**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*.

On Appeal from the United States District Court
for the Northern District of Texas

**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**


LETITIA JAMES
*Attorney General*
*State of New York*
28 Liberty Street
New York, New York 10005
(212) 416-6279

BARBARA D. UNDERWOOD
*Solicitor General*
ESTER MURDUKHAYEVA
*Deputy Solicitor General*
GALEN LEIGH SHERWIN
*Assistant Solicitor General*
*of Counsel*


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## INTRODUCTION AND INTERESTS OF AMICI

Mifepristone is a safe, reliable, and effective method for early pregnancy termination and, in combination with the drug misoprostol, is the only drug approved by the U.S. Food and Drug Administration (FDA) for medication abortion.[1] Since the FDA approved the drug in 2000, more than five million individuals have used mifepristone to safely terminate pregnancies or manage miscarriages.

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 defendants' appeal from the district court's order purporting to retroactively "stay" the effective date of the FDA's approval of

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[1] Mifepristone was initially approved under the brand name Mifeprex®. Amici generally refer to the drug by its generic name, mifepristone, and the term "medication abortion" to refer to the method of pregnancy termination using medication. The term "chemical abortion" used throughout plaintiffs' complaint and briefs and adopted by the district court is not an accepted medical term.

mifepristone twenty-three years after that date has passed.[2] Each of the amici States has an important interest in protecting the health, safety, and rights of its residents, including an interest in ensuring safe access to essential reproductive health care.[3] The continued availability of mifepristone is critical to safeguarding that interest.

Amici States further have a unique perspective on how strongly the public interest weighs against the preliminary relief granted by the district court. The FDA's determination that mifepristone is safe and effective comports with the overwhelming medical consensus developed over more than two decades of use in the United States and globally. The agency's subsequent regulatory actions, including authorizing the generic version of the medication, permitting qualified clinicians other

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[2] The Supreme Court granted a stay of the district court's order in its entirety (ECF No. 201) after a divided panel of this Court stayed the order in part (ECF No. 183).

[3] Several amici States are plaintiffs in *Washington v. U.S. Food & Drug Administration*, No. 23-cv-03026 (E.D. Wash.), which challenges certain restrictions on mifepristone. The district court in that case has preliminarily enjoined the FDA from altering the status quo with respect to mifepristone in those States. *See* Order Granting in Part Pls.' Mot. for Prelim. Inj., *Washington v. U.S. Food & Drug Admin.*, No. 23-cv-3026 (E.D. Wash. Apr. 7, 2023), ECF No. 80.

than physicians to dispense the drug, and removing requirements that the drug be dispensed in person, are also backed by overwhelming evidence. Mifepristone is an essential component of comprehensive reproductive health care, accounting for a majority of first-trimester abortions performed in the U.S. and also representing the recommended treatment for early pregnancy loss. The availability of mifepristone has proven critical to amici States in improving abortion access, particularly in low-income, underserved, and rural communities which experience higher rates of maternal mortality and morbidity, and where nonmedication abortion alternatives (e.g., "procedural abortion") may be unavailable.

Conversely, upholding the district court's order could result in substantial nationwide harms. Curtailing access to the safest and most common medication used for first-trimester abortion will result in more abortions taking place later in pregnancy, further increasing costs and medical risks. Many in need of abortion care will be forced to undergo procedural abortions, which although safe, are more invasive, more expensive, and less available than medication abortion. Others will resort to abortion outside of the regulated health care system or will be

prevented from accessing abortion entirely. In addition, disrupting access to mifepristone in States where abortion remains lawful would place a potentially unbearable strain on already overburdened health care systems and cause broad repercussions, worsening pregnancy-related morbidity and mortality, impeding delivery of other essential medical care, and deepening entrenched health disparities.

In addition, the district court's ruling would create extraordinary uncertainty in the pharmaceutical industry and may jeopardize the development and approval of thousands of innovative drugs and treatments. The district court's disregard for the FDA's drug-approval process creates an untenable risk to amici States, whose health care systems rely on the stability and integrity of the FDA's regulatory regime and the continued availability of FDA-approved drugs to prevent and treat a range of conditions and diseases.

Finally, amici States have a strong interest in safeguarding their sovereign decisions 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 concluded that the U.S. Constitution does not protect the right to obtain an abortion, it emphat-

ically 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. Allowing the district court's order to stand could eviscerate the sovereign decisions of many amici States by disrupting access to medication abortion in States where abortion remains lawful.

## ARGUMENT

## POINT I

### MEDICATION ABORTION IS A SAFE AND EFFECTIVE METHOD FOR TERMINATING PREGNANCIES

The experience of many of the amici States confirms what numerous studies have demonstrated: mifepristone is extraordinarily safe and effective. Since its approval in 2000, an estimated 5.6 million women in the U.S. have used mifepristone to terminate a pregnancy.[4] According to current estimates, medication abortion now accounts for more than half of all abortions performed in the U.S.[5]

The determination that mifepristone is safe and effective is based on ample, high-quality evidence gleaned from more than a quarter century of clinical research and practice in the U.S. and globally.[6] For

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[4] *See* U.S. Food & Drug Admin., *Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022* (n.d.).

