NO. 23-10362

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

Alliance for Hippocratic Medicine, et al.,
Plaintiffs-Appellees
v.
Food & Drug Administration, et al.,
Defendants-Appellants
Danco Laboratories, LLC,
Intervenor-Appellant

On Appeal from the United States District Court for the Northern District of Texas, Amarillo Division, No. 2:22-cv-00223

UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF OF AMICI CURIAE DOCTORS FOR AMERICA AND THE REPRODUCTIVE HEALTH COALITION IN SUPPORT OF APPELLANTS

Christopher J. Morten
Counsel of Record
SCIENCE, HEALTH & INFORMATION CLINIC
MORNINGSIDE HEIGHTS LEGAL SERVICES, INC.
Columbia Law School, 435 W 116th St
New York, NY 10027
Tel.: (212) 854-4291
cjm2002@columbia.edu

Thomas S. Leatherbury
THOMAS S. LEATHERBURY LAW, PLLC
Cumberland Hill School Building
1901 N. Akard St
Dallas, TX 75201
Tel.: (214) 213-5004
Tom@tsleatherburylaw.com

Counsel for Amici Curiae Doctors for America and The Reproductive Health Coalition

SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

1. No. 23-10362, *Alliance for Hippocratic Medicine, et al., v. Food & Drug Administration, et al.*

2. The undersigned counsel of record certifies that—in addition to the persons and entities listed in Appellant's Certificate of Interested Persons—the following listed persons or entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

Amici Curiae
Doctors for America
The Reproductive Health Coalition

Attorneys for Amici Curiae
Thomas S. Leatherbury
Thomas S. Leatherbury Law, PLLC
Christopher J. Morten
Columbia Law School Science, Health & Information Clinic

No publicly traded company has an ownership interest of 10% in any of the entities listed above.

Respectfully submitted,
/s/ Christopher J. Morten
Christopher J. Morten
Counsel for Amici Curiae
Doctors for America & The
Reproductive Health Coalition

Under Federal Rule of Appellate Procedure 29(a) and Fifth Circuit Rule 29, Doctors for America ("DFA") and The Reproductive Health Coalition ("RHC") hereby move to request leave from this Court to file a brief of 4,596 words as amici curiae in support of Appellants' appeal.

I. Interests of Amici Curiae

Movants DFA and RHC are prospective amici curiae with unique expertise and strong interest in the outcome of this case.

DFA is a 501(c)(3) non-profit, national organization of over 27,000 physicians and medical students representing all medical specialties. DFA seeks to improve the health of every American through its four guiding principles: (1) Every person in America has a fundamental right to equitable, high-quality, and affordable health care; (2) Everyone should have the opportunity to lead a healthy life; (3) Every part of society should value and promote healthy families and communities; and (4) Doctors should take a leadership role in improving health care and ending health disparities. DFA does not accept any funding from the pharmaceutical or medical device industries, which enables DFA to ensure that patients are placed before politics and profits. This case could limit patient access to an essential medicine, potentially impacting patients across the nation; thus, this case is of profound interest to DFA, its members, and their patients. *See* Fed. R. App. 29(a)(3)(A); (b)(3).

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 Women's Association. 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. Thus, this case is of profound interest to RHC and its member organizations. *See* Fed. R. App. P. 29(a)(3)(A).

II. Desirability and Relevance of Proposed Brief

The submission of this brief is "desirable" and the matters it addresses are "relevant to the disposition of the case." *See* Fed. R. App. P. 29(a)(3)(B). The issues presented in this case include the safety and efficacy of mifepristone, the propriety of its use in medicine, and the quality of the evidence base on which FDA has approved the drug. The attached amici curiae brief seeks to provide the Court with first-hand accounts from physicians regarding the safety and efficacy of mifepristone in their medical practices, the harmful ramifications of curtailing access to

mifepristone, and the professional difficulties such curtailment could cause for physicians.

DFA and the RHC are expert on the safety and efficacy of mifepristone and its use in medical practice and expert on FDA regulation of drugs more broadly. 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 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. 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."[1]

[1] *Citizen Petition from the American College of Obstetricians and Gynecologists*, https://emaaproject.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-American-

DFA previously sought and received leave to file an amicus brief at the district court. DFA and the RHC subsequently sought and received leave of this Court to file an amicus brief at an earlier stage of this appeal. *See* Unopposed Mot. of Doctors for America and Reproductive Health Coalition to File Amicus Br., ECF. No. 70; April 11, 2023 Order of this Court, ECF No. 91; Br. for DFA and the RHC as Amici Curiae, ECF No. 119.

