No. 23-10362

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE, AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS, SHAUN JESTER, D.O., REGINA FROST-CLARK, M.D., TYLER JOHNSON, D.O., GEORGE DELGADO, M.D.,

Plaintiffs-Appellees,

v.

FOOD & DRUG ADMINISTRATION, ROBERT M. CALIFF, Commissioner of Food and Drugs, JANET WOODCOCK, M.D., in her official capacity as Principal Deputy Commissioner, U.S. FOOD AND DRUG ADMINISTRATION, PATRIZIA CAVAZZONI, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services,

Defendants-Appellants,

DANCO LABORATORIES, L.L.C,

Intervenor-Appellant.

On Appeal from the United States District Court for the
Northern District of Texas (Hon. Matthew J. Kacsmaryk)

BRIEF OF PHYSICIANS FOR REPRODUCTIVE HEALTH AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS AND STAY OF THE DISTRICT COURT'S ORDER

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CERTIFICATE OF INTERESTED PERSONS

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

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INTEREST OF AMICUS CURIAE[1]

Physicians for Reproductive Health ("PRH") is a doctor-led nonprofit that seeks to assure meaningful access to comprehensive reproductive health services, including contraception and abortion, as part of mainstream medical care. Since its founding in 1992, PRH has organized and amplified the voices of medical providers to advance reproductive health, rights, and justice. PRH's network is comprised of over 450 PRH-trained physicians working in fifty states, the District of Columbia, and Puerto Rico. PRH has insight into the challenges providers and patients face when confronted by actions designed or applied to prevent pregnant people from accessing necessary medical care, which harm people's ability to live freely with dignity, safety, and security.

In public discussions of reproductive health care, PRH seeks to share the physician's distinctive voice, expertise, and experience. To that end, PRH has long gathered and shared stories of doctors who provide reproductive health services. The elimination of mifepristone directly impacts PRH's network of physicians by

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[1] Pursuant to Federal Rule of Appellate Procedure 29, undersigned counsel for PRH certify that: no party's counsel authored this *amicus* brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this *amicus* brief; and no person or entity, other than PRH, their fellows, or their counsel, contributed money intended to fund the preparation or submission of this *amicus* brief. All parties have consented to PRH filing this *amicus* brief in this litigation.

significantly constraining their ability to provide their patients with a range of safe and effective options for ending a pregnancy or managing a miscarriage. PRH and its network of providers can attest that mifepristone is a safe and effective[2] drug and is critical to offering high quality comprehensive reproductive health care to patients.

SUMMARY OF ARGUMENT

For over twenty years, mifepristone has been part of the standard of care in reproductive health. Mifepristone is used on a regular basis by providers nationwide and around the world in gynecological procedures, obstetric care, medication abortion, and miscarriage management. Decades of medical research and multiple objective assessments have shown that mifepristone is safe and effective. Ignoring the wealth of scientific evidence supporting the safety and efficacy of mifepristone, the District Court purports to stay the U.S. Food and Drug Administration's ("FDA") approval of mifepristone. Unless stayed by this Court,

[2] Unless otherwise noted, this brief will use the terms "effective" or "successful" in describing medication abortion using the standard definition of success in the Medical Abortion Reporting of Efficacy ("MARE") Guidelines: the proportion of patients who were able to expel their pregnancy without the need for surgical intervention. *See* Abigail Aiken et al., *Safety and Effectiveness of Self-Managed Medication Abortion Provided Using Online Telemedicine in the United State*s, The LANCET Regional Health - Americas, 4 (Vol. 10, June 2022) (citing MARE Guidelines).

the withdrawal of mifepristone will have far reaching impacts on reproductive health, medical ethics, and patient autonomy.

Decades of rigorous, detailed studies and the experience of over five million patients who have used mifepristone in the U.S. have allowed providers to understand and communicate the risks, benefits, and potential outcomes of mifepristone use in medication abortion and miscarriage management. Providers are obligated to disclose to their patients not only the benefits of mifepristone use but also the risks, and patients use this information to make informed decisions about an appropriate course of treatment.

The District Court ignored the evidence and real-life experiences of providers and patients—instead considering studies that have been discredited—and mistakenly concluded that mifepristone lacks "meaningful therapeutic value." The District Court agreed with Plaintiffs-Appellees' erroneous assertion that its decision would increase and promote patient well-being and healthy outcomes. As physicians and experts in reproductive health, PRH knows this is false. Eliminating access to mifepristone will hurt patients by eliminating their ability to choose treatment that is medically sound, and will jeopardize patient health.

