UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its member organizations, their members, and these members' patients; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS, on behalf of itself, its members, and their patients; AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of itself, its members, and their patients; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS, on behalf of itself, its members, and their patients; SHAUN JESTER, D.O., on behalf of himself and his patients; REGINA FROST-CLARK, M.D., on behalf of herself and her patients; TYLER JOHNSON, D.O., on behalf of himself and his patients; and GEORGE DELGADO, M.D., on behalf of himself and his patients,

Plaintiffs,

No. 2:22-cv-00223-Z

v.

U.S. FOOD AND DRUG ADMINISTRATION; 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; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

UNOPPOSED MOTION FOR THE STATES OF NEW YORK, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAI'I, ILLINOIS, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NORTH CAROLINA, OREGON, PENNSYLVANIA, RHODE ISLAND, WASHINGTON, AND WISCONSIN, AND THE DISTRICT OF COLUMBIA FOR LEAVE TO FILE A BRIEF AS AMICI CURIAE IN SUPPORT OF DEFENDANTS AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

The States of New York, California, Colorado, Connecticut, Delaware, Hawai‘i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Washington, and Wisconsin, and the District of Columbia respectfully move this Court for leave to file the attached brief as amici curie in support of defendants and in opposition to plaintiffs' motion for preliminary injunction. For the reasons described below, amici's proposed brief contains relevant material that may aid the Court in resolving the issues raised by plaintiffs' motion. Counsel for the parties have been consulted regarding this motion, and all parties have indicated they do not oppose.

Amici States have a substantial interest in this case. The continued availability of mifepristone for medication abortions is critical to safeguarding each of the amici State's interest in protecting the health, safety, and rights of its residents, including an interest in ensuring safe access to essential reproductive health care. An order requiring the FDA to withdraw its approval of mifepristone will have devasting consequences for the residents of amici States. It would make medication abortion largely unavailable, leaving women seeking abortion with no choice other than to undergo a nonmedication abortion procedure, and drastically reduce access to abortion overall. And because medication abortion is the most common method used to terminate pregnancy during the first trimester, eliminating access to this method will result in more abortions taking place later in pregnancy, further increasing costs and medical risks. Finally, annulling the FDA's approval of mifepristone would, in effect, eviscerate amici States' sovereign decisions to protect the right to choose to terminate a pregnancy as it could prevent countless persons in amici States from obtaining an abortion.

The attached brief explains that in the experience of amici States, medication abortion is a safe and effective method for terminating pregnancies. The brief describes how the FDA's

determinations regarding the overall safety and efficacy of medication abortion are consistent with the overwhelming medical consensus and supported by voluminous evidence based on years of clinical research and practice. The brief further argues that medication abortion is an indispensable component of reproductive health care and describes how it has helped promote access to abortion in rural and underserved communities. Amici present data and studies showing that medication abortion not only promotes access to abortion as early as possible when it is safest and least expensive, but also that it vastly improves access to reproductive health care, particularly for low-income individuals, women of color, and those living in rural and underserved communities.

As amici also describe in their brief, annulling the FDA's approval of mifepristone would have devastating consequences for the residents of amici States. The brief explains that without the ability to obtain medication abortion, individuals seeking abortion would need to turn to other methods that are more costly, less accessible, and involve greater risks. The brief explains how these harms are heightened following the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), and will impact women both in States where abortion is available and also in States where abortion is banned. The information from amici's own experiences will assist this Court in assessing the likelihood of success on the merits, weighing the equities of plaintiffs' motion, and determining whether an injunction serves the public interest.

CONCLUSION

The Court should grant amici curiae leave to file the attached brief in support of defendants and in opposition to plaintiffs' motion for preliminary injunction.

Dated: New York, New York
February 10, 2023

Respectfully submitted,

LETITIA JAMES
Attorney General
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/s/ Galen Leigh Sherwin*
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CERTIFICATE OF CONFERENCE (Local Rule 7.1)

Galen Leigh Sherwin, counsel for movants, conferred via email with counsel for plaintiffs. Counsel for plaintiffs has indicated they do not oppose this motion for permission to file the attached brief as amici curiae.