[5] Rachel K. Jones et al., Guttmacher Inst., *Medication Abortion Now Accounts for More than Half of All US Abortions* (last updated Dec. 1, 2022).

[6] *See* U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy through Ten Weeks Gestation* (last updated Jan. 4, 2023) (hereinafter "*Questions & Answers*"); U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., *Risk Evaluation and Mitigation Strategy (REMS) Memorandum: REMS*

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example, a recent comprehensive survey of abortion care in the U.S. by the National Academies of Sciences, Engineering, and Medicine concluded that medication abortion using mifepristone is 96.7% effective and that complications are rare, i.e., "occurring in no more than a fraction of a percent of patients."[7] The World Health Organization includes the mifepristone/ misoprostol regimen in its guidelines for abortion care,[8] and has long included the combination regimen in its Model List of Essential Medicines—i.e., those medicines "that satisfy the priority health care needs of a population" and "are intended to be available in functioning health systems at all times."[9] And the leading national medical associations have staunchly defended

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*Modification* (Mar. 29, 2016); *see also* U.S. Gov't Accountability Off., *Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* (2018).

[7] Nat'l 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*"); *accord* Mary Gatter et al., *Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 Days*, 91 Contraception 269, 270 (2015).

[8] *See* World Health Org., *Abortion Care Guideline* xxix, 16-17, 67-68 (2022) (hereinafter "WHO, *Guideline*").

[9] World Health Org., *World Health Org. Model List of Essential Medicines, 22nd List, 2021: Overview* (Sept. 30, 2021).

mifepristone's safety record, characterizing it as "thoroughly studied . . . and conclusively safe." Br. of Medical & Public Health Societies as Amici Curiae in Supp. of Def.-Appellants at 8 (Apr. 11, 2023), ECF No. 111. The FDA's approval of the generic version of mifepristone in 2019 rested on the same body of evidence, supplemented with additional safety data gleaned from nearly two additional decades of use.[10]

The FDA's subsequent decisions to lift certain restrictions on mifepristone's use were similarly supported by robust data, aligning the conditions for use more closely with clinical protocols and recommendations by leading medical associations. Among other steps, the FDA approved labeling changes expanding the approved period of use for mifepristone from seven to ten weeks of pregnancy.[11] And the FDA elimi-

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[10] U.S. Food & Drug Admin., *Questions & Answers*, *supra*; U.S. Food & Drug Admin., *Abbreviated New Drug Application Approval Letter for Mifepristone Tablets, 200 mg*, ANDA No. 091178 (Apr. 11, 2019).

[11] *See* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch, *Supplemental Approval Letter for Mifeprex*, NDA No. 020687/S-020 (Mar. 29, 2016); Am. Coll. of Obstetricians & Gynecologists (ACOG), *Medication Abortion up to 70 Days of Gestation*, 102 Contraception 225, 225 (2020) (hereinafter "ACOG, *Medication Abortion*"); WHO, *Guideline*, *supra*, at xxix, 16-17, 67-70 (endorsing mifepristone's use as safe up to 12 weeks of gestation).

nated the requirement that mifepristone be dispensed only by physicians, permitting prescribing by qualified advanced practice clinicians—a step long supported by major medical associations.[12]

In 2020, the FDA further suspended enforcement of the in-person dispensing requirement on an emergency basis in response to the Covid-19 pandemic—a change for which many amici States had advocated.[13] The FDA permanently suspended the in-person dispensing requirement in 2023.[14] These changes opened the door for medication abortion to be

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[12] *See*, *e.g.*, ACOG, Comm. on Health Care for Underserved Women, Comm. Op. No. 815, *Increasing Access to Abortion*, 136 Obstetrics & Gynecology 107 (2020); Am. Pub. Health Ass'n, Pol'y No. 20112, *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants* (Nov. 1, 2011). The term "advanced practice clinicians" is generally understood to include nurse practitioners, certified nurse-midwives, and physician assistants. *See* NASEM, *Safety and Quality of Abortion* Care, *supra*, at 102.

[13] *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, U.S. Food & Drug Admin. (Mar. 30, 2020). ACOG, supported by many amici States, further brought suit in federal court seeking temporary suspension of the REMS during the pandemic. *See ACOG v. U.S. Food & Drug Admin.*, Nos. 20-1784, 20-1824, 20-1970, 2021 WL 538307 (4th Cir. Feb. 12, 2021).

[14] Letter from Patrizia Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch., to Graham Chelius, Soc'y of Fam. Plan., Cal. Acad. of Fam. Physicians (Dec. 16, 2021); U.S. Food & Drug Admin., *Questions &*

(*continued on the next page*)

offered via telemedicine and dispensed by certified retail pharmacies, consistent with state law.[15] The conclusion that medication abortion can be provided safely outside of a brick-and-mortar setting has been repeatedly endorsed by leading medical associations, reinforced by clinical practice experience during the pandemic, and borne out by many amici States' experience with telemedicine prescribing for women within their borders.[16]

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*Answers*, *supra*. The 2023 determination was issued after the amended complaint was filed, and plaintiffs have not further amended or otherwise asked that it be enjoined. Thus, the validity of the 2023 REMS is not properly before the district court or this Court.

