the drug.²¹ The GAO report considered many of the same concerns raised by plaintiffs in this case fifteen years later.

¹⁹ The report was prepared at the request of three Republican members of Congress during the Bush administration: Senator Enzi, Senator DeMint and Representative Bartlett. *See* GAO-08-751, *supra*, at 1.

²⁰ *Id.* at 38, 41.

²¹ *Id.* at 4.

In 2016, after approving a REMS for mifepristone, FDA approved a supplemental NDA. Add. 768-75. In 2018, the GAO reviewed this 2016 approval, and after evaluating 62 studies and articles that supported the efficacy of the proposed changes as well as adverse event data, concluded FDA “followed its standard review process when it approved the [2016 supplemental new drug application].”²²

FDA has repeatedly demonstrated that its approval of mifepristone is based on a rigorous review of scientific data and literature supporting the safety and efficacy of the drug, which has been validated by the decades of experience of many Americans who, in consultation with their health care providers, have chosen to use mifepristone for a medication abortion.²³

²² U.S. Gov’t Accountability Off., GAO-18-292, *Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* cover pg. (2018); *see id.* at 11-16.

²³ *See Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022* at 1, U.S. Food & Drug Admin., <https://www.fda.gov/media/164331/download> (last visited Apr. 11, 2023) (“The estimated number of women who have used mifepristone in the U.S. for medical termination of pregnancy through the end of June 2022 is approximately 5.6 million women.”).

III. A JUDICIAL STAY OF APPROVAL OF MIFEPRISTONE WOULD PROFOUNDLY DISRUPT THE SCIENCE-BASED, EXPERT-DRIVEN PROCESS THAT CONGRESS DESIGNED FOR DETERMINING WHETHER DRUGS ARE SAFE AND EFFECTIVE

The consequences of the district court’s remedy could extend far beyond mifepristone, for it undermines the science-based, expert-driven process that Congress designed for determining whether drugs are safe and effective. By disrupting FDA’s two-decade old approval of mifepristone, the district court has interfered with the longstanding statutory framework and erroneously awarded an extraordinary remedy by substituting its judgment for FDA’s scientific determination.

As a result, the district court’s order undermines the well-established statutory and regulatory framework for the approval of new drugs and the due process generally accorded to drug marketing application holders by statute.²⁴ Its perilous consequences reach far beyond mifepristone. Providers and patients rely on the availability of thousands of FDA-approved drugs to treat or manage a range of medical conditions, including asthma, HIV, infertility, heart disease, diabetes,

²⁴ Section 505(e) of the FDCA allows for withdrawal of approval of an application with respect to any drug under the section only “after due notice and opportunity for hearing to the applicant.” 21 U.S.C. § 355(e).

and more.²⁵ Moreover, the prospect of courts second-guessing FDA’s rigorous drug safety and effectiveness determinations will disrupt industry expectations and could chill pharmaceutical research and development. “Developing new drugs is a costly and uncertain process,” and only about 12 percent of drugs entering clinical trials are approved by FDA.²⁶ Were each court to take the “legally untenable . . . position of making for itself judgments entrusted by Congress to” FDA, *Nat’l Mining Ass’n*, 812 F.3d at 866, the unpredictability of piecemeal judicial intervention will upend industry expectations, dampening incentives for companies to incur the research and development costs necessary to develop new drugs. Consequently, patient access to life-improving and potentially lifesaving new drugs will suffer, and public interest strongly favors preserving the integrity of FDA’s drug-approval process.

IV. INVALIDATING FDA’S APPROVAL WOULD REDUCE ACCESS TO ABORTION, EXACERBATING AN ALREADY SIGNIFICANT REPRODUCTIVE HEALTH CRISIS

In the aftermath of the Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Organization*, abortion has become inaccessible in much of the

²⁵ See generally U.S. Dep’t of Health & Hum. Servs., *Approved Drug Products with Therapeutic Equivalence Evaluations* (43rd ed. 2023), <https://www.fda.gov/media/71474/download>.

²⁶ Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* at 2 (2021).

