Nos. 23-235, 23-236

IN THE
Supreme Court of The United States

FOOD & DRUG ADMINISTRATION ET AL., *Petitioners*,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE ET AL.,
Respondents.

DANCO LABORATORIES, L.L.C., *Petitioner,*
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE ET AL.,
Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF *AMICI CURIAE* DOCTORS FOR AMERICA AND THE REPRODUCTIVE HEALTH COALITION IN SUPPORT OF PETITIONERS

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Amici Doctors for America (DFA) and The Reproductive Health Coalition (RHC) file this amicus brief in support of Petitioners.[1]

DFA is a nonpartisan, not-for-profit, 501(c)(3) organization of over 27,000 physicians and medical students in all 50 states, representing all medical specialties. DFA mobilizes doctors, other health professionals, and medical trainees to be leaders who put patients over politics to improve the health of patients, communities, and the nation. DFA's work focuses on access to affordable care, community health and prevention, and health justice and equity. DFA focuses solely on what is best for patients rather than 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 a Food and Drug Administration (FDA) Task Force to educate, mobilize, and empower a multispecialty group of clinicians to provide unbiased expertise to evaluate and respond 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 patient-

[1] 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.

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 reforms to the Prescription Drug User Fee Act (PDUFA) to make user fee agreements more patient-centered, ensuring both timely access to drugs and biologic medicines as well as timely collection of data by the FDA, to prove these medicines' effectiveness and safety.[2] Some of the reforms that the DFA FDA Task Force advocated were included in the Food and Drug Omnibus Reform Act passed at the end of 2022.[3] Recently, DFA's FDA Task Force also advocated the addition of miscarriage[4] 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."[5]

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[2] *Ensuring Safe and Effective Drugs and Biologics: Hearing on FDA User Fee Reauthorization Before the S. Comm. on Health*, 117th Cong. (2022) (written testimony of Reshma Ramachandran, M.D., M.P.P., Leader, FDA Task Force, Drs. for Am.), https://www.congress.gov/117/meeting/house/114371/witnesses/HHRG-117-IF14-Wstate-RamachandranR-20220203.pdf.

[3] Press Release, Kyle Shields, *Press Release: Doctors for America's FDA Task Force Applauds Senate End of Year Package*, DRS. FOR AM. (Dec. 20, 2022), https://doctorsforamerica.org/press-releasedoctors-for-americas-fda-task-force-applauds-senate-end-of-year-package/.

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

[5] Citizen Petition from the Am. Coll. of Obstetricians and Gynecologists to Lauren Roth, Assoc. Comm'r for Pol'y, FDA

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 member organizations include Doctors for America, American Medical Women's Association, American Pediatric Surgical Association, Civic Health Alliance, Committee of Interns and Residents, Daré Bioscience, Doctors For Fertility, Georgia Health Professionals for Reproductive Justice, GLMA: Health Professionals Advancing LGBTQ+ Equality, Healthcare Across Borders, 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 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 access the full scope of reproductive health care, including abortion.

Amici have a strong interest in protecting the autonomy of patients and clinicians and upholding

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(Oct. 4, 2022), 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.

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,[6] supports the practice of clinicians across the United States. Affirming the Fifth Circuit's decision would impose restrictions on access to mifepristone that would disrupt medical practice nationwide, including care for conditions beyond induced abortion, such as the management of early pregnancy loss (miscarriage). The Fifth Circuit's decision would limit the ability of clinicians nationwide to safely manage these conditions, creating an ethical dilemma for clinicians. DFA and the RHC respectfully ask the Court to reverse the decision of the Fifth Circuit.

I. SUMMARY OF ARGUMENT

Clinicians across the country wish to express their grave concerns about the Fifth Circuit's decision. The Fifth Circuit's decision threatens to unsettle long-settled law, disturb much of the FDA's essential regulatory work, obstruct safe and effective care to patients in need, and harm public health.

This brief focuses on public health. *Amici* submit this brief to emphasize the profound harms to American health care that would likely flow if the Fifth Circuit's decision is upheld.

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[6] Ctr. for Drug Eval. & Rsch., FDA, Approval Letter for MIFEPREX (mifepristone) Tablets (Sep. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf.

