No. 23-10362

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,

Plaintiffs-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION, et al.,

Defendants-Appellants,

DANCO LABORATORIES, LLC,

Intervenor-Defendant-Appellant.

BRIEF FOR 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, AND WISCONSIN, AND THE DISTRICT OF COLUMBIA AS AMICI CURIAE IN SUPPORT OF APPELLANTS' APPLICATIONS FOR A STAY

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

INTRODUCTION AND INTERESTS OF AMICI 1

ARGUMENT 4

POINT I

MEDICATION ABORTION IS SAFE AND EFFECTIVE AND INDISPENSABLE TO REPRODUCTIVE HEALTH CARE 4

POINT II

ABSENT A STAY, THE DISTRICT COURT'S ORDER WOULD HAVE DEVASTATING CONSEQUENCES 8

CONCLUSION 15

TABLE OF AUTHORITIES

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INTRODUCTION AND INTERESTS OF AMICI

In 2000, the U.S. Food and Drug Administration (FDA) approved mifepristone as a single-dose oral medication used for early-term abortions. Plaintiffs (several anti-abortion organizations and physicians) filed this lawsuit and preliminary injunction motion challenging the FDA's initial approval and several subsequent regulatory actions pertaining to mifepristone. The U.S. District Court for the Northern District of Texas (Kacsmaryk, J.) granted plaintiffs' motion and stayed the effective date of the FDA's approval of mifepristone—more than twenty years after that date has passed. The district court's ruling was legally erroneous, undermines the regulatory scheme for drug approvals, and presents devastating risks to millions of people across the country.

Amici 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, and Wisconsin, and the District of Columbia submit this brief in support of appellants' emergency applications for a stay of the district court's order. The continued availability of mifepristone for

medication abortions is critical to safeguarding amici States' important interest in protecting the health, safety, and rights of their residents, including an interest in ensuring safe access to essential reproductive health care.[1]

Mifepristone is proven to be a safe, reliable, and effective method for early pregnancy termination and, as part of a regimen taken in combination with the drug misoprostol, is the only drug approved for medication abortion in the United States. The availability of mifepristone has been particularly critical in providing access to abortion in low-income, underserved, and rural communities where a nonmedication abortion procedure (or "procedural abortion") may be unavailable. And because medication abortion is the most common method used to terminate pregnancy during the first trimester, curtailing access to this method will result in more abortions taking place later in pregnancy, further increasing costs and medical risks.

[1] Several amici States are plaintiffs in *Washington v. U.S. Food & Drug Administration*, No. 23-cv-3026 (E.D. Wash.), which challenges certain restrictions on the use of mifepristone.

Amici also have a strong interest in safeguarding their sovereign decision to protect their residents' ability to obtain abortions in the wake of *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022). Although the Supreme Court, reversing longstanding precedent, concluded that the U.S. Constitution does not protect the right to obtain an abortion, the Court endorsed the States' authority to safeguard access to abortion for their residents, explaining that it was "return[ing] the issue of abortion to the people's elected representatives." *Id.* at 2243. The district court's order could eviscerate the sovereign decisions of many amici States by disrupting access to mifepristone across the country, including in States where abortion is lawful.

ARGUMENT

POINT I

MEDICATION ABORTION IS SAFE AND EFFECTIVE AND INDISPENSABLE TO REPRODUCTIVE HEALTH CARE

The experience of amici States confirms what numerous studies have demonstrated: medication abortion is safe and effective and an integral component of reproductive health care.

Since the FDA approved mifepristone in 2000, an estimated 4.9 million women in the U.S. have used this method to terminate a pregnancy.[2] According to current estimates, medication abortion now accounts for more than half—or 54%—of all abortions performed in the U.S."[3] A recent comprehensive survey of abortion care in the U.S. conducted by the National Academies of Sciences, Engineering, and Medicine concluded that medication abortion is safe and effective and that complications are rare, i.e., "occurring in no more than a fraction of

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[2] *See* FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary through 6/30/2021* (n.d.).

