Nos. 22A901, 22A902

In the Supreme Court of the United States

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safety

INTEREST OF AMICI CURIAE [1]

Amici Doctors for America ("DFA") and The Reproductive Health Coalition ("RHC") file this amicus brief in support of Applicants' applications for emergency relief, including Applicants' requests that the Court enter an administrative stay and stay the preliminary injunction pending appeal.[2]

DFA is a nonpartisan, not-for-profit, 501(c)(3) organization of over 27,000 physician and medical student advocates in all 50 states, representing all medical specialties. DFA mobilizes doctors and medical students to be leaders in putting patients over politics to improve the health of patients, communities, and the nation. DFA takes a special interest in access to affordable care, community health and prevention, and health justice and equity. DFA focuses solely on what is best for patients, not on the business side of medicine, and does not accept any funding from pharmaceutical or medical device companies. This uniquely positions DFA as a medical organization that puts patients over politics and patients over profits.

In support of its mission, DFA formed an FDA Task Force to educate, mobilize, and empower a multispecialty group of clinicians to provide unbiased expertise in evaluating and responding to the FDA regulatory process in a way that maximizes

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[1] Undersigned counsel for amici curiae certify, pursuant to Rule 37.6, that this brief was not authored in whole or part by counsel for any of the parties; no party or party's counsel contributed money for the brief; and no one other than amici and their counsel have contributed money for this brief.

[2]

meaningful clinical outcomes for patients. To support an FDA that puts patients first, the FDA Task Force has advocated in support of patient-centered regulatory reform through public testimony, op-eds, educational meetings with policymakers, and more. For example, DFA's FDA Task Force has written letters, testified, and met with policymakers to advocate for reforms to the Prescription Drug User Fee Act ("PDUFA") to make user fee agreements more patient-centered in order to ensure timely access to drugs and biologic medicines proven to be effective and safe.[3] Recently, the FDA Task Force has also advocated for the addition of miscarriage management as an indication to mifepristone's label "[t]o ensure access to the safest and most effective treatments for miscarriage, and to preserve patient choice in miscarriage management."[4][5]

The RHC comprises a wide range of health professional associations and allied organizations, collectively representing over 150 million members, who advocate with a unified voice to protect access to reproductive care. The RHC was founded in June 2022 by the executive directors of Doctors for America and the American Medical

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[3] Written Testimony of Reshma Ramachandran, M.D., M.P.P. at Hearing on "FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics," Subcommittee on Health, DOCTORS FOR AMERICA (2022), https://doctorsforamerica.org/written-testimony-of-reshma-ramachandran-m-d-m-p-p-athearing-on-fda-user-fee-reauthorization-ensuring-safe-and-effective-drugs-and-biologics-subcommittee-on-health/ (last visited Feb. 7, 2023).

[4] The terms "miscarriage" and "early pregnancy loss" are used interchangeably. See American College of Obstetricians and Gynecologists, ACOG Practice Bulletin No. 200: Early Pregnancy Loss, 132 OBSTETRICS & GYNECOLOGY e197 (2018).

[5] Citizen Petition from the American College of Obstetricians and Gynecologists, https://emaaproject.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-American-College-of-Obstetrician-and-Gynecologists-et-al-10.3.22-EMAA-website.pdf (last visited Feb. 7, 2023).

Women's Association. The RHC's member organizations include Doctors for America, American Medical Women's Association, ACT Access, American College of Physicians, American Pediatric Surgical Association, Civic Health Alliance, Committee of Interns and Residents, Daré Bioscience, Doctors For Fertility, Genius Shield, Georgia Health Professionals for Reproductive Justice, GLMA: Health Professionals Advancing LGBTQ+ Equality, Healthcare Across Borders, Indiana Pelvic Pain Specialists, Medical Students for Choice, National Association of Hispanic Nurses, National Association of Nurse Practitioners in Women's Health, National Coalition on Health Care, National Medical Association, Nurses for America, Patient Care Heroes, Renalis Health, Shattering Glass, The Innovators Law Firm, Vot-ER, Women in Medicine ®, and Women in Medicine, Inc. The RHC's work focuses on a patient's right to dignity, autonomy, privacy, and the expectation of a trusted relationship with their clinician; protection of the clinician's ethical obligation to provide care, including their access to comprehensive training; and a commitment to an evidence-based approach to policy and practice. The RHC supports the rights of all individuals to have access to the full scope of reproductive healthcare, including abortion.

