No. 22A901

In the Supreme Court of the United States

DANCO LABORATORIES, LLC,

Applicant,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

ON APPLICATION TO STAY THE ORDER ENTERED BY THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS AND FOR AN ADMINISTRATIVE STAY

BRIEF OF PHYSICIANS FOR REPRODUCTIVE HEALTH AS *AMICUS CURIAE* IN SUPPORT OF APPLICANT AND ADMINISTRATIVE STAY

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**Admission pending in the State of New York*

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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 physicians in all 50 states, the District of Columbia, and Puerto Rico, as well as over 450 fellows. 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 and harming their 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. Restrictions on mifepristone directly impact PRH's network of physicians by 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.

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[1] No counsel for any party has authored this brief in whole or in part, and no person has made any monetary contribution intended to fund the preparation or submission of this brief.

[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).

SUMMARY OF ARGUMENT

For over twenty years, mifepristone has been an essential medication in full spectrum reproductive health care in the United States. Mifepristone is used on a regular basis by providers nationwide and around the world in gynecology as the standard of care in procedures, obstetric care, medication abortion, and miscarriage management. Ignoring the wealth of scientific evidence supporting the safety and efficacy of mifepristone, the District Court purported to "stay" the medication's over 22-year-old FDA approval on a motion for preliminary injunction. A Fifth Circuit panel purported to walk back that stay by invalidating "only" the U.S. Food & Drug Administration's ("FDA") regulatory changes since 2016, but the impact of the Fifth Circuit's order remains devastating to the provision of care. The order attempts to reinstate medically unnecessary and burdensome restrictions on mifepristone properly removed by the FDA, including the ability to provide mifepristone via telehealth, and effectively blocks the approval of the FDA's 2019 approval of the generic medication, which accounts for two-thirds of the mifepristone sold in this country. The decision bears no resemblance to how medication is regulated by the FDA and would throw the provision of medication abortion care in the country into chaos. Unless stayed by the Court, the orders below will have immediate and 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.

In largely upholding the District Court's stay, the Fifth Circuit ignored the evidence and real-life experiences of providers and patients and mistakenly concluded that mifepristone, in some respect, is "dangerous[]."[3] As physicians and experts in reproductive health, PRH's providers know that this is false. Restricting access to mifepristone will hurt patients by limiting their ability to select the safe and effective course of treatment that is medically sound and best for them, and it 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 of care medical practice nationwide.[4]

For all these reasons, as discussed further below, this Court should grant the Applicant's emergency request.

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[3] Unpublished Order, at 27, *Alliance for Hippocratic Medicine et al., v. FDA, et al.*, No. 23-10362 (5th Cir. Apr. 12, 2023) [hereinafter "Order"].

[4] 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.[5] Providers also commonly prescribe mifepristone in combination with misoprostol to manage miscarriages and pregnancy loss.[6]

Under the guise of protecting patient well-being, the Fifth Circuit determined that unnecessary heightened safeguards are necessary to limit access to and distribution of mifepristone because "serious complications" affecting patient health can occur.[7] The medical evidence 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 up through around ten weeks gestation and miscarriage management in patients who do not expel the uterine contents on their own. First, focusing on safety, the medical evidence plainly demonstrates that the anecdotes and "data"

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[5] 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).

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

[7] Order at 12.

submitted by Respondents and relied upon by the Fifth Circuit are not indicative of how safe mifepristone use is.[8] 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.[9] 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 patients taking mifepristone either at home or before a physician.[10] These findings, as well as the professional experiences of PRH fellows, are consistent with the multitude of studies that indicate the risk of hospital admission following a medication abortion is extremely low.[11] 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 that she has "never witnessed an adverse reaction to mifepristone in [her] practice."

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[8] *Id.* at 13 ("Mifepristone users who present themselves to the plaintiffs have required blood transfusions, overnight hospitalization, intensive care, and even surgical abortions.").

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

[10] *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).

[11] *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.").

Mifepristone is safe and effective through around ten weeks gestation. The overwhelming medical evidence and physician experiences, both prior to 2016 and after, demonstrate this point.[12] The President and CEO of PRH, Dr. Jamila Perritt, widely views mifepristone as safe and effective beyond ten weeks. In fact, outside the U.S., mifepristone is used beyond ten weeks, and the World Health Organization recommends mifepristone can be safely used at twelve weeks.[13]

To put its safety in perspective, mifepristone has a lower complication rate than many other FDA-approved drugs widely available across the U.S. with fewer restrictions.[14] Dr. Nisha 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 are comparatively quite small. The real-world experiences of using mifepristone speak volumes. Dr. Mae Winchester, a PRH fellow and maternal fetal specialist practicing in Ohio, explains that it is "exceptionally rare with mifepristone use to see complications" and that she personally has never observed a patient need medical help after a medication abortion.