Many of PRH's providers prescribe and administer mifepristone on a regular basis. As experienced medical professionals, with training in obstetrics, gynecology, and complex family planning specialties, these providers are in the

unique position to offer first-hand perspectives and experiences on the safety and efficacy of mifepristone, how providers share information and obtain informed consent from patients electing a course of treatment involving mifepristone, why access to mifepristone is critical, and the ways that limiting access to mifepristone would disrupt the standard medical practice nationwide.[3]

For all these reasons, as discussed further below, this Court should stay the District Court's Order staying the FDA's approval of mifepristone.

[3] Included in this *amicus* brief are narratives from PRH providers, many of whom specialize in obstetrics, gynecology, and complex family planning, compiled from interviews conducted by undersigned counsel. The providers each personally reviewed and approved the versions of their accounts herein. The medical opinions expressed are their own and not necessarily shared by the institutions with which they are affiliated.

ARGUMENT

I. The Proven Safety and Efficacy of Mifepristone Allows Providers to Obtain Informed Consent from Patients

The safety and effectiveness of mifepristone have been overwhelmingly and consistently confirmed. Mifepristone was first approved in 2000 by the FDA after years of study for use in combination with misoprostol to terminate a pregnancy, *i.e.*, a medication abortion. For over two decades, patients, in consultation with their providers, have elected for medication abortions over procedural options. In recent years, medication abortion accounted for over 50% of abortions performed in the U.S.[4] Providers also commonly prescribe mifepristone in combination with misoprostol to manage miscarriages and pregnancy loss.[5]

Under the guise of protecting patient well-being, the District Court concluded that the safety and efficacy of mifepristone has not been sufficiently studied to warrant FDA approval, and that therefore patients are unable to provide informed consent for treatments involving mifepristone.[6] The medical evidence

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[4] Rachel Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, Guttmacher Institute (Jan. 2022) (quantifying medication abortions in the U.S. in 2020 and 2022).

[5] American College of Obstetricians and Gynecologists ("ACOG"), Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018).

[6] Opinion at 8, *Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.*, 22-CV-00223 (N.D. Tex. Apr. 7, 2023) [hereinafter "Opinion"].

and judgment of well-trained providers demonstrate that this contention is patently false.

A. Mifepristone is Safe and Effective for Use in Medication Abortion and for Miscarriage Management

Scores of medical and scientific research studies demonstrate the safety and efficacy of mifepristone use for both medication abortion and miscarriage management in patients who do not expel the uterine contents on their own. First, focusing on safety, the medical evidence plainly contradicts the District Court's conclusion that there are "fewer safety restrictions for women and girls today than ever before[,]" which has resulted in "[t]he physical and emotional trauma that chemical abortion inflicts on women and girls."[7] For example, in an October 2021 study, Advancing New Standards in Reproductive Health ("ANSIRH"), a leading research program based at the University of California San Francisco, published an overview of four recent U.S. studies on medication abortion and concluded that serious adverse events — including hospitalization, blood transfusion, and surgery — occurred in less than 1% of studied cases.[8] Another study found that significant adverse events (including hospital admission and emergency department treatment) with medication abortion are rare — 0.3% in a study of 20,000 medication abortion

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[7] *Id.* at 15, 61.

[8] ANSIRH, Issue Brief, *U.S. Studies on Medication Abortion Without In-Person Clinician Dispensing of Mifepristone*, at 1 (Oct. 2021).

patients taking mifepristone either at home or before a physician.[9] These findings are consistent with the multitude of studies that indicate the risk of hospital admission following a medication abortion is extremely low,[10] as well as with the professional experiences of PRH fellows. Dr. Aishat Olatunde, a PRH fellow who practices in Pennsylvania and who prescribes mifepristone on a routine basis, reports that she considers mifepristone to be "extremely safe" and she has "never witnessed an adverse reaction to mifepristone in [her] practice."

Similarly, mifepristone is a safe and advantageous option for patients who experience pregnancy loss and prefer to take prescribed medication to manage their miscarriage outside of a clinical setting. Miscarriages are common: 15% of all

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[9] *See* Daniel Grossman and Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared with in Person*, 130 OBSTETRICS & GYNECOLOGY 778, 780-81 (Oct. 2017). The study also found that telemedicine is an equally safe option for medication abortion. *See id.* (comparing adverse events for telemedicine and in-person patients and concluding that telemedicine is a non-inferior option with respect to safety).