[15] *See* U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg* (last modified Jan. 2023); U.S. Food & Drug Admin., *Questions & Answers*, *supra*.

[16] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 57-58; Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43, 44 (2021); Ellen R. Wiebe et al., *Comparing Telemedicine to In-Clinic Medication Abortions Induced with Mifepristone and Misoprostol*, 2 Contraception X 2:100023 (2020); Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics & Gynecology 296 (2011); Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person*, 130 Obstetrics & Gynecology 778 (2017).

Plaintiffs' misleading and cherry-picked allegations regarding the purported dangers of medication abortion conflict with amici States' experience and with the clinical evidence. The relatively few adverse events associated with mifepristone are well within an acceptable range for FDA approval. Indeed, mifepristone is as safe as or safer than numerous other types of FDA-approved drugs and products with fewer restrictions on their use, including Viagra (four times safer), penicillin (two times safer), and even acetaminophen.[17] The anecdotes on which plaintiffs rely do not remotely approach the substantial showing that would be required to overrule the agency's expert determinations, whether as to the initial approval, authorization of the generic medication, or the elimination of restrictions the agency has over time deemed medically unjustified.

Nor have plaintiffs offered any valid evidence that practice changes resulting from the FDA's regulatory actions since 2016 have

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[17] *See* Advancing New Standards in Reprod. Health, *Issue Brief: Analysis of Medication Abortion Risk and the FDA Report "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018"* (Apr. 2019); *see also* Br. of Medical & Public Health Societies as Amici Curiae in Supp. of Def.-Appellants, *supra*, at 8.

resulted in any increase in adverse outcomes. Given the widespread use of mifepristone in amici States, if plaintiffs' allegations regarding the risk associated with lifting these restrictions were accurate, those harmful effects would be impossible to hide at the population level. But amici States have seen no such effects—and in fact, the opposite is true.

Indeed, mifepristone's safety record is so conclusive that major medical associations, as well as several amici States, have advocated that the REMS designation be eliminated altogether. For example, the American Academy of Family Physicians has asserted that lifting the REMS is necessary "to conform to current evidence," and the American College of Obstetricians and Gynecologists has characterized the designation as "outdated" and medically unjustified.[18] And seventeen amici States are plaintiffs in a lawsuit asserting that the FDA's decision in 2023 to retain certain aspects of the REMS was arbitrary and capricious because it singles out an exceptionally safe drug for uniquely

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[18] *See* Letter from Michael L. Munger, Bd. Chair, Am. Acad. of Fam. Physicians, to Norman Sharpless, Acting Comm'r, U.S. Food & Drug Admin. (June 20, 2019); ACOG, *Position Statement: Improving Access to Mifepristone for Reproductive Health Indications* (Mar. 2021).

burdensome restrictions.[19] But regardless of whether the restrictions that *remain* are medically justified, clinical evidence overwhelmingly supports the FDA's determination to *lift* selected limitations imposed under the pre-2016 REMS.

In this case, allowing the district court to unilaterally substitute its judgment for the FDA's determinations—in defiance of the scientific evidence and in a manner that unduly burdens rather than assures safe access—contravenes the mandate of the FDA[20] and undermines the integrity of the FDA-approval process, with devastating consequences for the industry and the public.[21] Providers and patients in amici States rely on the availability of thousands of FDA-approved drugs to treat or manage a range of medical conditions experienced by their residents,

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[19] Am. Compl. at 4 ¶ 5 (Mar. 9, 2023), *Washington*, No. 23-cv-03026, ECF No. 35.

[20] *See* 21 U.S.C. § 355-1(f).

[21] *See* Br. of Pharmaceutical Companies, Executives & Investors as Amici Curiae in Supp. of Applicants at 2, *U.S. Food & Drug Admin. v. Alliance for Hippocratic Med.*, Nos. 22A901, 22A902 (U.S. Apr. 14, 2023).

including asthma, HIV, infertility, heart disease, diabetes, and more.[22] For each of these drugs, the FDA determined based on significant clinical data that the benefits of the drug outweighed any known and potential health risks.[23] Permitting the district court's order to stand risks upending this well-established regulatory framework and frustrates reliance interests in the stability of that system shared by amici States, manufacturers, patients, and providers alike.[24]

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[22] *See* U.S. Food & Drug Admin., *Fact Sheet: FDA at a Glance* (Nov. 2021).

[23] U.S. Food & Drug Admin., *Development & Approval Process* (last updated Aug. 8, 2022).

[24] *See* Br. of Pharmaceutical Companies, Executives & Investors as Amici Curiae in Supp. of Applicants, *supra*, at 2.