DFA's and the RHC's briefs have, to date, been the only amicus briefs to provide the district court and this Court with multiple first-hand accounts from physicians regarding the safety and efficacy of mifepristone in their medical practices and the harmful ramifications of enjoining access to mifepristone. DFA and the RHC expect that their proposed amici curiae brief will again be unique in this regard and will therefore aid this Court's decision-making.

DFA and the RHC respectfully request leave to submit an amici curiae brief of 4,596 words. DFA and the RHC respectfully direct the Court's attention to the attached proposed amici curiae brief. In the brief, DFA and the RHC share accounts of five physicians who have used mifepristone in their medical practices. DFA and the RHC have made every effort to keep these accounts (and surrounding text) as concise as possible while simultaneously ensuring that they provide the

College-of-Obstetrician-and-Gynecologists-et-al-10.3.22-EMAA-website.pdf (last visited Apr. 27, 2023).

Court with complete, accurate accounts of how mifepristone is used by physicians and their patients. The brief is under 6,500 words and therefore compliant with Fed. R. App. P. 29(a)(5).

* * * *

Under Federal Rule of Appellate Procedure 29(a)(4)(E), undersigned counsel certifies that no party's counsel authored this motion or the attached brief in whole or in part. No party, or party's counsel, made a monetary contribution intended to fund the preparation or submission of this motion or the attached brief. No person other than amici curiae or their counsel made such a monetary contribution.

All parties consent to the filing of the attached brief.

The proposed brief is timely because it is filed by May 1, 2023, consistent with the Court's April 19, 2023 order. ECF No. 206. The proposed brief is also compliant with Federal Rule of Appellate Procedure 29(a)(6) because it is filed within seven days of the principal briefs of Defendants-Appellants and Intervenor-Appellant.

Given their interest in this case, the prospective amici curiae DFA and the RHC respectfully request that they be granted leave to file the proposed brief.

Dated: May 1, 2023

Respectfully submitted,

By: */s/ Christopher J. Morten*

Christopher J. Morten
Counsel of Record
SCIENCE, HEALTH & INFORMATION CLINIC
MORNINGSIDE HEIGHTS LEGAL SERVICES, INC.
Columbia Law School, 435 W 116th St
New York, NY 10027
Tel.: (212) 854-4291
cjm2002@columbia.edu

Thomas S. Leatherbury
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Cumberland Hill School Building
1901 N. Akard St
Dallas, TX 75201
Tel.: (214) 213-5004
Tom@tsleatherburylaw.com

Counsel for Amici Curiae
Doctors for America &
The Reproductive Health Coalition

CERTIFICATE OF SERVICE

I certify that on May 1, 2023, I caused a true and accurate copy of the foregoing document to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit through the CM/ECF system. I certify that the participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Respectfully submitted,

/s/ Christopher J. Morten
Christopher J. Morten
Counsel for Amici Curiae
Doctors for America & The
Reproductive Health Coalition

CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This motion complies with the type-volume limitations of Federal Rules of Appellate Procedure 27(d)(2) because it contains 1,098 words, as determined by the word-count function of Microsoft Word, excluding the parts of the motion exempted by Federal Rule of Appellate Procedure 32(f).

2. This motion complies with the type-face requirements and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6) and Fifth Circuit Rules 32.1 and 32.2 because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

Respectfully submitted,

/s/ Christopher J. Morten
Christopher J. Morten
Counsel for Amici Curiae
Doctors for America &
The Reproductive Health Coalition

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Tel.: (212) 854-4291
cjm2002@columbia.edu

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2. The undersigned counsel of record certifies that—in addition to the persons and entities listed in Appellants' Certificate of Interested Persons—the following listed persons or entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

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Attorneys for Amici Curiae
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/s/ Christopher J. Morten
Christopher J. Morten
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I. INTEREST OF AMICI CURIAE

Amici Doctors for America ("DFA") and The Reproductive Health Coalition ("RHC") file this Amicus Brief in support of Defendants-Appellants' and Intervenor-Appellant's requests for reversal or vacatur of the district court's April 7, 2023 order.[1]

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 meaningful clinical outcomes for patients. To support an FDA that puts

[1] This brief is submitted with the consent of all parties. Undersigned counsel for amici curiae certify 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.