[10] *See, e.g.*, Mary Gatter et al., *Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 Days*., 91 CONTRACEPTION 269, 270 (Apr. 2015) (study of 13,373 women who used mifepristone found that rates of infection requiring hospitalization and blood transfusion were 0.01% and 0.03%, respectively); *see also* The National Academies of Science, Engineering and Medicine, *The Safety and Quality of Abortion Care in the United States* 56 (2018) (discussing four studies from 2013 through 2015 that "demonstrate[] that complications such as infection, hemorrhage requiring transfusion, or hospitalization, *i.e.* 'serious complications,' occur in fewer than 1.0 percent of patients.").

clinically recognized pregnancies end in miscarriage, and approximately 80% of all cases of pregnancy loss occur within the first trimester.[11] Many patients expel miscarriages without medical intervention, but this is not the case for every person or in every circumstance. In cases where medication management is needed or desired, mifepristone is often prescribed as pretreatment for the management of early pregnancy loss, and it is exceedingly safe.[12] A 2018 study of the pretreatment of first-trimester pregnancy loss with mifepristone followed by misoprostol had a higher likelihood of successful management of first-trimester pregnancy loss than with misoprostol alone.[13]

For second and third trimester pregnancy loss, mifepristone is used to induce labor and accelerate the process of vaginal delivery, which reduces the likelihood

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[11] Siobhan Quenby et al., *Miscarriage matters: the epidemiological, physical, psychological, and economic costs of early pregnancy loss*, 397 LANCET 1658 (2021).

[12] The District Court's ruling suggests that mifepristone is prescribed only to terminate a viable pregnancy. *See* Opinion at 53. In fact, mifepristone is commonly prescribed to aid in miscarriages to induce the passage of fetal tissue that the patient has not passed on their own. In other words, a patient can first experience a miscarriage and then be prescribed mifepristone for the same pregnancy.

[13] *See* Courtney Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 N. ENGL. J. MED. 2161, 2168 (June 2018) (additionally finding that pretreatment of mifepristone resulted in a higher likelihood of successful management of first-trimester pregnancy loss).

of adverse medical complications.[14] For these patients, mifepristone also increases the safety of vaginal deliveries of miscarried pregnancies. Dr. Jamila Perritt, the President and CEO of PRH, attests that "from a medical standpoint, mifepristone is the safer option we can give our patients, because the additional wait time for labor with the fetus[15] inside increases risk of hemorrhage, of infection, and of needing subsequent intervention."[16] Similarly, in the experience of Dr. Michael Belmonte, a PRH fellow who practices in Colorado, the longer a patient waits to expel a demised fetus or fetal tissue, the more susceptible the patient is to infection and bleeding, or in serious cases, the patient may require a hysterectomy — risks that can be reduced by administering mifepristone.

To put its safety in perspective, mifepristone has a lower complication rate than many other FDA-approved drugs widely available across the U.S.[17] Dr. Nisha

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[14] *See* ACOG and the Society for Maternal-Fetal Medicine, Practice Bulletin No. 10, 135(3) *Obstetric Care Consensus* e110, e122 (2020).

[15] The term "fetus" is used to refer to the period of the pregnancy eight weeks after the last menstrual period through the point of delivery. ACOG *Guide to Language and Abortion* (Mar. 2022).

[16] *See also* Marike Lemmers et al., *Medical Treatment for Early Fetal Death (Less Than 24 Weeks)*, COCHRANE DATABASE SYSTEMATIC REVIEWS 25 (June 17, 2019) (finding that the addition of mifepristone was more effective in inducing complete miscarriage).

[17] *See* Jay Cohen et al., *Comparison of FDA Reports of Patient Deaths Associated with Sildenafil and with Injectable Alprostadil*, 35 ANNALS PHARMACOTHERAPY 285, 287 (Mar. 2001); Anne Miles et al., *Penicillin Anaphylaxis: A Review of Sensitization, Treatment, and Prevention*, J. ASS'N

Verma, a PRH fellow who practices in Georgia, notes that virtually all FDA-approved drugs, such as Tylenol, Viagra, and penicillin, have some risk of serious adverse events, but that the risks associated with mifepristone comparatively are incredibly small. Dr. Mae Winchester, a PRH fellow and maternal fetal specialist practicing in Ohio, explains that it is "exceptionally rare to see complications" and that she personally has never observed a patient need medical help after a medication abortion.