The Fifth Circuit's decision, if affirmed, would reinstate medically unnecessary restrictions on access to mifepristone. For example, the Fifth Circuit's decision would impose a requirement that only physicians can become certified prescribers of mifepristone.[7] It would also require that mifepristone be dispensed in person in certain healthcare settings.[8] The decision could also cause a months-long shortage of mifepristone at a time when access to the medication is critical. Its manufacturers could be forced to endure the arduous process of seeking fresh approval from the FDA, relabeling and redistributing the medication, and recertifying prescribers, culminating in nationwide scarcity.[9] Affirming the Fifth Circuit's decision would have grave ramifications for patients and clinicians.

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[7] FDA, Risk Evaluation and Mitigation Strategy for MIFEPREX (mifepristone) Tablets, 200 mg, https://www.fda.gov/media/164648/download?attachment; Alice Miranda Ollstein, *Abortion Pill Ruling Sets Up Supreme Court Showdown*, POLITICO (Aug. 16, 2023, 3:31 PM), https://www.politico.com/news/2023/08/16/abortion-pill-restrictions-00111499 (last updated Aug. 17, 2023, 9:47 AM); Petition for Writ of Certiorari of Danco Lab'ys, L.L.C. at 35–36, *All. for Hippocratic Med. v. FDA*, No. 23-236 (U.S. Sept. 8, 2023).

[8] FDA, Risk Evaluation and Mitigation Strategy for MIFEPREX (mifepristone) Tablets, *supra* note 7.

[9] Petition for Writ of Certiorari of Danco Lab'ys, L.L.C., *supra* note 7, at 35 ("The [Fifth Circuit] recognized that because it ordered Mifeprex to be marketed with the 2011 labeling and under the 2011 REMS, access to medication abortion would be disrupted for the months it would take Danco to prepare, and FDA to approve, an application to revert to the 2011 labeling and REMS, and longer still [for all the re-labeling, re-certifying, and re-distribution procedures] . . . .").

This amicus brief contains firsthand accounts from clinicians across practice areas and across the country about the harms that the Fifth Circuit's unnecessary restrictions on access to mifepristone would cause.[10] In the series of narratives that follows, these clinicians affirm mifepristone's safety and effectiveness; underscore that it 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 clinicians' own words, describe how restricting access to mifepristone could jeopardize clinicians' ability to provide safe and effective health care, undermine the patient–clinician relationship, and impose on some clinicians an unacceptable choice between compliance with their ethical obligations and compliance with the law. These narratives also demonstrate how continued judicial interference with the FDA's and experts' decisionmaking could undermine clinicians' confidence and public confidence in the judiciary.

II. ARGUMENT

A. Clinicians affirm the evidence-based safety and effectiveness of mifepristone.

Medical research has consistently demonstrated that mifepristone is safe and effective and that significant adverse events and outcomes are

[10] Except for the publications of Dr. Jack Resneck, Dr. Joshua Sharfstein, Dr. Nisha Verma, and Dr. Daniel Grossman quoted below, all the accounts presented in this amicus brief were provided directly to counsel by the clinicians quoted. All these clinicians are members of Doctors for America.

exceedingly rare, occurring in less than a fraction of 1% of cases.[11] Mifepristone's safety and effectiveness have been demonstrated through rigorous investigation conducted before the FDA's approval of mifepristone and further confirmed by a large volume of scientific literature published after 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.[12]

Moreover, adverse events data tracked by the FDA since the approval of mifepristone reveals that mifepristone has an exceptionally low mortality rate: 0.65 per 100,000.[13] Mifepristone has a lower mortality rate than other common medications such as sildenafil (Viagra), which has a mortality rate roughly six times greater than mifepristone, and penicillin, which has a mortality rate three times greater than

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

[12] CTR. FOR DRUG EVALUATION & RSCH., FDA, 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 13 (2000), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf.

[13] Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 652 (2022).

mifepristone.[14] Further, numerous studies have shown the combined mifepristone/misoprostol regimen to be more than 95% effective for safe pregnancy termination.[15]

The clinicians' accounts presented here affirm that mifepristone has proven safe and effective in clinicians' practices. If medically unnecessary restrictions were 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 practices in Massachusetts. She attended medical school at the University of Illinois and completed her residency at Boston Medical Center. Dr. Hamlin provides a firsthand 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