Galen Leigh Sherwin also conferred via email with counsel for defendants and counsel for intervenor defendant, who confirmed that defendants and intervenor defendant do not oppose this motion for permission to file the attached brief as amici curiae.

Dated: New York, New York
February 10, 2023

/s/ Galen Leigh Sherwin
GALEN LEIGH SHERWIN

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,

Plaintiffs,

v. **No. 2:22-cv-00223-Z**

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

Defendants.

BRIEF FOR THE STATES OF NEW YORK, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAI'I, ILLINOIS, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NORTH CAROLINA, OREGON, PENNSYLVANIA, RHODE ISLAND, WASHINGTON, AND WISCONSIN, AND THE DISTRICT OF COLUMBIA AS AMICI CURIAE IN SUPPORT OF DEFENDANTS AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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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. More than twenty years later, plaintiffs (several anti-abortion organizations and physicians) filed this lawsuit challenging the FDA's initial approval and several subsequent regulatory actions pertaining to mifepristone. In this motion, plaintiffs seek a preliminary injunction requiring the FDA to withdraw its approval of mifepristone for medication abortion.

Amici States of New York, California, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Washington, and Wisconsin, and the District of Columbia submit this brief in support of the federal government's opposition to plaintiffs' motion. 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. The continued availability of mifepristone for medication abortions is critical to safeguarding that interest. 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. An order requiring the FDA to withdraw its approval of mifepristone would therefore make medication abortion largely unavailable, forcing those seeking abortion to either undergo a nonmedication abortion procedure (referred to herein as "procedural abortion") or forgo an abortion entirely and drastically reducing access to abortion overall. This would have devastating consequences for the residents of amici States. Procedural abortion is not only more invasive than medication abortion, but it is also generally more costly and difficult to obtain. Indeed, the availability of mifepristone has been

particularly critical in providing access to abortion in low-income, underserved, and rural communities where procedural abortion may be unavailable. And because medication abortion is the most common method used to terminate pregnancy during the first trimester, eliminating access to this method will result in more abortions taking place later in pregnancy, further increasing costs and medical risks.

Amici also have a strong interest in safeguarding their decision to protect their residents' ability to obtain abortions in the wake of the Supreme Court's decision in *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, there can be no question that the Court endorsed the States' authority to promote 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. Annulling the FDA's approval of mifepristone would, in effect, eviscerate amici's sovereign decisions to protect the right to choose to terminate a pregnancy as it could prevent countless persons in amici States from obtaining an abortion.

ARGUMENT

I. MEDICATION ABORTION IS A SAFE AND EFFECTIVE METHOD FOR TERMINATING PREGNANCIES.

The experience of amici States confirms what numerous studies have demonstrated: medication abortion is safe and effective. Although it is beyond the scope of this amicus brief to address the specifics of plaintiffs' allegations regarding the numerous agency actions challenged—taking place over a period of over twenty years—there can be no doubt that the FDA's overall conclusions regarding medication abortion's safety and efficacy are based on substantial evidence.

Currently the only FDA-approved option for medication abortion, mifepristone (the generic version of Mifeprex®),[1] is authorized as a part of a regimen in combination with the drug misoprostol to end unwanted pregnancy up through 70 days (i.e. 10 weeks) of pregnancy.[2] Under the standard regimen for medication abortion, the patient first takes mifepristone in a single dose on day one, followed by a second drug, misoprostol 24-48 hours later.[3] Since the FDA approved Mifeprex® to terminate pregnancy in 2000, an estimated 4.9 million women in the U.S. have used this method to terminate a pregnancy.[4] According to current estimates, medication abortion now accounts for more than half—or 54%—of all abortions performed in the U.S., underscoring "how central this method has become to US abortion provision."[5]

The FDA's determinations regarding the overall safety and efficacy of medication abortion are consistent with the overwhelming medical consensus and supported by voluminous evidence based on years of clinical research and practice. For example, a recent comprehensive survey of

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[1] Amici generally refer to the first medication used in the course of the regimen by its generic name, mifepristone, and the term "medication abortion" to refer to the two-drug regimen of mifepristone and misoprostol together. The term "chemical abortion" used by plaintiffs throughout their complaint and briefs is not an accepted medical term.