Second, medical studies confirm how effective mifepristone is for medication abortion and miscarriage management. In 1995, before the FDA approved mifepristone in the U.S., a French study showed that the overall rate of success when mifepristone is administered in medication abortion is 95.5%.[18] Over two decades later, mifepristone remains highly effective. A 2022 study of medication abortion provided through online telemedicine in the U.S. found that 96.4% of patients successfully expelled their pregnancy without the need for

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ACAD. MINOR PHYSICIANS 50-56 (1992); *see also* Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 651-52 (2022) (citing ANSIRH, *supra* note 8) (noting that mifepristone has a lower mortality rate than other common medications like penicillin, which has a morality rate three times higher than mifepristone, and Viagra, which has a morality rate more than six times greater than mifepristone).

[18] Elizabeth Aubény et al., *Termination of Early Pregnancy with Mifepristone and Increasing Doses of Misoprostol*, 40 INT'L. J. FERTILITY & MENOPAUSAL STUD. 2, 85-91 (1995).

surgical intervention.[19] In 2015, a study of 13,373 women whose medication abortion regimen consisted of taking mifepristone orally at a health center followed by misoprostol used at home concluded that the efficacy of the regimen was 97.7%.[20]

The same is true regarding the efficacy of mifepristone as used in miscarriage management. Studies confirm that administering mifepristone before misoprostol for patients with miscarriages results in a higher success rate of miscarriage management than misoprostol alone and reduces the need for a subsequent surgical procedure.[21]

High quality care for medication abortion and miscarriage management will be impacted if mifepristone is unavailable. Although misoprostol alone is a safe and effective option for medication abortion and miscarriage treatment, the option to add mifepristone to a treatment regimen can increase the efficacy of the treatment and may decrease side-effects for some patients.[22] Dr. Carolyn Sufrin, a

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19 *See* Aiken, *supra* note 2, at 4.

20 *See* Gatter, *supra* note 10, at 271.

21 Justin J. Chu et. al, *Mifepristone and Misoprostol Versus Misoprostol Alone for the Management of Missed Miscarriage (MifeMiso)*, 396 LANCET 770, 774 (Aug. 2020); *see also* Schreiber, *supra* note 13, at 2161.

22 *See* Heide Moseson et al., *Self-Managed Medication Abortion Outcomes: Results from a Prospective Pilot Study*, 17 REPRO. HEALTH 164, 164 (2020) (study of self-managed use of a misoprostol-alone regimen indicating safety and efficacy of misoprostol, with 95% of participants reporting complete abortions without the

PRH fellow who practices in Maryland, observes that in her practice, "mifepristone added to misoprostol increases the success of medication management, and decreases the likelihood of a procedure," meaning that all fetal tissue is passed and further treatment is unnecessary. Additionally, Dr. Belmonte states that based on his experience and in his medical judgment, the success rates of a medication abortion will be reduced if access to mifepristone is eliminated.

In sum, medical evidence available at the time mifepristone was first-FDA approved is consistent with the evidence available today: mifepristone is proven to be safe and effective for medication abortion and miscarriage management. Two decades of medical evidence and provider experience supports the FDA's approval and subsequent changes to the label, and this Court should not allow the District Court to second-guess the medical evidence, the judgment of trained medical professionals, and the expert judgment of the FDA.

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need for surgical intervention and no instances of adverse events); Jessica Beaman et al., *Medication to Manage Abortion and Miscarriage*, 35 J. GEN. INTERNAL MED 2398, 2398-99 (May 2020) ("Although misoprostol alone can be used to expel pregnancy tissue, combining it with mifepristone increases its efficacy for both abortion and miscarriage.").

B. Extensive Medical Evidence Enables Providers to Communicate the Risks and Benefits of Mifepristone in Order to Obtain Informed Consent

Patients give fully informed consent for use of mifepristone in their chosen medical treatments. The goal of informed consent is for providers to supply patients with information that is necessary and relevant to the patient's decision, including the risks and benefits of accepting or declining recommended treatment, and to assist patients as they identify the best course of action for their medical care.[23] The District Court held that the "lack of information on adverse events" prevents providers from properly informing their patients, which in turn prevents women and girls from giving informed consent to providers.[24] This conclusion is misplaced.

