IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*, Plaintiffs-Appellees, v. FOOD & DRUG ADMINISTRATION, *et al.*, Defendants-Appellants, v. DANCO LABORATORIES L.L.C., Intervenor-Appellant.	Case No. 23-10362 MOTION OF PHYSICIANS FOR REPRODUCTIVE HEALTH FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF IN SUPPORT OF DEFENDANTS-APPELLANTS

Pursuant to this Court's Order dated April 19, 2023, Physicians for Reproductive Health ("PRH") hereby moves this Court for an order granting it leave to file the attached *amicus curie* brief in support of Defendants-Appellants and Intervenor-Appellant. In support of this motion, PRH states:

1. 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 practicing in all 50 states, the District of Columbia, and Puerto Rico, as well as over 450 fellows. PRH's network includes providers who specialize in obstetrics, gynecology and complex family planning and prescribe mifepristone on a regular basis. As such, PRH can provide the Court with insight and perspective not available from the parties.

2. PRH seeks to file an *amicus* brief in the above-captioned case out of concern that the District Court's order in the below proceeding, *Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.*, 22-CV-00223 (N.D. Tex. Apr. 7, 2023) (the "Order"), which purports to stay the U.S. Food & Drug Administration's approval of mifepristone, will restrict access to a safe and effective medication and jeopardize patient health.

3. As required by Federal Rule of Appellate Procedure 29, PRH obtained the consent of all parties to the filing of this *amicus* brief. PRH also notes that it previously filed an *amicus curiae* brief in an earlier stage of this proceeding. Brief for Physicians for Reproductive Health as *Amicus Curiae* Supporting Defendants-Appellants, *Alliance for Hippocratic Medicine et al., v. FDA, et al.*, No. 23-10362 (5th Cir. Apr. 12, 2023) (Dkt 63).

4. A copy of PRH's proposed *amicus* brief is attached as Exhibit A. It is relevant to the disposition of this case because it details the medical evidence and

the unique perspectives of PRH providers demonstrating why mifepristone is safe and effective for use in medication abortion and for miscarriage management. The proposed brief also explains how the medical evidence enables providers to communicate the risks and benefits of mifepristone in order to obtain informed consent from patients.

5. The proposed brief illustrates how restricting access to mifepristone impedes patient autonomy by limiting their ability to select a safe and effective course of treatment and explains how patients who cannot access desired care face greater risks to their health.

6. Accordingly, PRH as *amicus curiae* respectfully proffers its brief to the Court and asks that the Court grant leave to file the same for the Court's consideration.

Dated: May 1, 2023

Respectfully submitted,

s/ Janice Mac Avoy

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CERTIFICATE OF SERVICE

I certify that, on May 1, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I further certify that, 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 May 1, 2023, by First Class Mail.

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EXHIBIT A

Brief of Physicians of Reproductive Health as *Amicus Curiae* in Support of Defendants-Appellants and Intervenor-Appellant

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

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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.

Amicus Curiae

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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 practicing 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

[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.

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 that its continued availability after more than two decades of use in the United States is critical to ensuring patients can continue to access high quality comprehensive reproductive health care.

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 in gynecology around the world, and nationwide it is the standard of care in gynecological procedures and obstetric services, as well as 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 U.S. Food & Drug Administration's ("FDA") approval on a motion for preliminary injunction. In

[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).

imposing the stay, the District Court mistakenly concluded that mifepristone, in some respect, is "dangerous[]."[3]

On applications for a stay pending appeal, a panel of this Court partially stayed the District Court's Order, blocking preliminary relief as to the FDA's 2000 approval of mifepristone, but leaving the court's order in effect as to the FDA's subsequent regulatory actions, including the 2016 REMS modifications and 2021 non-enforcement decision regarding the in-person dispensing requirement. That divided decision attempted to reinstate restrictions on mifepristone properly removed by the FDA, including the ability to provide mifepristone via telehealth, and effectively blocked the FDA's 2019 approval of the generic medication, which accounts for two-thirds of the mifepristone sold in this country. Defendants and Intervenor sought a stay of the panel's order from the Supreme Court of the United States. On April 21, 2023, the Supreme Court stayed the District Court's Order in its entirety pending final resolution of this appeal. Nevertheless, the District Court and the Fifth Circuit decisions prompted multiple weeks of chaos for those who prescribe and rely on access to mifepristone across the country.

As physicians and experts in reproductive health, PRH's providers know that mifepristone is safe and effective. Restricting access to mifepristone will hurt

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

patients by limiting their ability to select a safe and effective course of treatment that is medically sound and best for them, and it will jeopardize patient health. 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.

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 for medical practice nationwide.[4]

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[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.

For all these reasons, as discussed further below, the District Court's injunction should be vacated.