## POINT II

### MEDICATION ABORTION IS INDISPENSABLE TO REPRODUCTIVE HEALTH CARE, PARTICULARLY IN UNDERSERVED COMMUNITIES

Medication abortion is an essential component of reproductive health care. For more than two decades, residents in amici States have relied upon the availability of mifepristone to provide their residents with the numerous advantages medication abortion offers, including increased privacy, flexibility, and patient autonomy.[25] Mifepristone is also the standard treatment in many instances of early pregnancy loss.[26] And medication abortion has proven particularly crucial in promoting access for individuals in rural and underserved communities.

First, medication abortion promotes access to abortion as early as possible, when it is safest and least expensive. Medication abortion has contributed to an increase in the proportion of pregnancy terminations taking place at less than six weeks gestation, when risks are lowest, freeing up in-clinic appointments for later-stage or more complicated

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[25] *See* Br. of Medical & Public Health Societies as Amici Curiae in Supp. of Defs.-Appellants, *supra*, at 15-18.

[26] Kurt Barnhart, *Medical Management of Miscarriage with Mifepristone*, 396 Lancet 737 (2020).

care.[27] The associated decreases in expense and complication rates help lower health care costs and ease burdens on the system overall.

Second, medication abortion offers added flexibility for both patients and providers and has eased constraints on availability. Unlike procedural abortion, which is performed in a clinical setting, medication abortion does not require any special equipment and can safely be administered 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.[28] Between 2011 and 2014, provision of medication abortion in nonspecialized clinics and physicians' offices increased by 26% and 20%, respectively; in several cases, such a facility was the sole abortion provider in its geographic

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[27] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 5, 28-29; *see also* Advancing New Standards in Reprod. Health, *The Average Out-of-Pocket Cost for Medication Abortion Is Increasing, New Study Confirms* (Apr. 11, 2022).

[28] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 10. Because the in-person dispensing requirement for misoprostol was lifted in the 2016 REMS, it had long been standard practice for patients to take the second course of the regimen at home or in another setting of their choice, offering patients valuable control over location and timing. *See id.* at 56; ACOG, *Medication Abortion*, *supra*.

area.[29] And given the escalating violence at abortion clinics,[30] the availability of medication abortion within such mainstream settings has offered valuable privacy and security for patients and providers.

The FDA's approval of the generic version of the drug in 2019 has significantly expanded access to abortion services, and, as with introduction of generics generally, promises to significantly lower costs.[31] In addition, the FDA's decision to extend prescription authority to clinicians other than physicians has eased the acute shortage of providers in States authorizing advanced practice clinicians such as nurse practitioners and physician assistants to offer abortion services, allowing physicians to focus on more complex cases and other critical services without compromising patient health.[32]

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[29] *See* Rachel K. Jones & Jenna Jerman, *Abortion Incidence and Service Availability in the United States, 2014*, 49 Persps. on Sexual & Reprod. Health 17, 22 (2017).

[30] *See* Nat'l Abortion Fed'n, *2021 Violence and Disruption Report* (June 24, 2022); U.S. Dep't of Just., *Recent Cases on Violence Against Reproductive Health Care Providers* (last updated Oct. 18, 2022).

[31] *See* Anna North, *America's First Generic Abortion Pill, Explained*, Vox (Aug. 20, 2019).

[32] Am. Pub. Health Ass'n, Pol'y No. 20112, *supra*; AP Toolkit, *State Abortion Laws and Their Relationship to Scope of Practice* (n.d.).

Finally, eliminating the requirement for in-person dispensing has proven particularly critical in reaching low-income communities, communities of color, and rural and underserved areas where barriers to abortion access are most acute.[33] Eliminating this requirement has permitted clinicians to offer medication abortion services entirely remotely, by conducting patient intake, examination, prescription, and follow-up via telephone or videoconference. In addition, the FDA's recent changes to the REMS have allowed patients to obtain the medication through mail-order pharmacies, and as of January 2023, through properly certified retail pharmacies.[34] According to 2020 data,

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[33] *See* Liza Fuentes, Guttmacher Inst., *Inequity in US Abortion Rights and Access: The End of* Roe *Is Deepening Existing Divides* (Jan. 17, 2023).

[34] Plaintiffs' assert that the federal Comstock Act prohibits the distribution of mifepristone by mail. The U.S. Department of Justice's Office of Legal Counsel disagrees. *See* Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. O.L.C. __, pp. 1-2 (Dec. 23, 2022). Although a discussion of the Comstock Act is beyond the scope of this brief, amici States point out that the district court's interpretation of the Comstock Act would have potentially boundless effects on medical care delivery, preventing distribution of a host of devices, surgical instruments, and equipment used in obstetrics and gynecology and beyond, as well as numerous drugs routinely used to treat countless diseases and conditions.