To fulfill their professional duties, providers must understand the risks of any treatment option and appropriately explain those risks to their patients. The information provided to the patient need not include an exhaustive list of all possible risks and outcomes, but rather those that are relevant to the patient's circumstances in order to support informed decision making.[25] Providers are best

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[23] *See* ACOG Committee Opinion No. 819, *Informed Consent and Shared Decision Making in Obstetrics and Gynecology* (Feb. 2021).

[24] Opinion at 8.

[25] *See* ACOG Committee Opinion 819, *supra* note 23.

positioned to determine what medical information, including potential risks, is discussed with their patients to ensure they have the relevant information necessary to make an informed decision on appropriate medical treatment.[26]

As discussed *supra*, the consensus of the medical community is that mifepristone, as used in medication abortion and miscarriage management, is safe. Like virtually every other FDA-approved medication, mifepristone has side effects, which have been studied extensively. The most common side effects of mifepristone are heavy bleeding, nausea, and abdominal pain.[27] These effects are similar to those that occur with miscarriage and pregnancy. The *materialization* of these risks, however, is exceedingly rare, especially when used in medication abortion.[28] For example, less than 1% of patients obtain an emergency intervention for excessive bleeding.[29] Dr. Verma, who has been providing abortion and miscarriage management for eight years, cannot recall the last time a patient had an

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[26] *See also* American Medical Association Code of Medical Ethics, Informed Consent, Opinion 2.1.1.

[27] *See* Blake Autry & Roopma Wadhwa, *Mifepristone*, Nat'l Ctr. For Biotechnology Info (last updated May 8, 2022).

[28] *See* Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121(1) OBSTET. GYNECOL. 166, 166 (2013) (significant adverse events or outcomes were reported in 0.65% of over 233,000 medication abortions provided in 2009 and 2010).

[29] *See* ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation* (Oct. 2020).

adverse effect with mifepristone, because it is that uncommon in her practice. In contrast to this evidence, the District Court relies on an unsubstantiated claim on an anti-choice website that alleges that two patients died from mifepristone use in 2022.[30] In fact, Dr. Amy Caldwell, a board-certified obstetrician and gynecologist practicing in Indiana, who is referenced on the website, states that none of her patients died due to receiving mifepristone.

Based on the medical evidence and data available on the benefits, risks, and potential outcomes associated with mifepristone, their professional experiences, and their medical judgment, providers decide how and what to communicate to their patients. There are already numerous procedures in place to ensure informed consent for patients seeking abortion care, including an FDA requirement that certified providers sign and review with their patients a "Patient Agreement Form" before prescribing mifepristone, and provide and review with patients a medication guide about mifepristone.[31] As PRH providers attest, communicating the full spectrum of medical information about mifepristone, including discussions about risks, are a standard part of their practice. For example, Dr. Bhavik Kumar, a PRH

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[30] Opinion at 53.

[31] *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD AND DRUG ADMIN. (last visited Apr. 9, 2023).

fellow practicing in Houston, Texas, explains that if a patient is a candidate for a medication abortion, the provider communicates the risks and benefits for that treatment option (as well as for all other available options). Dr. Kumar states that it is standard to communicate the risks of a medication abortion, which can include nausea, bleeding, cramping, and incomplete abortion. When providers discuss these risks, they also discuss the other options available to the patient, including continuing with the pregnancy.

All told, the FDA — relying on its scientific expertise — determined that any risks associated with mifepristone were outweighed by the benefits. PRH is not aware of any legitimate medical evidence contradicting the FDA's determination. Most importantly, providers do not ignore any risks or effects associated with mifepristone. Instead, they communicate the risks (and all other appropriate medical information) to patients to consider when making an informed decision on an appropriate course of treatment in consultation with their provider.

II. Eliminating Access to Mifepristone Impedes Patient Autonomy and Jeopardizes Patient Health

A. Eliminating Access to Mifepristone Interferes with Ethical Obligations of Providers to Respect Patient Autonomy

This unwarranted and ideologically-motivated attempt to eliminate FDA approval of mifepristone limits the range of options providers can offer their patients. For over twenty years, providers have included the mifepristone-

misoprostol regimen used in medication abortion among the range of options for patients seeking abortion care, but providers may no longer be able to offer this option to patients. If the District Court's stay of the FDA approval stands, providers treating patients who want a medication abortion with mifepristone will be forced to withhold a valid and safe option, disregarding patient autonomy — a violation of medical ethics — or potentially to violate the law.