[3] Rachel K. Jones et al., *Medication Abortion Now Accounts for More than Half of All US Abortions*, Guttmacher Inst. (Feb. 24, 2022).

a percent of patients."[4] The World Health Organization authorizes use of medication abortion as safe through 12 weeks of pregnancy and has long included the mifepristone/misoprostol regimen in its Model List of Essential Medicines.[5]

Medication abortion, coupled with the growing adoption of telemedicine, has also greatly increased access to reproductive health care, particularly for those living in low-income communities, communities of color, and rural and underserved areas.[6] Medication abortion promotes access to early abortion, when it is safest and least expensive, thereby reducing complication rates, decreasing costs, and easing burdens on the health care system overall.[7]

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[4] *See* National Acads. of Scis., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States* 10, 55 (2018) (hereinafter "NASEM, *Safety and Quality of Abortion Care*").

[5] World Health Org., *WHO Model List of Essential Medicines, 22nd List, 2021: Overview* (Sept. 30, 2021); *see* World Health Org., *Abortion Care Guideline* xxix, 16-17, 67-68 (2022). Mifepristone is also commonly used in treating early pregnancy loss. *See* Kurt Barnhart, *Medical Management of Miscarriage with Mifepristone*, 396 Lancet 737, 737-38 (2020).

[6] *See* Letter from Att'ys Gen. to Alex M. Azar II, Sec'y, U.S. Dep't of Health & Hum. Servs., and Stephen Hahn, Comm'r, FDA (Mar. 30, 2020).

[7] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 5, 28-29.

Medication abortion can also safely be provided in a variety of contexts and practice areas—for example, in a private physician's office, an ob-gyn or family practice setting, or even at home with appropriate medical supervision.[8] The availability of medication abortion within mainstream medical settings not only lifts constraints on access but also offers added privacy and security for both patients and providers—benefits that are particularly critical given persistent and escalating violence at abortion clinics.[9]

Many amici States have therefore expended substantial resources in promoting access to medication abortion. For example, in Maine, which has among the highest rates of rural residents in the U.S., a major health clinic chain has made medication abortion available at its 16 health centers via telemedicine in order to provide access to residents who would otherwise have to travel long distances to urban centers.[10] New York City recently announced it will offer free medication abortion at four public

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[8] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 10.

[9] *See* National Abortion Fed'n, *2021 Violence and Disruption Report* (June 24, 2022).

[10] *See* Kanya D'Almeida, *Telemedicine Abortion Is Coming to Maine*, Rewire News Grp. (Feb. 29, 2016).

health clinics.[11] And several amici States, including Massachusetts, New York, and California, have taken steps to extend access to public university students by making medication abortion available at campus health centers.[12]

The district court's order ignores the substantial investments made by amici States in reliance on the longstanding approval of mifepristone. And the district court's unprecedented "stay" of a drug approval that occurred more than two decades ago undermines the integrity of the FDA-approval process not only for this drug but also for thousands of other FDA-approved drugs used by amici States' residents to treat or manage a range of medical conditions experienced by their residents, including asthma, HIV, infertility, heart disease, diabetes, and more. For each of these drugs, the FDA determined based on significant clinical data—just as it did with mifepristone—that the benefits of the drug

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[11] *See* Elizabeth Kim, *NYC Will Offer Free Abortion Pills at 4 City-Run Sexual Health Clinics*, Gothamist (Jan. 17, 2023).

[12] *See* Nadine El-Bawab, *Offering Abortion Pills on Campus Could Eliminate Boundaries to Access, Students Say*, ABC News (Oct. 15, 2022); Stephanie Hughes, *With* Roe v. Wade *Overturned, Colleges Prep to Provide Abortion Medication*, Marketplace (Oct. 10, 2022); Press Release, N.Y. Off. of the Governor, *Governor Hochul Announces Steps to Strengthen New York State's Safe Harbor for Abortion Care* (Jan. 10, 2023).

outweighed any known and potential risks. If permitted to stand, the district court's order invites revisiting all these decisions.