Amici have a strong interest in protecting the autonomy of patients and providers and upholding evidence-based medical care. Amici submit this brief to

ARGUMENT

I. Providers affirm the safety and effectiveness of mifepristone.

Medical research has consistently demonstrated that mifepristone is safe and effective and that adverse events and outcomes are exceedingly rare, occurring in less than a fraction of 1% of cases.[8] The safety and effectiveness of mifepristone has been demonstrated through rigorous investigation conducted prior to the FDA's approval of mifepristone and further confirmed by a large volume of scientific literature published after its approval. Studies supplied to the FDA at the time of approval in 2000 found adverse events requiring hospitalization in less than 1% of a sample size of over 2,000 patients.[9]

Many studies have shown that serious adverse incidents occur in less than 0.5% of medication abortions in the United States.[10] Moreover, adverse events data tracked by the FDA reveals that mifepristone has a very low mortality rate of 0.65 per 100,000.[11] Mifepristone has a lower mortality rate than other common

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[8] Kelly Cleland et al., Significant Adverse Events and Outcomes After Medical Abortion, 121 OBSTETRICS & GYNECOLOGY 166, 166 (2013).

[9] U.S. FOOD & DRUG ADMIN. CTR. FOR DRUG EVALUATION & RSCH., MEDICAL OFFICER'S REVIEW OF AMENDMENTS 024 AND 033 FINAL REPORTS FOR THE U.S. CLINICAL TRIALS INDUCING ABORTION UP TO 63 DAYS GESTATIONAL AGE AND COMPLETE RESPONSES REGARDING DISTRIBUTION SYSTEM AND PHASE 4 COMMITMENTS (2000), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf.

[10] Safety and Effectiveness of First-trimester Medication Abortion in the United States, ADVANCING NEW STANDARDS IN REPROD. HEALTH (June 2021), https://www.ansirh.org/sites/default/files/2021-06/medication-abortion-safety_2021_FINAL.pdf.

[11] Greer Donley, Medication Abortion Exceptionalism, 107 CORNELL L. REV. 627, 651-52 (2022).

medications such as sildenafil (Viagra), which has a mortality rate more than six times greater than mifepristone, and penicillin, which has a mortality rate three times greater than mifepristone. [12] Furthermore, numerous studies have shown the combined mifepristone/misoprostol medication abortion regimen to be more than 95 % effective. [13]

The providers' accounts presented here affirm that mifepristone has proven safe and effective in providers' practices. If medically unnecessary restrictions are imposed on access to mifepristone, these restrictions would not make treatment safer but would instead endanger the health of pregnant people.

Dr. Cheryl Hamlin is an obstetrician -gynecologist who now practices in Massachusetts. She attended medical school at the University of Illinois and completed her residency at Boston Medical Center. Dr. Hamlin provides a first -hand

Patients have a wide range of reasons to choose medication management over an aspirati

Mifepristone must remain readily available to those for whom the best option is a medication procedure.

As Dr. Hamlin describes, the safety and effectiveness of mifepristone is substantiated by scientific evidence showing that complications are extremely rare. Unnecessary restrictions on access to mifepristone—such as legal rules making it difficult for manufacturers to distribute mifepristone or rules requiring that the drug always be dispensed to patients in a doctor's office—could endanger the health of patients. These restrictions would inhibit the ability of physicians to provide evidence-based treatment grounded in the robust scientific data proving that mifepristone is safe and effective.

II. Providers underscore that mifepristone is a standard treatment option not only for abortion, but also for early pregnancy loss.

The most effective treatment option for medication management of early pregnancy loss (miscarriage) includes mifepristone taken in combination with misoprostol.[16] For successful management of early pregnancy loss, mifepristone followed by treatment with misoprostol is over 83% effective and results in complications requiring blood transfusion in only 2% of women.[17] Mifepristone is an evidence-based treatment that is the safest and best option for many patients who suffer early pregnancy loss. As physicians describe infra, inaccessibility of

[16] Honor Macnaughton, Melissa Nothnagle & Jessica Early, Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion, 103 AM. FAM. PHYSICIAN 473 (2021).
[17] Courtney A. Schreiber et al., Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss, 378 NEW ENG. J. MED. 2161, 2161 (2018).

mifepristone would undermine their ability to provide safe and effective management of early pregnancy loss.