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[14] *Id.*

[15] *See, e.g.*, Melissa J. Chen & Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review*, 126 OBSTETRICS & GYNECOLOGY 12, 17 (2015); Man-Wa Lui & Pak-Chung Ho, *First Trimester Termination of Pregnancy,* 63 BEST PRAC. & RSCH. CLINICAL OBSTETRICS & GYNAECOLOGY 13, 20 (2020); A.R.A. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided via Telemedicine: A National Cohort Study*, 128 BJOG 1464, 1469 (2021).

misoprostol is widely available globally, the combination of mifepristone and misoprostol is more effective. Patients who wish to avoid an aspiration procedure have the option of medical management for both miscarriage and termination of pregnancy. 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 an abortion procedure without aspiration, removing the need for local 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.[16] Advanced practitioners and providers other than OB/GYNs may be more comfortable providing medication

[16] Lawrence Leeman et al., *Can Mifepristone Medication Abortion Be Successfully Integrated Into Medical Practices That Do Not Offer Surgical Abortion?*, 76 CONTRACEPTION 96, 99 (2007).

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.[17] Most of the complications associated with medication abortions are due to the process itself, not the mifepristone. Mifepristone blocks progesterone, 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. Yes, misoprostol alone may be safely used for both induced abortions and miscarriages, but the

[17] Jillian T. Henderson et al., *Safety of Mifepristone Abortions In Clinical Use*, 72 CONTRACEPTION 175, 177–178 (2005).

> addition of mifepristone is more effective, reducing the already low risk of complications. The Mife/Miso regimen is the standard of care.
>
> 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.

An additional Doctors for America member-physician who prefers to remain anonymous offers the following account. She is an obstetrician-gynecologist who practices in New York State. This brief will refer to her as "Dr. Jane Doe."

Like Dr. Hamlin, Dr. Doe attests to the safety and effectiveness of mifepristone and the danger that would result should access to the drug be limited:

> I am an abortion provider in New York State. I have never once had a patient who had an injury or negative reaction to mifepristone. I have, however, provided abortion care in settings where mifepristone is not available. Thus, it requires us to manage abortion care with misoprostol only instead of mifepristone and misoprostol. Although abortions managed with misoprostol alone remain medically safe, there are countless

> advantages to abortions managed with mifepristone. Mifepristone makes abortion more effective. This means that limiting access to mifepristone increases risk of ancillary complications such as increased bleeding or infection. In certain circumstances, mifepristone can even reduce the risk of an unsuccessful abortion that would require more medications or possible procedures.
>
> Abortion in both the first and second trimester is more effective when both mifepristone and misoprostol are used in comparison to misoprostol only. In first trimester abortion, abortion is more effective—meaning complete abortion without surgical intervention—when patients use a mifepristone-misoprostol combination protocol. There is also data to support that patients have more satisfaction with a combo regimen. Patients given a combo method were more likely to report that the procedure was not difficult, whereas patients that took misoprostol-only regimens were more likely to report that the abortion took longer than expected.[18]

[18] Elizabeth G. Raymond et al., *Medication abortion with misoprostol-only: A sample protocol*, 121 CONTRACEPTION 1, 2 (2023) ("Of the 12,829 patients who provided outcome data, 78% [of patients on misoprostol only] aborted completely without a procedure or unplanned additional medications, a substantially lower proportion than the approximately 95% expected after the use of mifepristone and misoprostol at ≤10 weeks of gestation.").

> I have cared for many patients who desire medication abortion. For them, the most important thing is that the abortion is effective. They need to navigate abortion in the setting of things like taking care of other children, and going to work or school. If a medication abortion doesn't work, we can either give them more medication, or do a procedural abortion. Having an abortion that isn't complete means more time, bleeding, emotional energy, and occasionally a procedure that a patient never wanted in the first place.
>
> Mifepristone is also an important medication for second trimester induction/abortion. There are many reasons why patients have an induction of labor in the second trimester, before viability. These include fetal anomalies that are incompatible with life, fetal demise, and maternal indications where it would be dangerous for the patient to continue the pregnancy. The use of mifepristone prior to misoprostol markedly reduces time to induction completion, in comparison to misoprostol-only regimens.[19] Long inductions can lead to complications like hemorrhage and infections. Furthermore, second trimester inductions can be very emotionally

[19] Soc'y of Fam. Plan., *Labor Induction In the Second Trimester*, 81 CONTRACEPTION 4, 4 (2011).

> difficult for patients and their families. When mifepristone is not readily accessible, providers use a misoprostol-only regimen. While this continues to be effective and is a reasonable option, it does limit our ability to provide effective and patient-centered care.