89% of U.S. counties had no abortion clinic and 38% of women of reproductive age resided in such a county.[35] Another study showed 17% of people who had abortions traveled 50 miles or further to obtain care, and rural patients were eight times as likely as urban patients to travel more than 100 miles for abortion care (36% versus 4%, respectively).[36] The many practical and cost barriers associated with obtaining an abortion increase with distance traveled; these barriers include childcare needs, missed days of work and resulting lost income, lack of insurance, and travel costs and logistics.[37] Such barriers are steepest for low-income people and people of color, and for many, the barriers place abortion out of reach altogether.[38]

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[35] Jones & Jerman, *Abortion Incidence and Service Availability in the United States, 2020*, *supra*, at 20.

[36] Liza Fuentes & Jenna Jerman, *Distance Traveled for Abortion in the United States and Reasons for Clinic Choice*, 28 J. Women's Health, 1623, 1627 (2019).

[37] *See id.* at 1623-24; Sarah Varney, *Long Drives, Air Travel, Exhausting Waits: What Abortion Requires in the South*, KFF Health News (Aug. 3, 2021); Jenna Jerman et al., *Barriers to Abortion Care and Their Consequences for Patients Traveling for Services: Qualitative Findings from Two States*, 49 Persps. on Sexual & Reprod. Health 95 (2017).

[38] *See* Jill Barr-Walker, *Experiences of Women Who Travel for Abortion: A Mixed Methods Systematic Review*, 14 PLOS ONE e0209991,

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Because of medication abortion's potential to greatly mitigate these barriers, many amici States have implemented policies and invested significant resources to expand its availability. For example, in Maine, which has among the highest rates of rural residents in the U.S., a major clinic chain has since 2016 made medication abortion available at its 16 health centers via telemedicine.[39] Several amici States, including California, Massachusetts, and New York, have recently taken steps to make medication abortion available at public university campus health centers.[40] And many States have enacted legislation intended to protect providers of abortion, including those who provide care via telemedicine, against disciplinary consequences, loss of malpractice insurance, or legal action for performing or assisting in the performance

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at 19-21 (Apr. 9, 2019); Elizabeth A. Pleasants et al., *Association Between Distance to an Abortion Facility and Abortion or Pregnancy Outcome Among a Prospective Cohort of People Seeking Abortion Online*, 5 JAMA Network Open e2212065, at 10 (2022).

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

[40] *See* 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).

of lawful abortion care.[41] The availability of mifepristone, and the elimination of unnecessary restraints on its use and distribution, have thus enabled many amici States to vastly improve access to abortion care and further their broader health equity goals.

## POINT III

### THE DISTRICT COURT'S ORDER WOULD HAVE DEVASTATING NATIONWIDE CONSEQUENCES

If permitted to take effect, the district court's order would lead to massive disruptions and negative consequences in the delivery of reproductive health care nationwide. Suspending the FDA's initial 2000 approval of mifepristone would threaten manufacturing and distribution processes, impeding one of the most readily available and reliable methods for pregnancy termination during the first trimester of pregnancy. It would also seriously compromise treatment for miscarriages,

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[41] *See, e.g.*, Act of July 29, 2022, Ch. 127, 2022 Mass. Acts; Press Release, Mass. Off. of the Governor, *Governor Healey Announces Immediate Action to Protect Access to Medication Abortion in Massachusetts* (Apr. 10, 2023); Act of July 1, 2022, Ch. 50, 2022 N.J. Laws; S. 1213B, 246th Sess. (N.Y. 2023); Press Release, N.Y. Off. of the Governor, *supra*.

leading to needless increased risks.[42] Even a return to the pre-2016 REMS and labeling (as contemplated by this Court's initial stay ruling) would revert the country to a time when medication abortion was significantly more difficult to access than procedural abortion. This would inflict massive harms on amici States and their residents and thwart the goals of States wishing to protect rather than restrict abortion access.

Added obstacles to mifepristone's availability would drive numerous individuals seeking abortion to turn to other methods. Providers would be limited to alternative protocols for medication abortion, such as using misoprostol only, which although accepted under clinical guidelines when the mifepristone/misoprostol regimen is unavailable, is not the preferred treatment plan and would be unlikely to meet existing demand for mifepristone.[43] Many patients would seek procedural abortions—which, although safe, are unnecessarily invasive

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[42] *See* Br. of Physicians for Reproductive Health as *Amicus Curiae* in Supp. of Defs-Appellants at 6-7, 10-12 (Apr. 11, 2023), ECF No. 63.

[43] *See* WHO, *Guideline*, *supra*, at xxix, 67-71; ACOG, *Medication Abortion*, *supra*; Soc'y of Fam. Plan., *Misoprostol Only Is Safe and Effective* (March 16, 2023).

procedures for those for whom medication abortion would have been recommended, and are generally more costly to provide and to obtain.[44] Travel distances to obtain care would increase dramatically, further compounding costs and delays, and resulting in more later-gestation procedures, increased health risks, and adverse mental health outcomes.[45] Others desperate for care will seek abortion medications through online services or overseas pharmacies and self-manage their abortions outside of a medical setting.[46] Many who are unable to afford

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[44] *See, e.g.*, Br. for Amici Curiae the City of New York et al. at 18 (Apr. 11, 2023), ECF No. 117 (estimating that procedural abortion costs five times as much as a medication abortion to provide).