Dr. Cynthia Davis is an obstetrician-gynecologist in South Dakota. She attended medical school at the University of Florida and completed her residency at the University of Colorado. Dr. Davis conveys the importance of mifepristone for treating early pregnancy loss and the significant medical and ethical difficulties that she already observes due to onerous restrictions on access to mifepristone in her area:

> I speak from the experience of an obstetrician-gynecologist in a state where it has always been very difficult to obtain mifepristone. I am not an abortion provider, but I can tell you that the difficulty of obtaining this drug in treating pregnancy loss has significantly harmed many of my patients. When it is clear that a woman has lost her pregnancy but has not passed the tissue, the use of mifepristone combined with misoprostol is over 90% effective in resolving the missed pregnancy loss, compared to the 75% success rate of misoprostol alone. Given how common first-trimester pregnancy loss is, this treatment delay, often

medical guidelines. [18] I hope to continue to provide safe obstetric care, which involves mifepristone as an option for pregnant patients for both miscarriage and abortion care.

As Dr. Davis and Dr. Kaleka highlight, mifepristone is critical for managing early pregnancy loss. Unnecessary restrictions on access to mifepristone could result in misoprostol being the only practical option for management of early pregnancy by medication. Such a prospect is troubling. Medicine is practiced as a shared decision-making process between the physician and patient. For certain patients, offering misoprostol alone or pursuing expectant or surgical management might be the indicated course of care that a physician and their patient agree upon. But for other patients, mifepristone and misoprostol in combination is the best option based on their individual therapeutic and psychological needs. Imposing restrictions on access to mifepristone could limit providers' ability to help their patients make the choices that are safest and best for them, worsening maternal outcomes.

to make their own health care choices. It is therefore critic al, and central to medical ethics, that patients have the option to choose the treatment that best suits them.

For many patients, a combined mifepristone/misoprostol regimen is the best option. Patients may prefer or require medication abortion over surgical abortion for a variety of reasons, including pre -existing medical conditions, privacy, time constraints, transportation, the desire to avoid an invasive procedure, or other practical concerns. For instance, patients who are victims of abuse, inclu ding rape or incest, may prefer medication abortion to avoid retraumatization. [20]

Dr. H.Y. Stephanie Liou is a pediatrician in Chicago. She attended medical school at the University of Washington School of Medicine and completed her residency in pediatrics at the University of Chicago Comer Children's Hospital. Dr. Liou describes the importance of pregnant persons' ability to make autonomous medical decisions and the unique harms that could result to children and families if mifepristone was less accessible.

> I became a pediatrician because I love caring for children of all ages, from newborns to teenagers, and building relationships with families. I have also witnessed how physically and emotionally difficult it is to be a parent. Much of the rhetoric aro und abortion ignores the reality that many women wish to end a pregnancy because they are seeking to be the best possible mother to the children they already have. My patients' mothers are sole breadwinners, unable to take time off from work. They already have children with special needs, who require round -the-clock attention. Others have already risked their lives for motherhood due to medical conditions that make pregnancy incredibly dangerous and have

[20] See Decl. of Katherine B. Glaser, M.D., Ex. 7, at 6, Alliance for Hippocratic Medicine et al v. U.S. Food and Drug Administration et al. , No. 2:22-cv-00223 (N.D. Tex. Jan. 13, 2023), appeal docketed, No. 23-10362 (5th Cir. Apr. 10, 2023), ECF No. 28.

cried with me about their fear of leaving their child without a mother. Studies have shown that women who are turned away from receiving an abortion are more likely to experience bankruptcy or eviction, become or remain victims of physical violence, and develop life -threatening pregnancy complications such a s eclampsia and hemorrhage. [21] Their resulting children are also more likely to live in poverty and have poorer developmental outcomes. [22] This is why I believe it is crucial that all

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> self-determination were stolen by a legislature out to limit access to reproductive care without thought of the innumerable consequences they could not fathom, because they do not have to. Without ready and timely access to mifepristone, more women may be forced to make unwinnable, unfathomable choices of their own.
>
> The millions of nuanced reasons that women seek and consider abortion, sometimes ending very desired pregnancies, should be considered. The decision about pregnancy should be left to women and the doctors who counsel them, care for them, cry with them, celebrate and mourn with them.

As Dr. Liou and Dr. Palmer describe, respect for patient autonomy requires respect for the right of patients to make the difficult and nuanced choice to obtain a medication abortion. Imposition of medically unne cessary restrictions on access to mifepristone would intrude into the patient -physician relationship and undermine patients ' ability to make autonomous medical choices.

CONCLUSION

For the foregoing reasons, DFA and the RHC respectfully ask the Court to grant Applicants' applications for emergency relief , including Applicants' requests that the Court enter an administrative stay and stay the preliminary injunction pending appeal.

Dated: April 14, 2023

Respectfully submitted,

By: /s/ Christopher J. Morten

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