Dr. Doe also provides a firsthand account of the use of mifepristone in urgent care, such as when unexpected and sometimes tragic conditions emerge that require termination of pregnancy. Dr. Doe explains that mifepristone is the best option—the standard of care—for termination of irremediably unsafe pregnancies:

> Mifepristone is an incredibly safe medication. An in-person requirement for prescribing mifepristone provides only additional barriers to care without any benefits. As a provider in Western New York, I have had patients travel multiple hours to receive in-person care that could have easily gotten care through telemedicine. An in-person requirement creates a huge barrier to patients who don't have easy access to transportation, or who have financial or childcare restrictions that limit their ability to travel.
>
> I care for many patients on Labor and Delivery who are undergoing induction of labor for termination of pregnancies in the second trimester. These are often highly desired pregnancies for which

> termination is indicated because of either health conditions in the patient that would make continuing the pregnancy unsafe, or abnormalities in the pregnancy that are not compatible with life. Standard of care is to use mifepristone in these terminations (which are well beyond 7 weeks) because using mifepristone with misoprostol vs. misoprostol alone causes a 40% to 50% reduction in time to abortion. This ultimately means decreased bleeding for the patient. Furthermore, second trimester induction of labor is often physically, mentally, and emotionally exhausting for patients, and having medications that decrease time to abortion is huge for these patients.

As Dr. Hamlin and Dr. Doe describe, mifepristone's safety and effectiveness are substantiated by scientific evidence showing that complications are extremely rare. Thus, this option is popular among patients. As Dr. Hamlin noted, many of her patients choose medication abortion with mifepristone over aspiration and other abortion options. Indeed, a majority of Americans—53% in 2020—now choose medication abortion over alternatives.[20]

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[20] Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, Guttmacher Inst. (Feb. 24, 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions (last updated Dec. 1, 2022).

Contrary to the scientific evidence, the Fifth Circuit's ruling would reinstate the medically unnecessary requirement that patients be physically present in certain healthcare settings to obtain mifepristone. The ability to physically travel to a doctor's office for mifepristone is a significant hurdle for many patients who are poor or lack access to transportation.[21] Limiting access in this way would not only inconvenience patients; it would force patients to choose either more invasive procedures or a potentially less effective, misoprostol-only medication abortion. Limiting access to mifepristone would also inhibit clinicians' ability to provide the standard-of-care evidence-based treatment grounded in robust scientific data proving safety and efficacy, whether taken at home or in a doctor's office. Limiting access could impose on clinicians an impossible choice between providing the best possible care and compliance with the law.

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[21] *See, e.g.*, Elizabeth A. Pleasants et al., *Association Between Distance to an Abortion Facility and Abortion or Pregnancy Outcome Among a Prospective Cohort of People Seeking Abortion Online*, 5 JAMA NETWORK OPEN 1, 9 (2022) ("Living farther from an abortion facility is associated with increased burdens in the process of seeking an abortion, including direct and indirect travel costs, which can pose a particular challenge for individuals with economic disadvantages."); 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, 2045–46 (2022) ("This study characterized changes in travel time to US abortion facilities before and after the *Dobbs* decision and found significantly longer travel times to abortion facilities post-*Dobbs* . . . .").

B. Clinicians 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.[22] For successful management of early pregnancy loss, mifepristone followed by treatment with misoprostol is over 83% effective and results in adverse events requiring blood transfusion in only 2% of women.[23] Mifepristone is an evidence-based treatment that is the safest and best option for many patients who suffer early pregnancy loss. As clinicians describe *infra*, restricting mifepristone would undermine their ability to safely and effectively manage early pregnancy loss. This, in turn, would likely heighten the emotional and physical trauma already associated with miscarriage.

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

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[22] Honor MacNaughton et al., *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 AM. FAM. PHYSICIAN 473, 473–74 (2021).

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

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 transfusions and surgeries they otherwise would not have needed. I have seen women avoid any future pregnancies for fear of similar 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 clinician 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 the inaccessibility of mifepristone would have on the management of early miscarriage and

how that inaccessibility has already caused harm to rural and underserved communities:

> 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 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 give 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.[24] 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 (miscarriage). Unnecessary restrictions on access to mifepristone could result in misoprostol being the only practical option for management of early pregnancy loss by medication. Such a prospect is not in patients' best interests. Medicine is practiced as a shared decisionmaking process between the clinician and patient. For certain patients, offering misoprostol alone or pursuing expectant or surgical management might be the indicated course of care that a clinician 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 unnecessary restrictions on access to mifepristone could limit clinicians' ability to help their patients make the choices that are safest and best for them, worsening maternal outcomes.[25]

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[24] *See id.* at 2162.