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[12] *See* FDA Center for Drug Evaluation and Research, *Medical Review 020687 of Mifeprix*, 21 (Mar. 29, 2016) ("The original approved dosing regimen remains safe and effective but the new proposed dosing regimen is effective and should be approved for use in gestations through 70 days (10 weeks) gestation.").

[13] World Health Organization, *Self-Managing Recommendation 50: Self-Management of Medical Abortion In Whole or In Part at Gestational Ages <12* (last visited Apr. 13, 2023); *see also* Heidi Moseson et al., *Effectiveness of Self-Managed Medication Abortion Between 13 and 24 Weeks Gestation: A Retrospective Review of Case Records From Accompaniment Groups in Argentina, Chile, and Ecuador*, 102(2) CONTRACEPTION 91 (Aug. 2020) (study relying on evidence-based information from countries in which abortion is legally restricted concluded that self-managed medication abortion with accompanying network support and linkages to the formal health system may be an effective and safe option for abortion beyond the first trimester).

[14] *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 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 9) (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).

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 clinically recognized pregnancies end in miscarriage, and approximately 80% of all cases of pregnancy loss occur within the first trimester.[15] Many patients manage 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. 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.[16]

For second and third trimester pregnancy loss, mifepristone is used to induce labor and accelerate the process of vaginal delivery, which reduces the likelihood of adverse medical complications.[17] For these patients, mifepristone also increases the safety of vaginal deliveries of miscarried pregnancies. Dr. Perritt 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[18] inside increases risk of hemorrhage, of infection, and of needing subsequent intervention."[19]

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[15] Siobhan Quenby et al., *Miscarriage Matters: The Epidemiological, Physical, Psychological, and Economic Costs of Early Pregnancy Loss*, 397 LANCET 1658 (2021).

[16] *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).

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

[18] 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).

[19] *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).

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.

Moreover, the safety of mifepristone does not depend on providers dispensing and administering the drug in a health-care setting. Studies show that medication abortion is equally safe when prescribed in-person as it is through telehealth.[20] In fact, the experience of the Covid-19 pandemic has demonstrated that mifepristone is as safe when prescribed through telehealth and mailed directly to patients as it is when a physician or other health care provider oversees its administration.[21]

The Fifth Circuit panel, like the District Court, relies on Respondents' cherry-picked anecdotes about patients experiencing ectopic pregnancies to call attention to a supposed scenario that the FDA allegedly did not consider when it lifted the in-person office visit requirement for accessing mifepristone. The Order states that without an in-person visit, a patient with an ectopic pregnancy may never know that the embryo is growing in her fallopian tube, and that taking mifepristone may put her life in danger by causing fallopian tube rupture.[22] This represents a misunderstanding of ectopic pregnancy. Ectopic pregnancies (which are very rare) are medical emergencies whether or not a patient takes mifepristone. A patient who seeks

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[20] *See e.g.*, Grossman and Grindlay, *supra* note 10, at 781 (comparing adverse events for telemedicine and in-person patients and concluding that telemedicine is a non-inferior option with respect to safety); Aiken, *supra* note 2, at 4.

[21] Ushma D. Upadhyay et al., *Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic*, 4(8) JAMA NETWORK 1 (Aug. 2021) (no patients reporting adverse events in a study of fully remote medication abortion using mifepristone).

[22] Order at 15.

mifepristone via a telehealth visit is screened for symptoms of ectopic pregnancy and is directed to seek emergency treatment, rather than mifepristone, if those symptoms are present. As Dr. Carolyn Sufrin, a PRH fellow who practices in Maryland, explained, "the introduction of mifepristone on top of someone having an ectopic pregnancy doesn't change the fact that ectopic pregnancy requires emergency care." No PRH physicians have prescribed mifepristone to address ectopic pregnancies, and several have identified ectopic pregnancies as a result of either imaging or telehealth screening questions and diverted those patients to appropriate care. Ever since the approval of mifepristone, prescribers have been required to have the ability to screen for ectopic pregnancy. All medical providers who treat early pregnancy are trained in diagnosing ectopic pregnancies.