[2] *See* FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy through Ten Weeks Gestation* (last updated Jan. 4, 2023) (internet); National Acads. of Scis., Eng'g & Med. (NASEM), *The Safety and Quality of Abortion Care in the United States* 53 (2018) (internet) [hereinafter NASEM, *Safety and Quality of Abortion Care*]. Mifepristone is also commonly used for the management of miscarriages. *See* American Coll. of Obstetricians & Gynecologists (ACOG), *Improving Access to Mifepristone for Reproductive Health Indications* (Mar. 2021) (internet). (For authorities available on the internet, full URLs appear in the Table of Authorities. All URLs were last visited on February 9, 2023.)

[3] *See* ACOG, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 31, 35 (2020) (internet); NASEM, *Safety and Quality of Abortion Care*, *supra*, at 10, 55.

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

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

abortion care in the U.S. conducted by the National Academies of Sciences, Engineering, and Medicine concluded that medication abortion—like procedural abortion—is safe and effective and that complications after medication abortion are rare, i.e., "occurring in no more than a fraction of a percent of patients."[6] 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—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."[7] Accordingly, as the FDA concluded in 2016, the "safety profile of Mifeprex is well-characterized and its risks well-understood after more than 15 years of marketing. Serious adverse events are rare, and the safety profile of Mifeprex has not substantially changed."[8]

Plaintiffs' inflated allegations regarding the purported dangers of medication abortion (*see, e.g.*, Compl. ¶¶ 59-73) do not comport either with amici's experience or with the clinical evidence, particularly when viewed, as they must be, in context of the entire record before the agency. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 44 (1983); *Carey Salt Co. v. NLRB*, 736 F.3d 405, 425 (5th Cir. 2013). The relatively few adverse events associated with medication abortion are well within an acceptable range for FDA approval. Indeed, evidence shows that medication abortion is as safe or safer than numerous other types of FDA-

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[6] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 10, 55.

[7] World Health Org., *WHO Model List of Essential Medicines, 22nd List, 2021: Overview* (Sept. 30, 2021) (internet); *see* World Health Org., *Abortion Care Guideline* xxix, 16-17, 67-68 (2022) (internet); World Health Org., *Model List of Essential Medicines, 22nd List, 2021*, at 50 (2021) (internet).

[8] FDA, Ctr. for Drug Evaluation & Rsch., *REMS Memorandum REMS: Modification* (Mar. 29, 2016) (internet); *see also* U.S. Gov't Accountability Off. (GAO), *Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* (Mar. 2018) (internet) (describing FDA review process and safety monitoring efforts).

approved drugs and products, including Viagra (four times safer), penicillin (two times safer), and even acetaminophen.[9] Requiring the FDA to withdraw or suspend its approval of mifepristone despite the overwhelming clinical data demonstrating its safety and efficacy undermines the integrity of the FDA-approval process for other drugs. 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, including asthma, HIV, infertility, heart disease, diabetes, and more.[10] 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 outweighed any known and potential risks.[11]

Given the widespread use of mifepristone, if plaintiffs' allegations regarding the magnitude of risk associated with medication abortion were accurate, those harmful effects would be impossible to hide at the population level. But amici have seen no such effects—and in fact, the opposite is true. Plaintiffs' allegations are simply insufficient to overcome the agency's considered determinations regarding the overall safety and efficacy of medication abortion.[12]

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[9] *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) (internet).

[10] FDA, *Fact Sheet: FDA at a Glance* (Nov. 2021) (internet) (noting that the FDA has approved of over 20,000 prescription drug products).

[11] FDA, *Development & Approval Process* (last updated Aug. 8, 2022) (internet).