Patient autonomy, the right of patients to make decisions about their medical care, is a core principle and ethical obligation of medical providers. Respecting patient autonomy acknowledges an individual's right to hold views, to make decisions, and to take actions based on their own personal health situations, values, and beliefs.[32] However, patient autonomy is diminished when providers cannot abide by a patient's informed decision to receive a safe and effective course of treatment where the treatment may be prohibited.

There are many reasons why a patient may elect a course of treatment involving mifepristone. For example, mifepristone gives patients the option to manage and time their abortions or miscarriages in a location that best fits their needs. As Dr. Winchester explains, one benefit of a medication abortion is that it allows patients to choose when and where they would like the treatment to occur.

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[32] ACOG Committee Opinion No. 390, *Ethical decision making in obstetrics and gynecology* (Dec. 2007, *reaff'd* 2016).

In addition, mifepristone used in medication abortions and for miscarriage management allows patients to avoid pelvic exams and instrumentation intervention, which may be preferable for certain patients. For instance, Dr. Atsuko Koyama, a pediatric emergency medicine physician in Arizona and PRH fellow, observes in her practice that many young patients have never had an internal vaginal exam and may prefer a less physically invasive option, like medication abortion. Dr. Belmonte and Dr. Winchester also explain that patients who have experienced sexual assault and domestic violence may factor in the same considerations when determining whether mifepristone is a desirable option.

Privacy is another reason why some patients may elect a course of treatment involving mifepristone. Medication abortion, unlike procedural abortion, can be managed in the privacy of one's home or designated location and not in a clinical setting or a hospital. For Black people, Indigenous people, people of color, LGBTQ+ people, and people who are immigrants, removing an option that allows for increased privacy and independence while managing an abortion or miscarriage will exacerbate existing distrust in the medical system.[33] Dr. Koyama observes

[33] The District Court distorts the history of eugenics, disenfranchising the very populations it claims to support. *See* Opinion at 64. The eugenics movement was premised on the racist idea that Black women and women of color lack the intellectual capacity to make choices about their health. In some communities, the legacy of these racist laws manifests as distrust in the medical system. PRH

that the medical community is "hoping to build trust and earn the trust of so many people who historically have been disenfranchised or underserved by the medical system, and a positive experience getting treatment might lead to someone being more proactive in the future with the medical system."

Finally, patients may elect to use mifepristone during a later miscarriage or in response to fetal demise because it reduces the time it takes to pass a failed pregnancy, thereby shortening a hospital stay when vaginal delivery is warranted. In Dr. Belmonte's experience, mifepristone typically allows a patient to induce labor and deliver their demised fetus in 8 to 12 hours, and the patient can often go home the same day. Without mifepristone, patients in their second and third trimesters who miscarry and must vaginally deliver the demised fetus are forced to spend days in the hospital's maternity ward with other patients delivering newborns. As Dr. Perritt explains, this can be upsetting and traumatic for grieving parents who are forced to listen to crying babies and celebrations while they mourn.

Mifepristone has been available in the U.S. for over 20 years, and not only do patients continue to elect to undergo a course of treatment involving mifepristone, but patients also report confidence in their decision to seek

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decries any comparison between its mission to provide reproductive healthcare and the eugenics movement.

medication abortion or use mifepristone in their miscarriage management. For example, with respect to medication abortion, the vast majority of patients express satisfaction with their decision.[34] Patients should be able to select medical treatment that they determine, in consultation with their provider, is the most appropriate for their care. The Court should not interfere with that decision when the medical care in question is safe, effective, and medically appropriate.

B. Eliminating Access to Mifepristone Jeopardizes Patient Health

Restricting access to safe and effective health care jeopardizes the health and well-being of patients. Restricting access to mifepristone would be no exception. The District Court's reasoning that a stay of approval would promote patient health lacks any basis in fact.