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, many 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.[6]

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.[7] The medical evidence

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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 8.

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 at least ten weeks gestation and miscarriage management in patients who do not expel the uterine contents on their own. First, the anecdotes and "data" submitted by Plaintiffs and relied upon by the District Court are not consistent with the overwhelming majority of studies which show how safe mifepristone use is. 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 demonstrating that serious adverse events — including hospitalization, blood transfusion, and surgery — occurred in less than 1% of studied cases.[8] Another 2017 study found that significant adverse events (including hospital admission and emergency department treatment) with medication abortion are very rare — 0.3% in a study of 20,000 medication abortion

[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 in-person before a physician.[9] 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.[10] For example, 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."

As the FDA properly found in 2016 based on substantial scientific evidence, mifepristone is safe and effective through at least ten weeks gestation. The overwhelming medical evidence and physician experiences, both prior to 2016 and after, demonstrate this point.[11] Indeed, the President and CEO of PRH, Dr. Jamila

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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.").

11 *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.").

Perritt, a board-certified obstetrician and gynecologist with a comprehensive background in complex family planning in Washington, D.C., views mifepristone as safe and effective beyond ten weeks, consistent with additional high-quality evidence, real-world practice outside the United States, and with the recommendation of the World Health Organization that mifepristone can be safely used at twelve weeks.[12]

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.[13] 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

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[12] 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).

[13] *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 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).

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."

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.[14] 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.[15]

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

[15] *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).

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.[16] 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[17] inside increases risk of hemorrhage, of infection, and of needing subsequent intervention."[18] 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 and dispensed in-person as

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

[17] 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).

[18] *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).

when it is prescribed through telehealth and delivered by mail.[19] 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.[20]

The District Court relied on Plaintiffs' cherry-picked anecdotes about patients experiencing ectopic pregnancies to fault the FDA for allegedly not considering this condition when it lifted the in-person office visit requirement for accessing mifepristone. A panel of this Court relied upon Plaintiffs' assertion in their brief that "without an in-person visit, it is impossible to rule out an ectopic pregnancy," placing a woman "at an increased risk of rupture or even death."[21] Plaintiffs' brief presents either an alarming misunderstanding of ectopic pregnancy or a misleading presentation of how it presents in actual patients. Ectopic pregnancy is a very rare medical emergency in which an embryo grows outside of the uterus. Ectopic pregnancies are medical emergencies whether or not a patient takes mifepristone. A patient who seeks mifepristone via a telehealth visit is

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19 *See e.g.*, Grossman and Grindlay, *supra* note 9, 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.

20 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).

21 Unpublished Opinion, *Alliance for Hippocratic Medicine et al., v. FDA, et al.*, No. 23-10362 at 16 (5th Cir. Apr. 12, 2023) [hereinafter "Opinion"] (citing Plaintiffs' motion for a preliminary injunction at 886).

screened for symptoms of ectopic pregnancy and is directed to seek emergency medical treatment immediately, 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. All medical providers who treat early pregnancy are trained in diagnosing ectopic pregnancies, and are in fact required to be able to screen for ectopic pregnancy.

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%.[22] 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

[22] 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).

pregnancies without the need for intervention.[23] 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%.[24]

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.[25]

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.[26] Dr. Sufrin observes that in her practice, "mifepristone added to

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

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

25 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 15, at 2161.

26 *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

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 miscarriage management after ten weeks gestation and management of fetal demise later in pregnancy. Two decades of medical evidence and provider experience supports the FDA's approval and subsequent changes to the REMS ("risk evaluation and mitigation strategies"), and this Court should not allow the district court to second-guess the expert judgment of the FDA.

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.").

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.[27]

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.[28] 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.[29]

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

[28] *See id.*

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

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 all other FDA-approved medication, mifepristone is associated with potential risks and side effects, which have been studied extensively. The most common side effects of mifepristone are heavy bleeding, nausea, and abdominal pain.[30] These effects are similar to what patients typically experience in connection with miscarriage, childbirth, procedural abortion, and pregnancy. The *materialization* of these risks, however, is exceedingly rare, especially when used in medication abortion up to ten weeks gestation.[31] For example, less than 1% of mifepristone patients obtain medical intervention for excessive bleeding.[32] 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.[33]

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

[31] *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).