[12] *See* FDA, *Questions and Answers on Mifepristone*, *supra*; *see also* GAO, *Food and Drug Administration: Information on Mifeprex Labeling Changes*, *supra* (nonpartisan report finding that FDA had "followed its standard review process when it approved the application and revised labeling reflecting certain changes, including the indication and dosing regimen, for the drug Mifeprex" and "based its approval on reviews of peer-reviewed published studies, articles, and other information submitted by Mifeprex's sponsor.").

II. MEDICATION ABORTION IS AN INDISPENSABLE COMPONENT OF REPRODUCTIVE HEALTH CARE AND HAS HELPED PROMOTE ACCESS TO ABORTION IN RURAL AND UNDERSERVED COMMUNITIES.

In addition to being safe and effective, medication abortion is also an essential component of reproductive health care. For more than two decades, residents in amici States have relied upon the numerous benefits provided by medication abortion, including increased flexibility, patient autonomy, and availability—benefits that have been particularly crucial in promoting access for individuals living in rural and underserved communities.

One of medication abortion's principal benefits is that it promotes access to abortion as early as possible when it is safest and least expensive. Medication abortion has contributed to a rise in the proportion of pregnancy terminations taking place at less than six weeks gestation, when it is safest, and has freed up time for in-clinic appointments for those who need later stage or more complicated care.[13] In addition to offering benefits to individuals, the associated decreases in cost and complication rates help lower health care costs and ease burdens on the system overall. This beneficial trend is expected to continue as the percentage of abortions performed via medication continues to rise.[14]

Second, medication abortion offers added flexibility for both patients and providers. Unlike procedural abortion, which is necessarily performed in a clinical setting, medication abortion is the result of a drug regimen that does not require any special equipment and can 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 as discussed

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[13] *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) (internet).

[14] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 5.

below.[15] Nationwide, between 2011 and 2014, provision of medication abortion in nonspecialized clinics and physicians' offices increased by 26% and 20%, respectively; in several cases, those facilities were the sole abortion-providing facility in their geographic area.[16] In many States, medication abortion may also be prescribed by advanced practice clinicians, including physician assistants, nurse practitioners, and certified nurse midwives, within their training and scope of practice.[17] The availability of medication abortion within a variety of 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 clinics known to provide abortion.[18]

Moreover, medication abortion may also be safely provided outside of a brick-and-mortar clinical setting. Since 2011, the FDA has placed mifepristone under a Risk Evaluation and Mitigation Strategy (REMS), which among other limitations required dispensing of mifepristone in person in a clinical setting.[19] However, the same restrictions did not apply to misoprostol, and it had long been standard practice for patients to take the second course of the regimen at home or in another

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

[16] *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) (internet).

[17] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 14, 112-114; American Pub. Health Ass'n, *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants*, Policy 20112 (Nov. 1, 2011) (internet); AP Toolkit, *State Abortion Laws and Their Relationship to Scope of Practice* (internet).

[18] *See* National Abortion Fed'n, *2021 Violence and Disruption Report* (June 24, 2022) (internet) (reporting steady increase in harassment and violence at abortion clinics over 45-year period); U.S. Dep't of Just., *Recent Cases on Violence Against Reproductive Health Care Providers* (last updated Oct. 18, 2022) (internet).

[19] FDA, *Questions and Answers on Mifepristone*, *supra*; Kaiser Fam. Found., *The Availability and Use of Medication Abortion* (Jan. 4, 2023) (internet).

setting of their choice,[20] offering patients valuable control over location and timing. More recently, the FDA modified the REMS to lift the in-person dispensing requirement for mifepristone—first as a result of stay-at-home orders implemented during the COVID-19 pandemic and now permanently.[21] This policy revision permitted U.S. clinicians to offer access to medication abortion entirely remotely by conducting patient intake, examination, prescription, and follow-up via telephone or videoconference, and allowed patients to obtain the medication through a mail-order pharmacy.[22] The FDA has since also permitted mifepristone to be dispensed from certified retail pharmacies with a prescription where otherwise consistent with state law.[23]

The FDA's regulatory decisions to relax the in-person dispensing restriction were consistent with the widespread adoption of telemedicine following its successful use during the pandemic. These decisions were supported by ample research demonstrating that telemedicine is a safe and effective method for delivering medication abortion[24] and were endorsed by leading medical

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[20] NASEM, *Safety and Quality of Abortion Care*, *supra*, at 56; ACOG, *Medication Abortion Up to 70 Days of Gestation*, *supra*.