[45] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 116; Fuentes & Jerman, *supra*, at 1623; Barr-Walker, *supra*, at 17; Rachel K. Jones & Jenna Jerman, Guttmacher Inst., *Time to Appointment and Delays in Accessing Care Among U.S. Abortion Patients* (Aug. 2016).

[46] *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); Abigail R.A. Aiken et al., *Safety and Effectiveness of Self-Managed Medication Abortion Provided Using Online Telemedicine in the United States: A Population Based Study*, 10 The Lancet Reg'l Health - Americas 4 (2022); Daniel Grossman & Nisha Verma, *Self-Managed Abortion in the US*, 328 JAMA 1693, 1693-94 (2022).

those added costs will be denied access to abortion altogether and forced to carry unwanted pregnancies to term.[47]

Further, restricting the availability of medication abortion in States where abortion remains lawful would exacerbate the drastic reduction in access across large swaths of the country in the wake of *Dobbs*. Abortion is currently unavailable in over a dozen States where bans or near-total restrictions are in effect or subject to pending litigation, and extremely limited in several more.[48] These States are home to approximately 22 million women of childbearing age, representing

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[47] *See* Fuentes & Jerman, *supra*, at 3; Kirsten M. J. Thompson et al., *Association of Travel Distance to Nearest Abortion Facility with Rates of Abortion*, 4 JAMA Network Open e2115530, at 6-8 (2021); Katrina Kimport, *Abortion After* Dobbs*: Defendants, Denials, and Delays*, 8 Sci. Advances eade5327, at 1-2 (Sept. 2022).

[48] Soc'y of Fam. Plan., *#WeCount Report* 2 (Oct. 28, 2022) ("Since the *Dobbs* decision, in states with bans or severe restrictions, there were 7,870 fewer abortions in July and 8,040 fewer in August, for a cumulative total of 15,910 fewer people who had abortions in those states."). Numerous state bans or restrictions are subject to pending litigation. *See* Ctr. for Reprod. Rts., *After* Roe *Fell: Abortion Laws by State.*

almost one third of the total population of women ages 15-49.[49] At least 62 clinics have been shuttered since the end of June 2022, and travel time to obtain abortion has increased significantly across the U.S.[50] And new data suggests that in the six months following *Dobbs*, "many thousands of pregnant people living in states where abortion is banned and restricted were unable to obtain abortion care."[51] Many amici States have already experienced a steep rise in demand at clinics as out-of-state patients flood into their States to receive necessary care, stretching them past their capacity and dramatically increasing wait times for care for patients from both within and outside of their States.[52] These impacts are expected to worsen as the many new legal

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[49] *See* Marielle Kirstein et al., Guttmacher Inst., *100 Days Post-Roe: At Least 66 Clinics across 15 US States Have Stopped Offering Abortion Care* (Oct. 6, 2022).

[50] *See id.*; Caitlin Myers et al., *Abortion Access Dashboard* (last updated Mar. 23, 2023); Benjamin Rader et al., *Estimated Travel Time and Spatial Access to Abortion Facilities in the US Before and After the* Dobbs v Jackson Women's Health *Decision*, 328 JAMA 2041, 2043-45 (2022).

[51] Soc'y of Fam. Plan., *#WeCount Report* (Apr. 11, 2023).

[52] *See id.*; 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*

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risks created by *Dobbs*, disruptions in residency training, and an anticipated wave of additional state-level restrictions further depress access nationwide.[53]

Even a partial restoration of medically unnecessary restrictions on access to mifepristone could result in substantial burdens on already overtaxed health care systems and diminish many of the benefits medication abortion offers. For example, reinstating the physician-only dispensing requirement for mifepristone would shift physicians' limited time and attention away from more complex and later-term procedures, and restoring the in-person dispensing requirement would eliminate

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*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); Oriana Gonzalez & Nicole Cobler, *Influx of Out-of-State Patients Causes Abortion Delays*, Axios (Sept. 12, 2022); Cindy Carcamo, *A California Desert Town Has Long Been an Abortion Refuge for Arizona and Mexico. Now It's Overwhelmed*, L.A. Times (July 20, 2022).

[53] *See* Ferit Nirappil & Frances Stead Sellers, *Abortion Ban States See Steep Drop in OB/GYN Residency Applicants*, Wash. Post (Apr. 21, 2023); Jan Hoffman, *OB-GYN Residency Programs Face Tough Choice on Abortion Training*, N.Y. Times (Oct. 27, 2022); Julia Strasser et al., *Penalizing Abortion Providers Will Have Ripple Effects across Pregnancy Care*, Health Affs. (May 3, 2022) (hereinafter "Strasser et al., *Ripple Effects*"); Kimport, *Abortion After* Dobbs, *supra*, at 1-2.

access through telemedicine, cancelling out its significant utility in reaching rural and underserved communities and further straining providers' ability to handle the spiking demand in the wake of *Dobbs*.[54] The cumulative consequences would be catastrophic, worsening the provider shortage and further increasing delays and denials of abortion care.