POINT II

ABSENT A STAY, THE DISTRICT COURT'S ORDER WOULD HAVE DEVASTATING CONSEQUENCES

The district court's order—which stays the effective date of the FDA's approval of mifepristone twenty-three years after the fact—threatens devastating consequences nationwide, particularly in States that wish to protect rather than restrict abortion access.

Patients who may no longer be able to access mifepristone will instead seek procedural abortions—which, although safe, would constitute an unnecessarily invasive procedure for those who would have preferred a medication abortion. Others may be required to travel long distances or will seek abortion medications through online services and/or overseas pharmacies and self-manage their abortions outside of a medical setting.[13] Loss of access to medication abortion would also lead

[13] *See* Abigail R.A. Aiken et al., *Requests for Self-Managed Medication Abortion Provided Using Online Telemedicine in 30 US States Before and After the* Dobbs v. Jackson Women's Health Organization *Decision*, 328 JAMA 1768, 1768-70 (2022).

to more need for second-trimester abortions, with a resulting increase in health risks, costs, and delays.[14]

Many who are unable to afford the additional costs will be denied access to abortion altogether and be forced to carry unwanted pregnancies to term,[15] resulting in numerous harms, including poor birthing and infant health outcomes, higher rates of poverty, and lower educational attainment for both parents and children.[16] And because carrying a pregnancy to term is 14 times more risky than early abortion,[17] curtailing access to medication abortion would likely lead to a steep rise

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[14] *See* Liza Fuentes & Jenna Jerman, *Distance Traveled for Abortion in the United States and Reasons for Clinic Choice*, 28 J. Women's Health 1623, 1626 (2019).

[15] *See* Fuentes & Jerman, *supra*, at 1626; Kirsten M.J. Thompson et al., *Association of Travel Distance to Nearest Abortion Facility with Rates of Abortion*, JAMA Network Open 6-8 (July 6, 2021); Kristina Kimport, *Abortion After* Dobbs*: Defendants, Denials, and Delays*, 8 Sci. Advances (ade5327) 1-2 (Sept. 2022).

[16] *See, e.g.*, Diana G. Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (2021).

[17] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 216-18 (2012).

in birth-related mortality rates,[18] worsening a crisis already disproportionately faced by Black women.[19]

Because disrupting access to mifepristone could be tantamount to losing access to abortion for many people, the district court's order may exacerbate the many harms already associated with the drastic reduction in access to abortion care across large swaths of the U.S. Abortion is currently completely unavailable in the 13 States where bans or near-total restrictions are in effect or subject to pending litigation, and access is extremely limited in several more.[20] Those States are home to approximately 22 million women of childbearing age, representing almost one third of the total population of women ages 15-49.[21] If the

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[18] *See, e.g.*, Amanda Jean Stevenson, *The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant*, 58 Demography 2019, 2019-28 (2021).

[19] *See, e.g.*, Elyssa Spitzer et al., *Abortion Bans Will Result in More Women Dying*, Ctr. for Am. Progress (Nov. 2, 2022).

[20] *See* Center for Reprod. Rts., *After Roe Fell: Abortion Laws by State* (n.d.).

[21] *See* 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).

district court's order takes effect, many of these women may also be unable to access medication abortion in States where such care is legal.

The impacts on birth-related morbidity and mortality from being denied abortion are no longer hypothetical. In States without abortion access, resulting delays and denials of care have already led to dire health outcomes for women, including being forced to forgo cancer treatment, developing sepsis, being left bleeding for days after incomplete miscarriage, enduring risk of rupture due to ectopic pregnancy, and being forced to continue carrying a fetus that was nonviable.[22] The brunt of these harms continues to disproportionately fall on communities of color.[23]

States where abortion remains legal and available, including many amici States, have experienced a steep rise in demand at clinics as out-

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[22] *See* Jessica Valenti, *I Write About Post-Roe America Every Day. It's Worse than You Think*, N.Y. Times (Nov. 5, 2022); Pl.'s Mot. for TRO and Prelim. Inj., *Preterm Cleveland v. Yost*, No. A2203203 (Ohio C.P. Hamilton County Sept. 2, 2022); Complaint, *Zurawski v. Texas*, No. D-1-GN-23-000968 (Dist. Ct. Travis County Mar. 6, 2023).