[21] *See* FDA, *Questions and Answers on Mifepristone*, *supra*; 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) (internet).

[22] Although plaintiffs assert that federal law prohibits the distribution of medication abortion drugs by mail (Compl. ¶¶ 115-117), the U.S. Department of Justice's Office of Legal Counsel recently issued an opinion concluding that federal law "does not prohibit the mailing, or the delivery or receipt by mail, of mifepristone or misoprostol where the sender lacks the intent that the recipient of the drugs will use them unlawfully" and that "the mere mailing of such drugs to a particular jurisdiction is an insufficient basis for concluding that the sender intends them to be used unlawfully." 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) (internet).

[23] FDA, *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg* (last modified Jan. 2023) (internet); FDA, *Questions and Answers on Mifepristone*, *supra*.

[24] *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*

(*continued on the next page*)

associations, many of which not only support provision of medication abortion via telemedicine but also advocate for the REMS designation to be lifted altogether. For example, the American Academy of Family Physicians has requested that the FDA lift the REMS designation "to conform to current evidence," and the American College of Obstetricians and Gynecologists has characterized the designation as "outdated" and medically unnecessary.[25]

Many amici States have strongly supported provision of medication abortion via telemedicine in light of its strong safety record and its promise to vastly improve access to reproductive health care, particularly for those living in low-income communities, communities of color, and rural and underserved areas.[26] According to 2020 data, 89% of U.S. counties have no abortion clinic and 38% of women of reproductive age resided in such a county.[27] Further, a study conducted using 2014 data 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

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Experience During the COVID-19 Pandemic, 104 Contraception 43, 44 (2021) (internet); Ellen R. Wiebe et al., *Comparing Telemedicine to In-Clinic Medication Abortions Induced with Mifepristone and Misoprostol*, 2 Contraception: X 100023 (2020) (internet); Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics & Gynecology 296 (2011) (internet); Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person*, 130 Obstetrics & Gynecology 778 (2017) (internet).

[25] *See* Letter from Michael L. Munger, Bd. Chair, Am. Acad. of Fam. Physicians, to Norman Sharpless, Acting Comm'r, FDA (June 20, 2019) (internet); ACOG, *Improving Access to Mifepristone for Reproductive Health Indications*, *supra*.

[26] *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) (internet). ACOG, supported by many amici States, further brought suit in federal court seeking temporary suspension of the REMS during the pandemic. *See ACOG v. FDA*, Nos. 20-1784, 20-1824, 20-1970, 2021 WL 538307 (4th Cir. Feb. 12, 2021).

[27] Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2020*, 54 Persps. on Sexual & Reprod. Health 128, 134-35 (2022) (internet).

for abortion care (36% versus 4%, respectively).[28] The many logistical and cost barriers associated with obtaining abortion—including childcare needs, the necessity of taking time off from work and the resulting lost income, lack of health insurance coverage, and the need to arrange and pay for travel—are experienced most keenly by low-income people and people of color.[29] And those barriers only mount with increased distance and travel time to obtain care, further compounding delays, and resulting in more later-gestation abortions, higher costs, increased risks, and adverse mental health outcomes.[30] For many, abortion may be out of reach altogether.[31]

Medication abortion, coupled with the growing adoption of telemedicine, has been game-changing, greatly mitigating transportation- and distance-related barriers to access to early abortion care for those located within amici States.[32] For these reasons, many amici States have

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[28] 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) [hereinafter *Distance Traveled*] (internet).

[29] *See id.* at 1623-1624; Sarah Varney, *Long Drives, Air Travel, Exhausting Waits: What Abortion Requires in the South*, Kaiser Fam. Found. (Aug. 3, 2021) (internet); 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) (internet).