United States. Abortion is banned, with extremely limited exceptions for life-endangerment, in 12 states, and access is severely restricted in an additional 12 states.²⁷ Approximately 22 million women of childbearing age, representing almost one third of the total population of women ages 15 to 49—in addition to other people who may not identify as women but are capable of becoming pregnant and may need an abortion—now live in states where abortion is entirely unavailable or severely restricted.²⁸ At least 66 clinics across 15 states have stopped offering abortion care.²⁹ (Prior to June 24, 2022, those same 15 states had a total of 79 clinics that offered abortion care; now, there are only 13 such clinics, all located in Georgia.³⁰) Travel time and wait time to obtain abortion care have increased significantly across the United States. The shortage of providers has also stretched the capacity of clinics in states where abortion remains legal.³¹

²⁷ See *After Roe Fell: Abortion Laws by State*, Ctr. for Reprod. Rts., <https://reproductiverights.org/maps/abortion-laws-by-state/> (last visited Mar. 13, 2023).

²⁸ Marielle Kirstein et al., *100 Days Post-Roe: At Least 66 Clinics Across 15 US States Have Stopped Offering Abortion Care*, Guttmacher Inst. (Oct. 6, 2022), <https://www.guttmacher.org/2022/10/100-days-post-roe-least-66-clinics-across-15-us-states-have-stopped-offering-abortion-care>.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

The resulting delays and denials of care have already dangerously affected health outcomes for pregnant individuals. Some individuals report being forced to forgo cancer treatment,³² while others report developing sepsis,³³ being left bleeding for days after an incomplete miscarriage,³⁴ enduring the risk of rupture due to ectopic pregnancy or being forced to continue carrying a fetus diagnosed with a lethal fetal anomaly such as anencephaly.³⁵ For some individuals, pregnancy is a life-threatening condition, regardless of their desire to carry their fetus to term.³⁶ Since *Dobbs*, numerous individuals have been left struggling to

³² Affidavit of Dr. Sharon Liner in Support of Plaintiffs' Motion at 4-5, *Preterm-Cleveland v. Yost*, No. A2203203 (Ohio Ct. Com. Pl. filed Sept. 2, 2022).

³³ Complaint ¶¶ 17-25, *Zurawski v. Texas*, No. D-1-GN-23-000968 (Tex. Dist. Ct. filed Mar. 6, 2023); *see also id.* at 1 (plaintiffs were denied necessary and potentially lifesaving obstetrical care because medical professionals throughout the state feared liability under Texas's abortion bans).

³⁴ Frances Stead Sellers & Fenit Nirappil, *Confusion Post-Roe Spurs Delays, Denials for Some Lifesaving Pregnancy Care*, Wash. Post (July 16, 2022), <https://www.washingtonpost.com/health/2022/07/16/abortion-miscarriage-ectopic-pregnancy-care/>.

³⁵ *See* Complaint ¶¶ 82-94, *Zurawski*, *supra* note 33.

³⁶ *See, e.g.,* Ioannis T. Farmakis et al., *Maternal Mortality Related to Pulmonary Embolism in the United States, 2003-2020*, 5 Am. J. Obstetrics & Gynecology Maternal-Fetal Med. 100754 (2023); *What Are the Risks of Preeclampsia & Eclampsia to the Mother?*, Nat'l Insts. of Health, <https://www.nichd.nih.gov/health/topics/preeclampsia/conditioninfo/risk-mother> (last updated Nov. 19, 2018).

access the essential health care they need.³⁷ Reports from doctors and journalists highlight the increasing importance of mifepristone for reproductive health care in *Dobbs*' wake:

- One doctor who had “to stop providing abortion care to patients in Wisconsin for the past six months” observes “further difficulties for patients in rural settings.” Rural patients “are now being forced to birth, so the risks of bleeding and poor fetal and maternal outcomes have significantly risen. Mifepristone is vital to providing safe care for early pregnancy loss.”³⁸
- Another doctor recounts a patient who was raped when she was actively planning for pregnancy. The soonest a paternity test could be conducted was at 7 weeks gestation, while Texas, where the patient lived, had banned abortion after 6 weeks. The patient could not afford to travel out of state for termination, and had to seek a medication abortion before her sixth week.³⁹
- A woman residing in Louisiana, where all abortion (including in cases of rape and incest) has been banned after *Dobbs*, was refused treatment for her miscarriage when she was between 10 and 11 weeks pregnant. When asked whether treatment was available to alleviate her pain and speed up the process, the doctor replied: “We’re not doing that now.”⁴⁰

³⁷ See Jessica Valenti, *I Write About Post-Roe America Every Day. It’s Worse Than You Think*, N.Y. Times (Nov. 5, 2022), <https://www.nytimes.com/2022/11/05/opinion/election-abortion-roe-women.html>.