[25] Jack Resneck Jr., *Judge's Ruling on Mifepristone Has No Basis in Medical Science*, Am. Med. Assoc. (Apr. 12, 2023), https://www.ama-assn.org/about/leadership/judge-s-ruling-mifepristone-has-no-basis-medical-science ("Reduced access to

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

Respect for patient autonomy is a core tenet of clinicians' 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."[26] 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, some intensely personal, including preexisting medical conditions, privacy, time constraints, financial pressures, transportation, the desire to avoid an invasive procedure, or other practical concerns.

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mifepristone will almost certainly exacerbate the maternal mortality crisis in places that do not have access to this medication, and for historically marginalized racial and ethnic groups and those who have been economically and socially marginalized.").

[26] AM. COLL. OF OBSTETRICS & GYNECOLOGY, ACOG COMMITTEE OPINION NO. 390, DECEMBER 2007. ETHICAL DECISION MAKING IN OBSTETRICS AND GYNECOLOGY (2007), https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2007/12/ethical-decision-making-in-obstetrics-and-gynecology.pdf.

For instance, many rural patients prefer the relative accessibility, convenience, and ease of medication abortion. In her account above, Dr. Hamlin noted that "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."[27] For example, patients who reside on Massachusetts's islands live far from large medical centers that provide surgical abortions.[28] In those and other underserved areas, further limitations of mifepristone access, including requiring in-person dispensing and disallowing telehealth prescriptions, would burden patients with an arduous, additional journey and restrict their autonomy. Requiring that mifepristone be dispensed in person in certain healthcare settings effectively mandates that some patients travel dozens or hundreds of miles to receive the care they need. As Dr. Doe explained above, "[a]n in-person requirement creates a huge barrier to patients who don't have easy access to transportation, or who have financial or childcare restrictions that limit their ability to travel."[29] The Fifth Circuit's decision, if affirmed, would impose this unnecessary and harmful in-person dispensing requirement on patients and their caregivers.

Meanwhile, patients who are victims of abuse, including cases of rape or incest, may prefer medication abortion to surgical abortion for another reason: because the minimal invasiveness of medication abortion can lower the risk of

[27] *Supra* section II.A.
[28] *Id.*
[29] *Id.*

retraumatization.[30] Providing them with the option of medication abortion is essential to respect their autonomy.

Dr. H.Y. Stephanie Liou is a pediatrician in Illinois. 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 people's ability to make autonomous medical decisions and the unique harms that could result to pregnant people and their families if mifepristone were 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

[30] *See* Decl. of Katherine B. Glaser, M.D., Ex. 7, at 6, *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223 (N.D. Tex. Jan. 13, 2023).

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.[31] Their resulting children are also more likely to live in poverty and have poorer developmental outcomes.[32] 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

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[31] *The Harms of Denying a Woman a Wanted Abortion Findings from the Turnaway Study*, ADVANCING NEW STANDARDS IN REPROD. HEALTH, https://www.ansirh.org/sites/default/files/publications/files/the_harms_of_denying_a_woman_a_wanted_abortion_4-16-2020.pdf.

[32] *Id.*

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.[33] 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

[33] Rachael H. Phelps et al., *Mifepristone Abortion in Minors*, 64(6) CONTRACEPTION 339, 339 (2001); Katherine Kortsmit et al., *Abortion Surveillance – United States, 2019*, 70 SURVEILLANCE SUMMARIES 1, 17 (Nov. 26, 2021).

this age group.[34]

> 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.[35] 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

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[34] *Adolescents: Safety and Effectiveness*, IPAS, https://www.ipas.org/clinical-update/english/recommendations-for-abortion-before-13-weeks-gestation/adolescents-safety-and-effectiveness/ (Sept. 19, 2023).

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

would provide women with even fewer options following sexual assault or rape, undermining patient autonomy and interfering with clinicians' ability to care for their patients:[36]

> As I glanced at my schedule, I noticed with delight a familiar patient, Josie,[37] 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 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,

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

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

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–clinician relationship

and undermine patients' ability to make autonomous medical choices.