[30] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 116; Fuentes & Jerman, *Distance Traveled*, *supra*, at 1623; Jill Barr-Walker, *Experiences of Women Who Travel for Abortion: A Mixed Methods Systematic Review*, PLOS ONE, Apr. 2019, at 17 (internet); Rachel K. Jones & Jenna Jerman, *Time to Appointment and Delays in Accessing Care Among U.S. Abortion Patients*, Guttmacher Inst. (Aug. 2016) (internet).

[31] *See* Barr-Walker, *Experiences of Women Who Travel for Abortion*, *supra*, at 19-21; 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*, JAMA Network Open, at 10 (May 13, 2022) (internet).

[32] Medication abortion via telemedicine cannot eliminate the need to travel to obtain abortion in all circumstances, particularly for patients located in States in which abortion is prohibited or heavily restricted who may need to travel outside of their State, sometimes for significant distances, in order to receive reproductive health care. *See generally*, Laurie Sobel et al., *The Intersection of State & Federal Policies on Access to Medication Abortion via Telehealth*, Kaiser Fam. Found. (Feb. 7, 2022) (internet).

already taken targeted steps to support expanded access to medication abortion or are planning to do so in the near future. For example, in Maine, which has among the highest rates of rural residents in the U.S., a major health clinic chain has since 2016 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.[33] The city of New York recently announced that it will offer free medication abortion at four public health clinics.[34] And several amici States, including Massachusetts, New York, and California, have recently taken affirmative steps to make medication abortion available at public university campus health centers, with the goal of extending access broadly to students across their States.[35]

Although much work remains to be done to promote more equitable access to reproductive health care, in amici's experience medication abortion has already played a critical role in minimizing barriers and expanding access, particularly for those who live in rural and underserved communities.

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

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

[35] *See* Nadine El-Bawab, *Offering Abortion Pills on Campus Could Eliminate Boundaries to Access, Students Say*, ABC News (Oct. 15, 2022) (internet); Stephanie Hughes, *With* Roe v. Wade *Overturned, Colleges Prep to Provide Abortion Medication*, Marketplace (Oct. 10, 2022) (internet); 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) (internet).

III. ANNULLING THE U.S. FOOD AND DRUG ADMINISTRATION APPROVAL OF MIFEPRISTONE WOULD HAVE DEVASTATING CONSEQUENCES.

The consequences of annulling the FDA's approval of medication abortion—currently the most common method of obtaining early abortion—would be nothing short of catastrophic, causing shock waves nationwide.

As a threshold matter, without the option of medication abortion, individuals seeking abortion would need to turn to other methods. Many would seek procedural abortions—which, although safe, would amount to an unnecessary and invasive procedure for those who would have preferred a medication abortion. And as discussed above, it would require many to travel, often long distances, to obtain care they could otherwise have obtained completely or partially through telemedicine. Others will seek abortion medications through online services and/or overseas pharmacies and self-manage their abortions outside of a medical setting.[36] Loss of access to one of the most readily available and reliable methods for pregnancy termination during the first trimester of pregnancy would also lead to more need for second-trimester abortions—which fewer facilities perform—with a resulting increase in health risks, costs, delays, and distance necessary to travel to obtain care.[37] Many who are unable to afford the additional costs associated with

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[36] *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, at 4 (2022) (internet) (noting that 1% of patients who self-managed their own abortion with pills obtained online experienced adverse health outcomes); Daniel Grossman & Nisha Verma, *Self-Managed Abortion in the US*, 328 JAMA 1693, 1693-94 (2022).

[37] *See* Fuentes & Jerman, *Distance Traveled*, *supra*, at 3.

abortion travel, and with the likely need for an abortion at a later gestational age, will be denied access to abortion altogether and be forced to carry unwanted pregnancies.[38]

Denial of abortion 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.[39] And because carrying a pregnancy to term is 14 times more risky than early abortion,[40] foreclosing access to medication abortion would likely lead to a steep rise in birth-related mortality rates.[41] Evidence shows that States with restrictive abortion laws have higher morbidity and mortality rates.[42] And estimates suggest that should a total abortion ban go into effect nationwide, those rates would rise by 21% overall purely due to the increased risks associated with

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

[39] *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) (internet); 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).