Limited access to abortion care is in turn associated with numerous harms, including poor birthing and infant health outcomes, higher rates of poverty, and lower educational attainment for both parents and children.[55] And because carrying a pregnancy to term is 14

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[54] Amelia Thomson-DeVeaux, *Virtual Abortions Surged After* Roe *Was Overturned—But the Texas Ruling Could Change That*, FiveThirtyEight (Apr. 11, 2013).

[55] *See* Diana G. Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (2021); Diana G. 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, 411-13 (2018); Heidi D. Nelson et al., *Associations of Unintended Pregnancy with Maternal and Infant Health Outcomes: A Systematic Review and Meta-Analysis*, 328 JAMA 1714, 1714-29 (2022).

times more risky to the pregnant person than early abortion,[56] curtailing access to medication abortion nationwide would likely lead to a steep rise in birth-related complications and deaths.[57] Estimates suggest that those rates would rise by 21% overall should a total abortion ban go into effect nationwide, purely due to the increased risks associated with bearing a child, with Black women experiencing the highest estimated increase of 33%.[58] Indeed, restrictive abortion laws have long been linked to higher morbidity and mortality rates.[59] Impeding access

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[56] 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).

[57] *See* Amanda Jean Stevenson et al., *The Maternal Mortality Consequences of Losing Abortion Access* (June 29, 2022) (unpublished manuscript); 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).

[58] *See* Stevenson et al., *The Maternal Mortality Consequences of Losing Abortion Access*, *supra*.

[59] *See* 2 Ibis Reprod. Health & Ctr. for Reprod. Rts., *Evaluating Priorities: Measuring Women's and Children's Health and Well-Being against Abortion Restrictions in the States* 16-18 (2017); Guttmacher Inst., *Induced Abortion Worldwide* (Mar. 2018).

to medication abortion would therefore worsen a mortality crisis already disproportionately faced by Black women.[60]

These outcomes are not merely hypothetical. In States instituting bans on abortion in the wake of *Dobbs*, resulting delays and denials of care have led to dire harms for pregnant individuals, endangering their mental and physical health, their future fertility, and their lives.[61] These include 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 nonviable fetus.[62]

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[60] *See* Elyssa Spitzer et al., Ctr. for Am. Progress, *Abortion Bans Will Result in More Women Dying* (Nov. 2, 2022); Nelson et al., *supra*, at 14-29; Samantha Artiga et al., Kaiser Fam. Found., *What Are the Implications of the Overturning of* Roe v. Wade *for Racial Disparities?* (July 15, 2022).

[61] *See* Anjali Nambiar et al., *Maternal Morbidity and Fetal Outcomes among Pregnant Women at 22 Weeks' Gestation or Less with Complications in 2 Texas Hospitals After Legislation on Abortion*, 227 Am. J. Obstetrics & Gynecology 648 (2022); Eugene Declercq et al., Commonwealth Fund, *The U.S. Maternal Health Divide: The Limited Maternal Health Services and Worse Outcomes of States Proposing New Abortion Restrictions* (Dec. 14, 2022).

[62] *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

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These harmful outcomes would cause ripple effects across the entire health system. In many amici States, the same facilities providing abortion also offer other critical services, such as pre- and post-natal care, family planning, cancer screening, and other critical forms of preventative health care. Delays resulting from increased demand for abortion procedures (in lieu of medication abortions) will obstruct access to all care offered 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 chronic diseases, and worsened overall health outcomes.[63] Underserved groups, including women of color, low-income women, people with disabilities, and LGBTQ individuals, will be hardest hit.[64] And increasingly poor overall health outcomes will impose

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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).

[63] *See* Strasser et al., *Ripple Effects*, *supra*.

[64] *See id.*; Theresa Chalhoub & Kelly Rimary, Ctr. for Am. Progress, *The Health Care System and Racial Disparities in Maternal Mortality* (May 10, 2018); Christine Dehlendorf et al., *Disparities in Family Planning*, 202 Am. J. Obstetrics & Gynecology 214 (2010);

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substantial costs on amici States and local governments.[65] By contrast, in amici States' experience, the alleged strains on the health care system purportedly caused by the FDA's regulatory decisions, which the district court accepted as fact, have simply never materialized.

In addition, the district court's decision would undermine the development and availability of thousands of drugs relied on by amici's residents to treat and prevent a range of conditions. The market stability provided by the FDA's drug-approval regime is crucial to fostering and developing new drugs and maintaining ready access to available drugs.[66] The district court's analysis undermines this regime in ways that will inevitably chill research and development of new drugs and therapies. This, in turn, could deprive amici States of

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Lindsey Dawson et al., Kaiser Fam. Found., *LGBT+ People's Health and Experiences Accessing Care* (July 22, 2021).

[65] *See* Br. for Amici Curiae the City of New York et al., supra, at 15-18; Br. of Local Governments as Amici Curiae in Supp. of the Government's & Intervenor's Requests for a Stay Pending Appeal at 2, 15-16 (Apr 11, 2023), ECF No. 125.