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.[2] Recently, the FDA Task Force has also advocated for the addition of miscarriage[3] 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]

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

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[2] *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).

[3] 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).

[4] *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).

American Medical 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 highlight the ways in which mifepristone, which has been approved for use in the

United States for over twenty years,[5] supports the practice of physicians across the United States. Imposition of further restrictions on access to mifepristone could disrupt medical practice nationwide, including care for conditions beyond induced abortion, such as the management of early pregnancy loss (miscarriage).

II. SUMMARY OF ARGUMENT

Doctors across the country wish to express to this Court their concerns about potential changes in law that could undo mifepristone's FDA approval or otherwise reduce access to the drug. Imposition of new restrictions on access to mifepristone could have grave ramifications. This amicus brief contains first-hand accounts from physicians across practice areas and across the country about the harms that medically unnecessary limits on access to mifepristone would cause.[6]

In the series of narratives that follows, providers affirm the safety and effectiveness of mifepristone; underscore that mifepristone is a standard treatment option not only for abortion, but also for early pregnancy loss (miscarriage); and emphasize that the accessibility of mifepristone is essential to protect patient autonomy. These accounts, in providers' own words, describe how restricting access to mifepristone could jeopardize physicians' ability to provide safe and effective

[5] U.S. Food & Drug Admin. Ctr. For Drug Evaluation & Rsch., Approval Letter for mifepristone (MIFEPREX) tablets (Sep. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.htm.

[6] The accounts presented in this amicus brief were provided directly to counsel by the doctors quoted. All the doctors quoted are members of Doctors for America.

healthcare, undermine the patient-physician relationship, and impose upon some doctors an unacceptable choice between compliance with their ethical obligations and compliance with the law.

III. ARGUMENT

A. 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.[7] 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.[8]

Many studies have shown that serious adverse incidents occur in less than 0.5% of medication abortions in the United States.[9] Moreover, adverse events data

[7] Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 OBSTETRICS & GYNECOLOGY 166, 166 (2013).
[8] 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.
[9] *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.

tracked by the FDA reveals that mifepristone has a very low mortality rate of 0.65 per 100,000.[10] Mifepristone has a lower mortality rate than other common 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.[11] Furthermore, numerous studies have shown the combined mifepristone/misoprostol regimen to be more than 95% effective.[12]

The providers' accounts presented here affirm that mifepristone has proven safe and effective in providers' practices. If mifepristone's approval were undone or if medically unnecessary restrictions were imposed on access to mifepristone, these changes 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 account of mifepristone's safety profile and its ability to expand access to care:

> Mifepristone is widely used both as a medication used to terminate a pregnancy as well as for medical management of a miscarriage. While misoprostol is widely available globally, the combination of

[10] Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 651-52 (2022).
[11] *Id.*
[12] *See, e.g.*, Melissa J. Chen & Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review.*, 126 OBSTETRICS & GYNECOLOGY 12 (2015); Man-Wa Lui & Pak-Chung Ho, *First trimester termination of pregnancy*, 63 BEST PRACTICE & RESEARCH CLINICAL OBSTETRICS & GYNAECOLOGY 13, 20 (2020).

mifepristone and misoprostol is more effective. Patients who wish to avoid a surgical procedure have the option of medical management for both miscarriage and termination of pregnancy or an aspiration procedure. Imposition of unnecessary limits on access to mifepristone would significantly affect the options and therefore the health of those in need of this treatment.

Patients have a wide range of reasons to choose medication management over an aspiration procedure. Some choose medication abortion because they are afraid of a surgical procedure. Others, who are driving long distances, may not be able to get a ride. They then have the option of a procedure without anesthesia.

Most importantly, mifepristone means improved access to care. Outpatient offices which may not have the capability of providing aspiration procedures may be able to readily provide medication abortion.[13] Advanced practitioners and providers other than OB/GYNs may be more comfortable providing medication procedures. Even in states where abortions are widely available, there are still large areas where access to non-medication abortion procedures is minimal or non-existent. Cape Cod and the Islands in Massachusetts, for example, represent an underserved area, where driving to Boston, or in the case of the Islands, taking a ferry, adds, at times, insurmountable barriers. It can be and should be easy for all providers to offer medication abortion.