[40] 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) (internet).

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

[42] *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) (internet); Guttmacher Inst., *Induced Abortion Worldwide* (Mar. 2018) (internet).

bearing a child, with Black women experiencing the highest estimated increase—33%.[43] Accordingly, impeding access to medication abortion, the method currently accounting for the majority of all abortions, would undoubtedly lead to an unprecedented spike in mortality, worsening a crisis already disproportionately faced by Black women.[44]

The drastic reduction in access to abortion care across large swaths of the U.S. since the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* offers a stark preview of the devastating consequences—in amici States and nationwide—should access to medication abortion be eliminated. Abortion is currently completely unavailable in the 13 States where bans or near-total restrictions are in effect, and access is extremely limited in several more.[45] Approximately 22 million women of childbearing age, representing almost one third of the total population of women ages 15-49, now live in States where abortion is currently entirely unavailable or severely restricted.[46] At least 62 clinics have been shuttered since the end of June 2022, and travel time to obtain abortion has accordingly increased significantly across the U.S.[47] These impacts are expected

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

[44] *See* Elyssa Spitzer et al., *Abortion Bans Will Result in More Women Dying*, Ctr. for Am. Progress (Nov. 2, 2022) (internet); Nelson et al., *Associations of Unintended Pregnancy with Maternal and Infant Health Outcomes*, *supra*, at 14-29.

[45] Society of Fam. Plan., *#WeCount Report* 2 (2022) (internet) ("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* Center for Reprod. Rts., *After Roe Fell: Abortion Laws by State* (internet).

[46] *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) (internet) [hereinafter *100 Days Post*-Roe].

[47] *See id.*; Caitlin Myers et al., *Abortion Access Dashboard* (internet); 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).

to worsen as the many new legal risks created by *Dobbs*, disruptions in residency training, and an anticipated wave of additional state-level restrictions further depress the number of providers nationwide.[48]

In those States where abortion is banned, the impacts on birth-related morbidity and mortality from being denied abortion are no longer hypothetical.[49] The 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.[50] The more access to abortions is denied, the more such needless and heartbreaking outcomes can be expected to increase, with the brunt of the harms falling on communities of color.[51]

Nor are these harms limited to States where abortion bans or severe restrictions are currently in place. States where abortion remains legal and available, including many amici States, have already experienced a drastic rise in demand at clinics as patients from States where abortion is

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[48] *See* Jan Hoffman, *OB-GYN Residency Programs Face Tough Choice on Abortion Training*, N.Y. Times (Oct. 27, 2022) (internet); Julia Strasser et al., *Penalizing Abortion Providers Will Have Ripple Effects across Pregnancy Care*, Health Affs. (May 3, 2022) (internet) [hereinafter *Ripple Effects*]; Kimport, *Abortion After* Dobbs, *supra*, at 1-2.

[49] *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) (internet); 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) (internet).

[50] *See* Jessica Valenti, *I Write About Post-Roe America Every Day. It's Worse than You Think*, N.Y. Times (Nov. 5, 2022) (internet); Pl.'s Mot. for TRO and Prelim. Inj., *Preterm Cleveland v. Yost*, No. A2203203 (Ohio C.P. Hamilton County Sept. 2, 2022) (internet).

[51] *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) (internet).

banned flood into their States to receive necessary care.[52] According to the Guttmacher Institute, 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."[53] For example, at one Illinois clinic, patients from States other than Missouri and Illinois rose to 40% of cases, compared to 5% before *Dobbs*.[54] In California, since *Dobbs*, demand has quadrupled at Planned Parenthood Mar Monte clinics, which serve more than half of the counties in California.[55] Likewise, the 19 clinics affiliated with Planned Parenthood of the Pacific Southwest, located in San Diego, Riverside, and Imperial Counties saw a 513% increase in demand following *Dobbs*, increasing wait times for critical reproductive health care services.[56] At these clinics, patients from Arizona make up the highest demographic of out-of-state patients seeking abortion care, increasing by 847% when compared to the two weeks before the *Dobbs* decision.[57] Similarly, Planned Parenthood clinics in Orange and San Bernardino Counties reported a 900%