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%.[23] Over two decades later, mifepristone has been proven highly effective time and time again. A 2022 study of medication abortion provided through online telehealth in the U.S. found that 96.4% of patients successfully ended their pregnancies without the need for intervention.[24] 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%.[25]

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[23] 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).

[24] *See* Aiken, *supra* note 2, at 4.

[25] *See* Gatter, *supra* note 11, at 271.

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 administering misoprostol alone and reduces the need for a subsequent procedure.[26]

High quality care for medication abortion and miscarriage management will be impacted if mifepristone is unavailable or its access restricted. 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.[27] Dr. Sufrin 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 medication abortion will be reduced if access to mifepristone is eliminated.

In sum, the medical evidence on safety available at the time mifepristone was first-FDA approved is consistent with the additional evidence available today: mifepristone is proven to be safe and effective for medication abortion up to (at a minimum) ten weeks gestation as well as later-term miscarriage management and management of fetal demise later in pregnancy. Two decades of medical evidence and provider experience supports the FDA's approval and

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[26] 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 16, at 2161.

[27] *See* Heidi 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 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.").

subsequent changes to the REMS ("risk evaluation and mitigation strategies"), and this Court should not allow the lower courts to second-guess the expert judgment of the FDA.

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 purpose 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.[28]

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.[29] Providers are best 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.[30]

As discussed *supra*, the consensus of the medical community is that mifepristone, as used in medication abortion up through approximately ten weeks gestation 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

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

[29] *See id.*

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

mifepristone are heavy bleeding, nausea, and abdominal pain.[31] 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 up to ten weeks gestation.[32] For example, less than 1% of patients obtain an emergency intervention for excessive bleeding.[33] Dr. Verma, who has been providing abortion and miscarriage management for eight years, cannot recall the last time a patient had an adverse effect with mifepristone, because it is that uncommon in her practice.[34]

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. As PRH providers attest, communicating the full spectrum of medical information about mifepristone, including discussions about risks, is a standard part of their practice. For example, Dr. Bhavik Kumar, a PRH 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

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

[32] *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).

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

[34] In contrast to this evidence, *amicus* notes that the District Court, in reaching its conclusion to issue a stay on FDA's approval, relied on an unsubstantiated claim on an anti-choice website that alleges that two patients died from mifepristone use in 2022. Unpublished Opinion, *Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.*, 22-CV-00223 at 53 (N.D. Tex. Apr. 7, 2023) [hereinafter "Opinion"]. Dr. Amy Caldwell, a board-certified obstetrician and gynecologist practicing in Indiana, who is referenced on the website, states that, in fact, none of her patients died due to receiving mifepristone.

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 use 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. Restricting Access to Mifepristone Impedes Patient Autonomy and Jeopardizes Patient Health

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

The lower courts' attempt to restrict 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 the orders below jeopardize that care. In the absence of a stay from this Court, providers treating patients who want a medication abortion with mifepristone may be forced to withhold a valid and safe option, disregarding patient autonomy — a violation of medical ethics — or potentially violating 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.[35] 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 or limited.

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. 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 outside 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

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

miscarriage will exacerbate existing distrust in the medical system.[36] Dr. Koyama observes 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 patients report confidence in their decision to seek medication abortion or use mifepristone in their miscarriage management. For example, studies show that with respect to medication abortion, the vast majority of patients are happy with their decision.[37] Patients should be able to select medical treatment that they determine, in consultation with their provider, is the most appropriate for

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[36] The District Court distorted the history of eugenics, *see* Opinion at 64, disenfranchising the very populations it claims to support, and the Fifth Circuit did not correct the record. 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 decries any comparison between its mission to provide reproductive healthcare and the eugenics movement.

[37] *See e.g.*, 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).

their care. The Court should not interfere with that decision when the medical care in question is safe, effective, and medically appropriate.

B. Restricting Access to Mifepristone Jeopardizes Patient Health

Restricting access to safe and effective health care jeopardizes the health and well-being of patients. The decisions below do not take into consideration the impact on patient health if mifepristone cannot be offered to patients. 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.