D. Clinicians worry that continued judicial interference with FDA regulatory decisionmaking will undermine trust in the judiciary.

As other amici have shown, the federal courts have historically tread carefully around questions of pharmaceutical safety and efficacy, out of deference to the expertise of medical professionals and the FDA.[38] The decisions of the district court and the Fifth Circuit upended that longstanding norm.

Clinicians across the country have expressed concerns over the quality and propriety of the district court's and Fifth Circuit's forays into complex scientific questions of pharmaceutical safety and efficacy.[39] Some clinicians have openly wondered

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[38] *See, e.g.,* Brief for Patient & Provider Advoc. Orgs. as Amici Curiae Supporting Petitioners at 1–2, *FDA v. All. for Hippocratic Med.*, No. 23-235 (U.S. Oct. 12, 2023), https://www.supremecourt.gov/DocketPDF/23/23-235/284843/20231012135619004_Nos.23-235_23-236_BriefofPatientandProviderAdvocacyOrgs.pdf; Brief for Am. Coll. of Obstetricians & Gynecologists et al. as Amici Curiae in Support of Petitioners at 5–6, *FDA v. All. for Hippocratic Med.*, No. 23-235 (U.S. Oct. 12, 2023), https://www.supremecourt.gov/DocketPDF/23/23-235/284910/20231012165311306_Amicus%20Brief%20of%20American%20College%20of%20Obstetricians%20and%20Gynecologists%20et%20al..pdf.

[39] *See* Brief for Patient & Provider Advoc. Orgs, *Hippocratic Med.*, No. 23-235, *supra* note 38; Brief for Am. Coll. of Obstetricians & Gynecologists, *Hippocratic Med.*, No. 23-235, *supra* note 38; *see also* Jack Resneck Jr., Opinion, *This Could*

whether, if FDA's regulation of mifepristone is overridden by judicial decision, more drugs will be restricted or perhaps taken off the market entirely by judicial fiat.[40]

Clinicians rely on the FDA and the expectations that FDA regulatory processes create. At the same time, clinicians inform the FDA and those regulatory processes in numerous ways, such as by serving on advisory boards, submitting adverse events to the FDA, and participating in clinical trials as investigators. The "[c]onfidence that the F.D.A. can do its work is essential for clinicians and patients," after all, because both "routinely depend on the agency's decision-making on matters of life and death."[41]

Be One of the Most Brazen Attacks on Americans' Health Yet, N.Y. TIMES (Apr. 20, 2023) https://www.nytimes.com/2023/04/20/opinion/abortion-pill-case-supreme-court.html (expressing the views of Dr. Jack Resneck, then-president of the American Medical Association, who wrote, "We simply cannot be a country where your access to the care you need is determined by the whims of ideologically driven judges and lawmakers without medical or scientific training."); Nisha Verma & Daniel Grossman, *Obstacles to Care Mount 1 Year After* Dobbs *Decision*, 330 JAMA 119, 119 (2023) (expressing the views of two clinicians, who stated, "Despite [the strong] medical evidence [of mifepristone's safety and efficacy], a federal district judge in Texas issued a preliminary ruling in *Alliance for Hippocratic Medicine v US Food and Drug Administration* that the approval process for mifepristone in 2000 was inappropriate and ordered the registration paused.").

[40] *See* Resneck, *Judge's Ruling*, *supra* note 25; Resneck, *This Could Be*, *supra* note 39; Joshua M. Sharfstein, Opinion, *I Worked at the F.D.A. The Abortion Pill Decision Is Dangerous*, N.Y. TIMES (Apr. 10, 2023), https://www.nytimes.com/2023/04/10/opinion/fda-mifepristone.html.

[41] Sharfstein, *supra* note 40.

Clinicians' longstanding reliance on and stakeholder interest in the FDA would be deeply shaken by a ruling that substitutes judges' inexpert opinions for expert ones. When the FDA is disempowered and overridden, clinicians are as well.