As well, there is a mountain of evidence that mifepristone is extremely safe. Mifepristone has been used since 2000 in the United States and longer in Europe. The risk of serious complications is extremely rare and certainly far less likely than the risks of childbirth.[14] Most of the complications associated with medication abortions are due to the process itself, not the mifepristone. Mifepristone blocks progesterone,

[13] Lawrence Leeman et al., *Can mifepristone medication abortion be successfully integrated into medical practices that do not offer surgical abortion?*, 76 CONTRACEPTION 96 (2007).
[14] Jillian T. Henderson et al., *Safety of mifepristone abortions in clinical use*, 72 CONTRACEPTION 175 (2005).

> which disrupts the lining of the uterus. This, in fact, is what happens monthly to stimulate a menses: sudden withdrawal of progesterone. If mifepristone were inadvertently given to a non-menstruating person, it would likely have no effect.
>
> Not having the full range of options to offer my patients would adversely affect my patients, potentially delaying care, causing them to require more invasive procedures and subjecting them to the associated risks. 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 mifepristone—such as legal rules that would make it difficult for manufacturers to distribute the drug or require that mifepristone 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.

B. 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.[15] For successful management of early pregnancy loss, mifepristone

[15] Honor Macnaughton, Melissa Nothnagle & Jessica Early, *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 AM. FAM. PHYSICIAN 473 (2021).

followed by treatment with misoprostol is over 83% effective and results in complications requiring blood transfusion in only 2% of women.[16] 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 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 state:

> 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 resulting in significant bleeding, infection, and psychological trauma, is devastating. I have seen this result in women requiring blood

[16] Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 NEW ENG. J. MED. 2161, 2161 (2018).

> transfusions and surgeries they otherwise would not have needed. I have seen women avoid any future pregnancies for fear of this situation's recurring trauma.
>
> Of course, other options exist to treat the clinical situations mentioned above. However, expectant management can result in acute bleeding episodes, increased risk of infection, anxiety, and depression, which I have witnessed in multiple patients over the years. Surgical management is often more expedient for clinical management. Still, there are risks, including bleeding, infection, uterine scarring resulting in infertility, and uterine perforation with possible damage to the bowel, bladder, or blood vessels. In addition, the costs associated with surgical management are often more than the family can absorb.
>
> And although there can be complications related to any medication, I have found mifepristone to be effective and safe in my many years of experience (over 30 years). It is heartbreaking to watch a family go through the difficulties related to pregnancy loss and, more so, to watch harm come to our women patients. Interference in the doctor-patient relationship by making mifepristone inaccessible disrespects a woman's autonomy and the sacred relationship between doctor and patient, much less the expertise in a physician's medical training.

Dr. Amy Kaleka is a family medicine provider in Wisconsin. She attended medical school at Central America Health Sciences University and completed her residency in family medicine at Virginia Tech Carilion School of Medicine. Dr. Kaleka explains the harms that inaccessibility of mifepristone would have on the management of early miscarriage, for which a standard treatment involves mifepristone:

> I am a family medicine and obstetrics provider in a state where an abortion ban already exists and has resulted in unsafe care for pregnant patients as it is, but imposing unnecessary restrictions on mifepristone could prevent me from being able to safely manage miscarriages in early pregnancy without hospitalizations. Having to stop providing abortion care to patients in Wisconsin for the past six months has revealed further difficulties for patients in rural settings, which are the same settings where no maternity wards exist in the hospital. These patients are now being forced to birth, so the risks of bleeding and poor fetal and maternal outcomes have significantly risen. Mifepristone is vital to providing safe care for early pregnancy loss.
>
> Increasing restrictions on medications that can improve safety outcomes of pregnant patients will inevitably lead to worse maternal outcomes. As providers, we do our best to perform safe and high quality care to prevent complications. The availability of mifepristone allows me to provide safe and high quality miscarriage management care to patients, reducing their likelihood of complications which ultimately reduces health care costs by avoiding hospitalizations. The use of this medicine is vital for medication management of miscarriages per the latest medical guidelines.[17] 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,

[17] *Id.* at 2162.