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[52] *See* Margot Sanger-Katz et al., *Interstate Abortion Travel Is Already Straining Parts of the System*, N.Y. Times (July 23, 2022) (internet); Angie Leventis Lourgos, *Abortions in Illinois for Out of State Patients Have Skyrocketed*, Chi. Trib. (Aug. 2, 2022) (internet) (reporting 700% increase in the number of out-of-state patients served in Illinois); Matt Bloom & Bente Berkland, *Wait Times at Colorado Abortion Clinics Hit 2 Weeks as Out-of-State Patients Strain System*, KSUT (July 28, 2022) (internet) (reporting 100% increase in wait times from before *Dobbs* was decided).

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

[54] Oriana Gonzalez & Nicole Cobler, *Influx of Out-of-State Patients Causes Abortion Delays*, Axios (Sept. 12, 2022) (internet).

[55] Marisa Kendall, *Demand Has Quadrupled at Some California Abortion Clinics since Roe Fell*, Mercury News (last updated Jan. 9, 2023) (internet).

[56] 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) (internet); Karma Dickerson, *More Out-of-State Patients Begin Arriving in California for Reproductive Health Services*, FOX40 (Sept. 20, 2022) (internet).

[57] Carcamo, *A California Desert Town*, *supra*.

increase in out-of-state patients seeking abortions following *Dobbs*.[58] Should access to medication abortion be limited or foreclosed, abortion providers in amici States would struggle to meet the additional spike in demand for procedural abortion, compounding delays and placing an untenable strain on an already overwhelmed system.

Finally, these harmful outcomes would not be experienced only by those seeking abortion but 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, and other critical forms of preventative health care. When increased demand for abortion care produces delays in accessing other forms of care at those facilities, the result will inevitably be higher rates of unintended pregnancy and sexually transmitted infections, including human papilloma virus and HIV/AIDS, 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.[59] 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.[60] 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.

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[58] ABC7 Eyewitness News, *Planned Parenthood Centers in SoCal Report Dramatic Increase in Abortion Patients from Out of State* (July 6, 2022) (internet).

[59] *See* Strasser et al., *Ripple Effects*, *supra*; Kirstein et al., *100 Days Post*-Roe, *supra*.

[60] *See* Strasser, *Ripple Effects*, *supra*; Theresa Chalhoub & Kelly Rimary, *The Health Care System and Racial Disparities in Maternal Mortality*, Ctr. for Am. Progress (May 10, 2018) (internet); Christine Dehlendorf et al., *Disparities in Family Planning*, 3 Am. J. Obstetrics & Gynecology 202, 214-20 (2010); Lindsey Dawson et al., *LGBT+ People's Health and Experiences Accessing Care*, Kaiser Fam. Found. (July 22, 2021) (internet); Kimport, *Abortion After* Dobbs, supra, at 1-2.

Against this stark backdrop, annulling—or even merely limiting—any of the FDA's actions relating to medication abortion would result in an even more drastic reduction in abortion access across the entire nation, worsening already dire outcomes, deepening entrenched disparities in access to health care, and placing a potentially unbearable strain on the health care system as a whole.

CONCLUSION

Plaintiffs' motion for a preliminary injunction should be denied.

Dated: New York, New York
February 10, 2023

Respectfully submitted,

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,

Plaintiffs,

v. **No. 2:22-cv-00223-Z**

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

Defendants.

ORDER

Upon consideration of the unopposed motion of the States of New York, California, Colorado, Connecticut, Delaware, Hawai‘i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Washington, and Wisconsin, and the District of Columbia for permission to file a proposed brief as amici curiae,

IT IS HEREBY ORDERED that the motion is granted and the amicus brief is accepted for filing.

DATE

Matthew J. Kacsmaryk
U.S. District Court Judge