[23] *See* Samantha Artiga et al., *What Are the Implications of the Overturning of* Roe v. Wade *for Racial Disparities?*, Kaiser Fam. Found. (July 15, 2022).

of-state patients flood into their States to receive necessary care.[24] The resulting "dramatic increases in caseloads mean clinic capacity and staff are stretched to their limits, resulting in longer wait times for appointments even for residents of states where abortion remains legal."[25] The elimination or drastic reduction in availability of medication abortion would leave providers in amici States to struggle to meet the additional spike in demand for procedural abortion, from both state residents and persons travelling from other states to obtain treatment. The result is to compound delays and place an untenable strain on an already overwhelmed system.

The harmful outcomes described above would cause ripple effects across the entire health care system. In amici States, many of the same facilities providing abortion also offer other critical health care services, such as pre- and post-natal care, contraceptive care, cancer screening,

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[24] *See* Margot Sanger-Katz et al., *Interstate Abortion Travel Is Already Straining Parts of the System*, N.Y. Times (July 23, 2022); Angie Leventis Lourgos, *Abortions in Illinois for Out of State Patients Have Skyrocketed*, Chi. Trib. (Aug. 2, 2022); Matt Bloom & Bente Berkland, *Wait Times at Colorado Abortion Clinics Hit 2 Weeks as Out-of-State Patients Strain System*, KSUT (July 28, 2022).

[25] Kirstein et al., *100 Days Post-*Roe, *supra*.

and other critical forms of preventative health care. Delays resulting from increased demand for abortion procedures will obstruct access to other forms of care at those facilities, inevitably resulting in higher rates of unintended pregnancy and sexually transmitted infections, barriers to early detection and treatment for breast, ovarian, and testicular cancers, and worsened health outcomes for patients' overall sexual and reproductive health and beyond.[26] Those harms will disproportionately impact groups already underserved by the health care system, including women of color, low-income women, people with disabilities, and LGBTQ individuals.[27] And in addition to jeopardizing the health of residents and deepening health care disparities, such outcomes would impose substantial costs on amici States and local governments.

In finding that nationwide preliminary relief was in the public interest, the district court ignored the considerable harms identified by amici States, the federal government, medical practitioners, and others.

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[26] *See* Julia Strasser et al., *Penalizing Abortion Providers Will Have Ripple Effects across Pregnancy Care*, Health Affs. (May 3, 2022); Kirstein et al., *100 Days Post-*Roe, *supra*.

[27] *See, e.g.*, Strasser, *supra*; Theresa Chalhoub & Kelly Rimary, *The Health Care System and Racial Disparities in Maternal Mortality*, Ctr. for Am. Progress (May 10, 2018).

Instead, the district court elevated the policy preferences of plaintiffs and States that have banned or restricted abortion, opining that the FDA's approval of mifepristone has harmed some "States' efforts to regulate chemical abortion." (Op. & Order 63.) But the Supreme Court recognized in *Dobbs* that "the people of the various States may evaluate" the interests of a woman who wants an abortion and the interests in fetal life differently, *Dobbs*, 142 S. Ct. at 2257, and mandated that "the authority to regulate abortion must be returned to the people and their elected representatives," *id.* at 2279. In this case, the district court disregarded *Dobbs* by promoting the policy interests of one group of States over all others and ordering relief that could impose drastic consequences on States that have made the different but equally sovereign determination to promote access to abortion care.

CONCLUSION

This Court should grant appellants' motion for a stay.

Dated: New York, New York
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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, Grace X. Zhou, an attorney in the Office of the Attorney General of the State of New York, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains 2,597 words and complies with the typeface requirements and length limits of Rules 27, 29, and 32(a)(5)-(7) and the corresponding local rules.

/s/ Grace X. Zhou