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.

C. Providers emphasize that the ready accessibility of mifepristone is essential to protect patient autonomy.

Respect for patient autonomy is a core tenet of physicians' professional ethics. The principle of respect for patient autonomy "acknowledges an individual's right to hold views, to make choices, and to take actions based on her own personal values and beliefs."[18] Respect for patient autonomy requires respect for the right of patients to make their own health care choices. It is therefore critical, 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

[18] American College of Obstetricians and Gynecologists, *ACOG Committee Opinion No. 390, December 2007. Ethical decision making in obstetrics and gynecology*, 110 OBSTETRICS & GYNECOLOGY 1479, 1481 (Dec. 2007, reaff'd 2016).

practical concerns. For instance, patients who are victims of abuse, including rape or incest, may prefer medication abortion to avoid retraumatization.[19]

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 around 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 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 as eclampsia and hemorrhage.[20] Their resulting children are also more likely to live in

[19] *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.

[20] *The Harms of Denying a Woman a Wanted Abortion Findings from the Turnaway Study*, ADVANCING NEW STANDARDS IN REPROD. HEALTH,

poverty and have poorer developmental outcomes.[21] This is why I believe it is crucial that all pregnant people are afforded the right to choose whether they wish to carry out a pregnancy.

One of my patients was a young toddler who had been diagnosed with asthma after numerous hospitalizations. His mother, a single parent, was struggling to make ends meet. She unexpectedly became pregnant and, after much thought and prayer, decided the right thing to do as a mother was to have an abortion. She was already stretched thin trying to give her toddler his medications multiple times a day while working two jobs to move out of their old, mold-filled apartment. Thanks to safe and timely access to mifepristone and misoprostol, she had an uneventful medication abortion at home while continuing to care for her son. Recently, she had her second child—a healthy baby boy—who was welcomed to this world by a very excited older brother in their beautiful, clean new apartment.

As a pediatrician in a country with one of the highest adolescent birth rates (as a result of inconsistent access to sex education and contraception), I have also witnessed firsthand how making mifepristone less accessible would disproportionately affect adolescents. Approximately 1/3 of pregnant teenagers in the United States choose abortion, which accounts for around 9% of all abortions.[22] My teen patients depend on medication abortion, given the added cost, time, travel, and logistical support needed to receive a surgical procedure. Multiple large-scale studies involving thousands of adolescents across the world have demonstrated that medication abortion with mifepristone and misoprostol is safe and effective in this age group.[23]

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https://www.ansirh.org/sites/default/files/publications/files/the_harms_of_denying_a_woman_a_wanted_abortion_4-16-2020.pdf (last visited April 10, 2023).

[21] *Id.*

[22] Rachel H. Phelps, Eric A. Schaff & Stephen L. Fielding, *Mifepristone Abortion in Minors*, 64(6) CONTRACEPTION 339, 339 (2001); Katherine Kortsmit et al., *Abortion Surveillance – United States, 2019*, 70(9) SURVEILLANCE SUMMARIES 1, 13 (2021).

[23] *Adolescents: Safety and Effectiveness*, IPAS, https://www.ipas.org/clinical-

> On the other hand, adolescent pregnancy and parenting pose significant short- and long-term risks to the physical and emotional health of the mother and the child. My clinical experiences are supported by a large body of research, which shows lower rates of school completion, higher rates of single motherhood, higher rates of preterm birth and low birth weight, increased rates of incarceration among male children, and increased rates of teen motherhood among female children born to adolescent mothers.[24] Without safe access to mifepristone, our nation's most vulnerable patients—children and adolescents—are the ones who will suffer the most. This is the absolute opposite of health equity.

Dr. Andrea Palmer is an obstetrician-gynecologist who lives and practices in Texas. She attended medical school at the University of Oklahoma College of Medicine and completed her residency at the University of Oklahoma Health Sciences Center. Dr. Palmer wishes to share with the Court an example of how loss of access to mifepristone would provide women with even fewer options following sexual assault or rape, undermining patient autonomy and interfering with doctors' ability to care for their patients[25]:

> As I glanced at my schedule, I noticed with delight a familiar patient, Josie,[26] scheduled for a new OB appointment. However, the moment I walked in the room, I knew this was not a typical new pregnancy visit. Josie's appointment brought unexpected and devastating news. Two

update/english/recommendations-for-abortion-before-13-weeks-gestation/adolescents-safety-and-effectiveness/ (last visited April 10, 2023).