[66] *See* Br. of Pharmaceutical Research & Manufacturers of America as Amici Curiae in Supp. of Applicants at 20, *U.S. Food & Drug Admin. v. Alliance for Hippocratic Med.*, Nos. 22A901, 22A902 (April 14, 2023); Br. of Pharmaceutical Companies, Executives & Investors as Amici Curiae in Supp. of Applicants, *supra*, at 17-18.

innovative new products that would improve the overall health and well-being of their residents. Likewise, the potential removal of other comparably essential, safe and effective drugs from the market under the framework used by the district court to invalidate mifepristone's approval could have catastrophic consequences for amici States, who rely on access to a range of drugs to safeguard and advance the public health.

In finding that nationwide preliminary relief was in the public interest, the district court ignored the considerable harms identified by amici States as well as by medical practitioners, the pharmaceutical industry, and others. Instead, the court elevated the policy preferences of plaintiffs and States that have banned or restricted abortion. 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 determinations to promote access to abortion care.

## CONCLUSION

This Court should reverse the district court's order granting plaintiffs' motion for preliminary relief.

Dated: New York, New York
May 3, 2023

Respectfully submitted,

LETITIA JAMES
*Attorney General*
*State of New York*

By: */s/ Ester Murdukhayeva*
ESTER MURDUKHAYEVA
Deputy Solicitor General

28 Liberty Street
New York, NY 10005
(212) 416-6279

BARBARA D. UNDERWOOD
*Solicitor General*
ESTER MURDUKHAYEVA
*Deputy Solicitor General*
GALEN SHERWIN
*Special Counsel*
*for Reproductive Justice*

(*Counsel list continues below.*)

KRIS MAYES
*Attorney General*
*State of Arizona*
2005 N. Central Ave
Phoenix, AZ 85004

ROB BONTA
*Attorney General*
*State of California*
1515 Clay Street
Oakland, CA 94612

PHILIP J. WEISER
*Attorney General*
*State of Colorado*
1300 Broadway
Denver, CO 80203

WILLIAM TONG
*Attorney General*
*State of Connecticut*
165 Capitol Avenue
Hartford, CT 06106

KATHLEEN JENNINGS
*Attorney General*
*State of Delaware*
820 N. French Street
Wilmington, DE 19801

ANNE E. LOPEZ
*Attorney General*
*State of Hawai'i*
425 Queen Street
Honolulu, HI 96813

KWAME RAOUL
*Attorney General*
*State of Illinois*
100 West Randolph Street
Chicago, IL 60601

AARON M. FREY
*Attorney General*
*State of Maine*
6 State House Station
Augusta, ME 04333

ANTHONY G. BROWN
*Attorney General*
*State of Maryland*
200 Saint Paul Place
Baltimore, MD 21202

ANDREA JOY CAMPBELL
*Attorney General*
*Commonwealth of Massachusetts*
One Ashburton Place
Boston, MA 02108

DANA NESSEL
*Attorney General*
*State of Michigan*
P.O. Box 30212
Lansing, MI 48909

KEITH ELLISON
*Attorney General*
*State of Minnesota*
102 State Capitol
75 Dr. Martin Luther King Jr. Blvd.
St. Paul, MN 55155

AARON D. FORD
*Attorney General*
*State of Nevada*
100 North Carson Street
Carson City, NV 89701

MATTHEW J. PLATKIN
*Attorney General*
*State of New Jersey*
25 Market Street
Trenton, NJ 08625

RAÚL TORREZ
*Attorney General*
*State of New Mexico*
P.O. Drawer 1508
Santa Fe, NM 87504

JOSHUA H. STEIN
*Attorney General*
*State of North Carolina*
114 W. Edenton Street
Raleigh, NC 27603

ELLEN F. ROSENBLUM
*Attorney General*
*State of Oregon*
1162 Court Street N.E.
Salem, OR 97301

MICHELLE A. HENRY
*Attorney General*
*Commonwealth of Pennsylvania*
Strawberry Square
Harrisburg, PA 17120

PETER F. NERONHA
*Attorney General*
*State of Rhode Island*
150 South Main Street
Providence, RI 02903

CHARITY R. CLARK
*Attorney General*
*State of Vermont*
109 State Street
Montpelier, VT 05609

ROBERT W. FERGUSON
*Attorney General*
*State of Washington*
P.O. Box 40100
Olympia, WA 98504

JOSHUA L. KAUL
*Attorney General*
*State of Wisconsin*
17 West Main Street
Madison, WI 53703

BRIAN L. SCHWALB
*Attorney General*
*District of Columbia*
400 6th Street, NW, Suite 8100
Washington, D.C. 20001

## CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, Ester Murdukhayeva, 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 6,440 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/ Ester Murdukhayeva*

## CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically with the Court's CM/ECF system on May 3, 2023. Service will be effectuated by the Court's electronic notification system upon all parties and counsel of record.

Dated: New York, New York
May 3, 2023

*/s/ Ester Murdukhayeva*