Reinstating the in-person dispensing requirement for mifepristone will further restrict access to medication abortion, which will disproportionately harm patients whose access to reproductive healthcare is already limited. Dr. Verma explains that "from the pandemic we know that medication abortion is completely safe and just as effective," and thus telehealth only serves to "improve access with these telehealth visits and receiving mailed medication. To remove the barriers is really important, particularly for people who live in rural areas and can't go down the street for care." In fact, a study of the impact of a Texas state law on the restricted use of medication abortion to comply with the FDA's labeling from 2000 found that the law not only drastically restricted access to medication abortion, but also disproportionately impacted low-income patients and those living farther from an open clinic.[38] An additional study, which examined the impact of a 2011 Ohio law that required the outdated seven-week FDA protocol,

[38] *See* Vinita Goyal et al., *Medication Abortion Use Among Low-Income and Rural Texans Before and During State-Imposed Restrictions and After FDA-Updated Labeling*, 223 J. AM. OBSTET. GYNECOL. e1-226, e2-227 (Aug. 2020).

found that patients who received abortions after the law went into effect were three times as likely to require additional intervention to complete the abortion, compared to when providers used evidence based-practice to prescribe mifepristone after seven weeks.[39]

Several PRH doctors noted that the alternative to telehealth for many rural or otherwise isolated (physically or emotionally) patients is not in-person care, but no care at all. A patient's ability to access care should not be determined by zip code. Telehealth has allowed medical professionals to evaluate and care for more patients, and telehealth in reproductive health is no different from any other specialty. Therefore, telehealth alleviates the many burdens involved in attending in-person appointments, such as travel time, costs, childcare, and time away from work. Dr. Winchester explains that "demanding in-person dispensing of mifepristone will make it more difficult for patients to access the care they need in a timely manner." Removing the ability to provide mifepristone with telehealth will harm patients.

Recently, access to abortion care — both medication abortions and procedural abortions — has become either practically unavailable or dramatically less accessible in many states.[40] As a result, patients in states with limited or no access to abortion care may need to travel (sometimes far distances) to receive care.[41] The real-life experiences of providers confirm this: Dr. Belmonte and Dr. Verma routinely see out-of-state patients seeking abortion care. This is not only unduly burdensome on patients, but it also strains providers and resources in states

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[39] Ushma D. Upadhyay et al., *Comparison of Outcomes before and after Ohio's Law Mandating Use of the FDA-Approved Protocol for Medication Abortion: A Retrospective Cohort Study*, PLOS MEDICINE 3 (Aug. 2016) (finding that medication abortion decreased 80% in Ohio from 2010 to 2014).

[40] 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).

[41] 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).

providing abortion access by increasing wait times at reproductive healthcare clinics. Dr. Verma discussed the many barriers a patient must overcome before they can present for care, which can include finding a provider, securing child care, securing financial resources, and travelling time. For example, Dr. 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 one of the most common forms of medication abortion is no longer available for large patient populations. These delays could force pregnant patients to jump through several hoops and make important medical decisions in an extremely limited time frame.

In addition, the Order, which purports to flip a switch and send the provision of care back to 2015, has already created mass confusion about what is lawful to prescribe and how to prescribe it — all of which will exacerbate the already existing harms outlined above. Providers may be chilled as they fear legal risk for prescribing medication that is scientifically proven to be safe and effective — and has been approved by the FDA — but which is called into question by the lower courts' orders. And as providers attempt to navigate the chaos that will ensue as a result of the lower court decisions, patients will be harmed. In the days or weeks it will take to sort out the regulatory nightmare the lower courts have created, patients will struggle to access care and, for some patients, some treatment options will be foreclosed altogether.

Patients who cannot access desired care face greater risks to their health. While serious risks from abortion at any gestational age are *extremely rare*, risks to patient health do increase as the pregnancy advances.[42] Moreover, given the current restrictions on abortion, a delay can

[42] ACOG Committee Opinion No. 613, *Increasing Access to Abortion*, at 2 (Nov. 2014, *reaff'd* 2017); Elizabeth Raymond & David Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTET. GYNECOL. 215, 217 (2012).

completely prevent a patient from receiving an abortion, because in some jurisdictions abortions are prohibited by law after a certain gestational age. Medical evidence demonstrates that carrying a pregnancy to term and giving birth poses greater risks to a patient's health than an abortion.[43]

There are also psychological risks associated with denying patients desired care. 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.[44] 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.

In sum, while the courts below decided to substitute their judgment for that of the FDA's and concluded that restricting the FDA approval of mifepristone is necessary to protect patients, the lower court orders will have the opposite result: they are likely to jeopardize and harm patient health.

CONCLUSION

For all the reasons set forth herein, PRH respectfully asks the Court to grant the pending stay applications.

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Respectfully submitted,

s/ Janice Mac Avoy
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[43] *See, e.g.*, Raymond & Grimes, 119 OBSTET. GYNCEOL. at 217 (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).

[44] 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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