[24] SAUL D. HOFFMAN & REBECCA A. MAYNARD, KIDS HAVING KIDS: ECONOMIC COSTS AND SOCIAL CONSEQUENCES OF TEEN PREGNANCY (2d ed. 2008).

[25] A version of Dr. Palmer's account was originally published on Medpage Today: Andrea Palmer, *Abortion Restrictions Rob Our Patients of Self-Determination*, MEDPAGE TODAY (2022), https://www.medpagetoday.com/opinion/second-opinions/98103 (last visited Feb 7, 2023).

[26] Patient names have been changed to protect their privacy.

weeks ago, she had joined a group of girlfriends for a night out to celebrate a coworker's birthday. Like any dedicated infertility couple, she and her husband had been timing their intercourse around her ovulation time and had sex that day. Tragically, that night of celebration ended with her as a victim of the most personally violating crime. That night she was drugged and raped.

Like most rape victims, Josie had stayed silent about her assault. Now two weeks after living with the shame, guilt, and pain of her attack she found out she was pregnant. Months and months of trying, years of hoping, and dozens of negative pregnancy tests later, and this was the one that was positive. Josie could not know who the father of this pregnancy was—her husband or the rapist. Obviously if this pregnancy were conceived with her husband, this would be the beginning of the next phase of their life together. But there was an unfortunate chance that this pregnancy was a product of rape. Understandably, she could not bear the thought of carrying that pregnancy to term.

The soonest paternity could have been established was 7 weeks gestation. However, Josie lives, and I practice, in Texas. This was November 2021, just a few months after passage of SB8 which banned abortion in the state of Texas after 6 weeks. As Josie and I cried together, we reviewed her options. She could choose to terminate now, but time was running out. At this point, she was just over 4 weeks gestation. She could choose to wait and determine paternity, but if she were pregnant as a product of her rape, she would need to travel out of state for termination. This was not something that she had the resources to do. She could not afford the time off work interstate travel would have required, and the waitlist for appointments in surrounding states was growing daily. Waiting was not an option for her. Carrying a pregnancy and raising a baby that was a product of rape from a random stranger was not an option for her. Josie sought out medication abortion before her sixth week.

> Josie barely had time to begin to process the trauma of her attack before she had to make an unwinnable, unfathomable choice. Her most precious dreams were stolen by a rapist, and her agency and options for 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 unnecessary restrictions on access to mifepristone would intrude into the patient-physician relationship and undermine patients' ability to make autonomous medical choices.

IV. CONCLUSION

For the foregoing reasons, DFA and the RHC respectfully ask the Court to reverse or vacate the district court's April 7, 2023 order.

Dated: May 1, 2023

Respectfully submitted,[27]

By: */s/ Christopher J. Morten*

Christopher J. Morten
Counsel of Record
SCIENCE, HEALTH & INFORMATION CLINIC
MORNINGSIDE HEIGHTS LEGAL SERVICES, INC.
Columbia Law School, 435 W 116th St
New York, NY 10027
Tel.: (212) 854-4291
cjm2002@columbia.edu

Thomas S. Leatherbury
THOMAS S. LEATHERBURY LAW, PLLC
Cumberland Hill School Building
1901 N. Akard St
Dallas, TX 75201
Tel.: (214) 213-5004
Tom@tsleatherburylaw.com

Counsel for Amici Curiae
Doctors for America &
The Reproductive Health Coalition

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CERTIFICATE OF SERVICE

I hereby certify that on May 1, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Christopher J. Morten
Christopher J. Morten
Counsel of Record
Counsel for Amici Curiae
Doctors for America &
The Reproductive Health Coalition

CERTIFICATE OF COMPLIANCE

This brief contains 4,596 words, as determined by the word-count function of Microsoft Word, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). In their attached motion for leave, amici curiae Doctors for America and The Reproductive Health Coalition have included a request for leave to submit an amici curiae brief of 4,596 words.

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5)(A) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface in Times New Roman font size 14.

/s/ Christopher J. Morten
Christopher J. Morten
Counsel of Record
Counsel for Amici Curiae
Doctors for America &
The Reproductive Health Coalition