As Dr. Joshua M. Sharfstein of the Bloomberg School of Public Health at Johns Hopkins, a physician and former principal deputy commissioner at the Food and Drug Administration, stated in a recent op-ed:

> The scientific and regulatory excellence of the F.D.A. is a point of national pride. Because of its independent, thorough and expert reviews of data, the agency remains the international gold standard for approving medications. Confidence that the F.D.A. can do its work is essential for clinicians and patients, who routinely depend on the agency's decision-making on matters of life and death. It is also necessary for companies and their investors to develop important new therapies for devastating conditions. If judges can interfere with legitimate and well-supported F.D.A. action, there is no reason to believe that the consequences will be limited to abortion medications.
>
> Courts can protect the work of the F.D.A. or they can destroy it. In issuing an order to keep mifepristone on the market in certain states, a federal judge in Washington State is supporting the many millions of Americans who depend

> on the F.D.A.'s scientific decisions. The Supreme Court will soon have to decide which side it is on.[42]

Courts simply do not have the FDA's scientific expertise or the agency's capacity to review voluminous safety and efficacy data gathered before and after drug approval. When federal courts disregard the evidence, the expert agency, and the medical professionals uniquely equipped to evaluate and act on that evidence, they risk undermining clinicians' trust in the federal courts.

Dr. Christa Williams is a family doctor in Michigan. She attended medical school at the University of Michigan and completed her residency at Thomas Jefferson University. Dr. Williams respectfully stresses the importance of judicial deference to medical expertise:

> I truly hope that the courts will recognize that they do not understand how to practice medicine. Until you are faced with a patient desperate to end a pregnancy because of life circumstances, you cannot possibly know how a scientifically unjustified restriction will be devastating to both the lives of patients and to reproductive health providers who want to give women sound choices about their care.

Dr. Janet Krommes is a rheumatologist who practices in New Jersey. She attended medical school

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[42] *Id.*

and completed her residency at Temple University. Dr. Krommes observes that there are some patients at extremely high risk of death from pregnancy; a court ruling that prevents clinicians from treating these patients with the best possible treatment would confront clinicians with an impossible choice between complying with the law and upholding the ethical obligations they owe their patients:

> As a rheumatologist, I prescribe critically needed medicines for autoimmune disease that can cause fetal defects. No method of contraception is fool-proof, and so we prescribe these life-saving medicines to women of child-bearing age with a discussion that an accidental pregnancy can occur. In that setting, medication abortion is the safest option, and obstacles to access can create a delay that results in great harm. Many of our patients, especially those with lupus and kidney or lung involvement are at extremely high risk of death if a pregnancy is continued. Those patients must have access to safe and legal means of abortion. In the past, some physicians have denied treatment for disease due to the risk of pregnancy. This must not be done when effective treatments are available.

Dr. Reshma Ramachandran is a family medicine physician who practices in New Haven, Connecticut. She attended medical school at the Alpert Medical School at Brown University,

completed her residency at Kaiser Permanente Los Angeles Medical Center, and currently chairs the Doctors for America FDA Task Force. She shares the following perspective with the Court:

> During my medical training in family medicine, I prescribed mifepristone in combination with misoprostol to patients for this indication and continued to care for these patients after their abortion. Not only were these medications effective for my patients in ending their pregnancy, but they were also safe. I now practice primary care in a federally qualified health center and run a research and policy program at Yale School of Medicine focused on FDA approval standards. I have reviewed the scientific evidence that informed FDA's initial approval and subsequent broader approval of mifepristone as well as the significant postapproval evidence that has been collected and reviewed by the agency. This coupled with my own clinical experience in continuing to take care of patients who have had safe abortions reinforces that FDA appropriately used its scientific expertise and judgment in making regulatory decisions for mifepristone.
>
> This case threatens FDA's careful regulatory review and approval process and, therefore, the trust of clinicians like me. This case would set a troubling

> precedent: judges driven by political motivations instead of scientific and public health judgment can disrupt our ability to practice sound medicine.
>
> At the FDA, teams of experts review data at the individual level to ensure the safety and efficacy of drugs. This includes physicians, biostatisticians, biomedical researchers, and other experts who ultimately come together to make a final recommendation on whether a drug should be allowed on the market and for what particular indication. If there are further scientific questions, the FDA also engages independent experts on these matters, further informing its decision. This level of complex, technical review requires significant scientific and clinical training. Upholding the Fifth Circuit decision would instead allow judges without these qualifications to supersede the scientific authority of the FDA. This would be a gross overstepping of the traditional role of the judiciary and put patients at risk.

III. CONCLUSION

For the foregoing reasons, DFA and the RHC respectfully ask the Court to reverse the decision of the Fifth Circuit.

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Respectfully submitted,

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