³⁸ Brief of *Amicus Curiae* Doctors for America at 6-7, *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-cv-00223-Z (N. D. Tex. Feb. 13, 2023), Dkt. No. 99.

³⁹ *Id.* at 9-10.

⁴⁰ Rosemary Westwood, *Bleeding and in Pain, She Couldn’t Get 2 Louisiana ERs to Answer: Is It a Miscarriage?*, WVCU (Dec. 29, 2022), <https://news.wvcu.org/2022-12-29/bleeding-and-in-pain-she-couldnt-get-2-louisiana-ers-to-answer-is-it-a-miscarriage>.

Mifepristone is part of standard treatment to manage early pregnancy loss.⁴¹

These examples bespeak a broader public health crisis aggravated by providers denying care for fear that their treatment will contravene state criminal law and lead to prosecution.⁴² No other practice of medicine bears witness to these types of denials of care based on state restrictions and ideological interference.

The district court's order would exacerbate these adverse health outcomes by eliminating the most common method of early abortion.⁴³ As a result, childbearing individuals would have to turn to procedural abortion, which is more invasive, may require extensive travel to obtain, has longer wait times, and is often much more expensive. Alternatively, affected individuals would have to seek other methods of medication abortion, even though the FDA-approved regimen using mifepristone is by far the most common and available method of medication abortion in the United States and is a method that FDA has long determined provides a "meaningful therapeutic benefit" over existing treatments. 21 C.F.R. § 314.500.

⁴¹ *See supra* note 1.

⁴² *See, e.g.,* Westwood, *supra* note 40.

⁴³ Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, Guttmacher Inst. (Feb. 24, 2022), <https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions>.

These health risks, as well as financial and logistical challenges, would disproportionately affect individuals already facing systemic barriers to health care, who could be forced to choose between a more costly procedural abortion and an unwanted pregnancy.⁴⁴ These particularly vulnerable groups may include low-income individuals, people of color, young people and those residing in rural areas.⁴⁵ Medication abortion using mifepristone is an important means for vulnerable groups to access medical care without having to bear the cost of long-distance travel to find access to procedural abortion and the difficulties associated with getting time off or finding child care.⁴⁶ By curtailing access to the most

⁴⁴ See Katherine O’Connell White, *POV: Overturning Roe v. Wade Will Worsen Health Inequities in All Reproductive Care*, BU Today (June 24, 2022), <https://www.bu.edu/articles/2022/overturning-roe-v-wade-will-worsen-health-inequities/>.

⁴⁵ See generally Eugene Declercq et al., *The U.S. Maternal Health Divide: The Limited Maternal Health Services and Worse Outcomes of States Proposing New Abortion Restrictions*, Commonwealth Fund (Dec. 14, 2022), <https://www.commonwealthfund.org/publications/issue-briefs/2022/dec/us-maternal-health-divide-limited-services-worse-outcomes>; see also Rosalyn Schroeder et al., *Trends in Abortion Care in the United States, 2017-2021*, *Advancing New Standards in Reprod. Health*, U.C.S.F. (2022).

⁴⁶ See Karen Brooks Harper, *Wealth Will Now Largely Determine Which Texans Can Access Abortion*, *Tex. Trib.* (June 24, 2022), <https://www.texastribune.org/2022/06/24/texas-abortion-costs/> (“About 73% of the people who call Fund Texas Choice for help with travel expenses are Black, Indigenous, Hispanic and Asian”); *id.* (“[T]hose working in wage-based jobs with no paid time off”); Chantel Boyens et al., *Access to Paid Leave Is Lowest Among Workers with the Greatest Needs 2*, *Urban Inst.* (July 2022).

common method of medication abortion, the district court’s stay erects additional barriers to health care for vulnerable populations.

Reduced abortion access is also associated with higher rates of poverty, and lower educational attainment for both children and parents.⁴⁷ *The Turnaway Study* conducted at the University of California, San Francisco found that being denied an abortion was associated with increased economic insecurity and household poverty for both the mother and children born as a result of abortion denial.⁴⁸

The unavailability of mifepristone will have an especially acute impact on Black maternal health. In 2021, the overall maternal mortality rate shot up by nearly 40 percent,⁴⁹ and the maternal mortality rate for Black women was especially high, at 69.9 deaths per 100,000 live births—1.3 times higher than it was in 2020, and 2.6 times higher than the rate for white women.⁵⁰ In 2020, maternal

⁴⁷ Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 Am. J. Pub. Health 407, 412 (2018).