Dr. Perritt explains that restricting access to mifepristone will not just limit patient options for abortion care; for some patients, it will eliminate abortion as an option entirely, because other less common methods of medication abortion, like misoprostol-alone regimens, may not be available and procedural abortion is not medically appropriate or available for everyone. For those patients, the pregnancy will likely need to be carried to term, even if the pregnancy jeopardizes the health

[34] *See* Aiken, *supra* note 2 (study finding that 95.5% of participants who provided information about their self-managed abortion felt they had made the right choice for them).

of the patient. Medical evidence demonstrates that carrying a pregnancy to term and giving birth poses greater risks to a patient's health than an abortion.[35]

For other patients, while procedural abortion may be medically appropriate, they may experience delay (potentially significant delay) in accessing such care, which may adversely affect patient health. Dr. Belmonte and Dr. Verma routinely see out-of-state patients seeking abortion care. Since the Supreme Court's ruling in *Dobbs v. Jackson Women's Health Organization*, access to abortion care in many states is either practically unavailable or more inaccessible.[36] As a result, patients in states with limited or no access to abortion care may need to travel (sometimes far distances) to receive the care they desire.[37] This is not only unduly burdensome on patients, but it also puts a strain on states providing abortion access by increasing wait times at reproductive healthcare clinics. For example, Dr.

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[35] *See, e.g.*, Elizabeth Raymond & David Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTET. GYNECOL. 215, 217 (2012) (in a 1998 to 2001 study, all studied maternal complications were found to be more common in women who gave birth compared to women who received abortion care).

[36] Marielle Kirstein et al., *100 Days Post-Roe: At Least 66 Clinics Across 15 US States Have Stopped Offering Abortion Care*, GUTTMACHER INSTITUTE (Oct. 2022).

[37] Many of the abortion-restrictive states are geographically contiguous, further extending the travel distance required for patients in some states to obtain an abortion in another state. Herminia Palacio, *Implications of Dobbs v Jackson Women's Health Organization*, American Public Health Association (Mar. 2023).

Winchester observes that the wait in her clinic for a procedural abortion is currently about two and a half weeks, and Dr. Belmonte witnessed wait times at one point of up to six weeks at the hospital he practices at in Colorado. PRH believes these delays will worsen if the most common form of medication abortion is no longer available.

Delays in receiving care can be particularly concerning for the health of pregnant patients. Given the current restrictions on abortion, a delay can completely prevent a patient from receiving an abortion, because in some jurisdictions abortions are prohibited by law after a certain gestational age. Delays in seeking abortion care can also have adverse consequences on patient health. While serious risks from abortion at any gestational age are *extremely rare* and do not approach the level of risk associated with carrying a pregnancy to term, risks to patient health do increase as the pregnancy advances.[38]

There are also psychological risks associated with denying patients desired care. Ignoring this, the District Court focused on the purported psychological risks associated with "the [patient] seeing [their] aborted child once it passes" post-medication abortion.[39] This is medically inaccurate. The two-drug regimen is

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[38] ACOG Committee Opinion No. 613, *Increasing Access to Abortion*, at 2 (Nov. 2014, *reaff'd* 2017); Raymond & Grimes, 119 OBSTET. GYNCEOL. at 217.

[39] Opinion at 11.

FDA-approved for only the first ten weeks of pregnancy. Until the eighth week of pregnancy, there is only a bean-sized embryo and during pregnancy weeks eight to ten, the fetus is typically the size of a grape, weighing about a quarter of an ounce. The District Court disregards evidence that patients who are denied abortions actually report greater anxiety and depression symptoms, lower self-esteem, and lower life satisfaction than patients who receive a desired abortion.[40] Dr. Belmonte described how providers at his hospital often witness the trauma faced by patients who experience difficulty or complete foreclosure in obtaining desired abortion care.

The District Court disregards the negative consequences patients could face with the elimination of mifepristone. Thus, while the District Court claims the stay of FDA approval of mifepristone is necessary to protect patients, the stay will have the opposite result: it is likely to jeopardize and harm patient health.

CONCLUSION

For all the reasons set forth herein, PRH respectfully asks the Court to stay the District Court's Order staying the FDA's approval of mifepristone.

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[40] M. Antonia Biggs et al., *Women's Mental Health and Well-Being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study*, 74 JAMA Psychiatry 169, 169 (Jan. 2017).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on April 11, 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, with the exception of the case participants referenced below, all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system. With respect to the below-listed attorneys, I further certify that true and correct copies of the foregoing documents were served on April 11, 2023, by First Class Mail.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 5,199 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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