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

[33] 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. *See* Order at 53

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 to ensure they are obtaining voluntary, informed consent – consistent with the laws and professional ethics that govern all medical care. As PRH providers attest, communicating the full spectrum of medical information about mifepristone, including discussions about risks, is a fundamental 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). 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

(citing Plaintiffs' reply brief). 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. *See also* Press Release, Planned Parenthood great Northwest, Hawai'I, Alaska, Indiana, Kentucky, PPGNHAIK Statement on Incorrect Indiana Data (April 11, 2023), https://www.plannedparenthood.org/planned-parenthood-great-northwest-hawaii-alaska-indiana-kentuck/press/ppgnhaik-statement-on-incorrect-indiana-data.

determination. Most importantly, providers do not ignore any risks or effects associated with mifepristone. Instead, just like for all other forms of medical care, 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 District Court's attempt to stay the 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 District Court's Order jeopardizes that care. If the Order were to ever take effect, 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 be faced with 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.[34] However, patient autonomy is diminished when providers cannot abide by a patient's informed decision to receive a safe and effective course of treatment because the treatment is prohibited or limited by court order or state law.

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 seeking abortion care 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.

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

Privacy is another reason why patients 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 miscarriage will exacerbate existing distrust in the medical system.[35] 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. "Without mifepristone," according to Dr. Winchester, "labor induction times for second or third trimester demise are much longer or unsuccessful." In Dr.

[35] The District Court distorted the history of eugenics, *see* Order at 64, disenfranchising the very populations it claims to support. 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.

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.[36] Patients should be able to select medical treatment that they determine, in consultation with their provider, is the most appropriate for their care. This 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 District Court's Order does not take into consideration

[36] *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).

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.

Recently, access to abortion care — both medication abortions and procedural abortions — has become either practically unavailable or dramatically less accessible in many states.[37] As a result, patients in states with limited or no access to abortion care may need to travel (sometimes far distances) to receive care.[38] 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 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,

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[37] 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).

[38] 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).

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, post-*Dobbes*, Dr. Belmonte at times has witnessed wait times of up to six weeks at the hospital where he practices 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.

Moreover, any order turning back the clock on FDA's regulation of mifepristone will only harm patients. If an in-person dispensing requirement for mifepristone is reinstated, it 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."

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.

Finally, since the District Court's Order issued on April 7, 2023 and the panel's Opinion issued on April 12, 2023, providers and patients have faced unwarranted confusion about the lawfulness of prescribing mifepristone, upending the status quo and exacerbating the harms to patient health and access to safe care. Providers have been forced to be in constant communication with professional groups and attorneys for hospitals and institutions, diverting their energies from patient service. As Dr. Verma explains, "we have been trying to communicate regularly through our Georgia OB/GYN Society and institutions with updates, but all the back and forth in the legal landscape has created more confusion during an already stressful and difficult time to be a clinician providing reproductive healthcare in our state." While she has "continued to have access to mifepristone," the "constant uncertainty and needing to contingency plan has distracted from

being able to just care for…patients as [she] would like to be able to do." Similarly, Dr. Kumar described "not knowing if [he] would or wouldn't be able to offer mifepristone as an option, after almost a decade of practice" was "troubling and stressful."

As providers attempt to navigate conflicting court orders and a shifting series of stays, patients have been and will continue to be harmed.[39] Dr. Olatunde explains that "these competing litigations make it even more challenging" for a patient seeking abortion, "because patients think they have less options or avoid presenting for care due to fear of repercussions or criminalization." Some patients may have unnecessarily postponed obtaining care; Dr. Olatunde described a patient who was unsure if she was still allowed to go forward with a medication abortion "because they weren't sure if it was still legal given what has been presented in the media from all the various cases." Dr. Belmonte also attests that "patients come in daily with fears that they won't be able to have a medication abortion at all or that it will be less effective because of the lack of mifepristone; the confusion is rampant." Without vacating the District Court's order, patients will continue to

[39] On the same day that the District Court issued its Order, another order out of the Eastern District of Washington enjoined Defendant-Appellants from "altering the status quo" with respect to mifepristone's availability in certain states. Order, *Washington v. FDA*, No. 23-3026 (E.D. Wash. Apr. 7, 2023).

face confusion and additional barriers when seeking safe medical care involving mifepristone.

Patients who cannot access desired care, including for any of the reasons discussed above, 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.[40] Moreover, 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. Medical evidence demonstrates that carrying a pregnancy to term and giving birth poses greater risks to a patient's health than an abortion.[41]

There are also psychological risks associated with denying patients desired care. Patients who are denied abortions report greater anxiety and depression symptoms, lower self-esteem, and lower life satisfaction than patients who receive a desired abortion.[42] Dr. Belmonte described how providers at his hospital often

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[40] 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).

[41] *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).

[42] 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).

witness the trauma faced by patients who experience difficulty or complete foreclosure in obtaining desired abortion care.

In sum, while the court below decided to substitute its judgment for that of the FDA's and concluded that reversing the FDA approval of mifepristone is necessary to protect patients, the District Court's Order 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 reverse the District Court's Order.

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Respectfully submitted,

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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 6,470 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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