⁴⁸ See Diana Greene Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (2020).

⁴⁹ Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, CDC (Mar. 16, 2023), <https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm>.

⁵⁰ *Id.*; Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2020*, CDC (Feb. 23, 2022), <https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm>.

death rates were 62 percent higher in abortion-restriction states than in abortion-access states.⁵¹ From 2018 to 2020, the maternal mortality rate increased nearly twice as fast in states with abortion restrictions than in states without them.⁵²

Additional restrictions on access to medication abortion threaten to further increase the maternal mortality rate—an issue disproportionately affecting Black women—and exacerbate an already grave Black maternal health crisis.⁵³

The district court’s order will further restrict abortion access, exacerbating the harmful effects from existing limitations. Just as *Dobbs* upended abortion access and led to chaos following the decision, eliminating access to mifepristone will further narrow options for care.

CONCLUSION

For the foregoing reasons, *Amici* Members of Congress respectfully request that the Court grant defendant-appellants’ emergency motion to extend the seven-day administrative stay pending resolution of stay proceedings in this court, and for a stay of the district court’s order pending appeal.

⁵¹ Declercq et al., *supra* note 45, at Exhibit 4.

⁵² *Id.*

⁵³ *See id.* at Conclusion.

Dated: April 11, 2023
New York, New York

Respectfully submitted,

s/ Boris Bershteyn
Boris Bershteyn
One Manhattan West
New York, NY 10001
(212) 735-3000
boris.bershteyn@probonolaw.com

William A. McConagha
Jennifer L. Bragg
Keyawna Griffith
1440 New York Ave NW
Washington, DC 20005

Attorneys for Amicus Curiae 240 Members of Congress

CERTIFICATE OF ELECTRONIC COMPLIANCE

I certify that on April 11, 2023, this motion was transmitted to Mr. Lyle W. Cayce, Clerk of the U.S. Court of Appeals for the Fifth Circuit, through the court's CM/ECF document-filing system, <https://efc.ca5.uscourts.gov>.

I further certify that: (1) required privacy redactions have been made, 5th Cir. R. 25.2.13; (2) the electronic submission is an exact copy of the paper document, 5th Cir. R. 25.2.1; and (3) the document has been scanned with the most recent version of a commercial virus scanning program and is free of viruses.

Dated: April 11, 2023
New York, New York

s/ Boris Bershteyn
Boris Bershteyn
Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font. The brief contains 5192 words, excluding the parts of the brief exempt by Federal Rule of Appellate Procedure 32(f).

Dated: April 11, 2023
New York, New York

s/ Boris Bershteyn
Boris Bershteyn
Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that I e-filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system on April 11, 2023. 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.

Dated: April 11, 2023
New York, New York

s/ Boris Bershteyn
Boris Bershteyn
Counsel for Amici Curiae

APPENDIX

List of Amici Curiae

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Sen. Patty Murray

Sen. Bernard Sanders

Sen. Richard J. Durbin

Sen. Richard Blumenthal

Sen. Tammy Baldwin

Sen. Michael F. Bennet

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Sen. Sherrod Brown

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Sen. Robert P. Casey, Jr.

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Sen. Catherine Cortez Masto

Sen. Tammy Duckworth

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Sen. John Fetterman

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Sen. Martin Heinrich

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Sen. Mazie Hirono

Sen. Tim Kaine

Sen. Mark Kelly

Sen. Angus S. King, Jr.

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Sen. Ben Ray Luján

Sen. Edward J. Markey

Sen. Robert Menendez

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Sen. Jon Tester

Sen. Chris Van Hollen

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Sen. Raphael Warnock

Sen. Elizabeth Warren

Sen. Peter Welch

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Sen. Ron Wyden

**190 Members of the
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Rep. Frank Pallone, Jr.

Rep. Jerrold Nadler

Rep. Diana DeGette

Rep. Barbara Lee

Rep. Alma S. Adams, Ph.D.

Rep. Pete Aguilar

Rep. Colin Allred

Rep. Jake Auchincloss

Rep. Becca Balint

Rep. Nanette Diaz Barragán

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Rep. Sanford Bishop

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