Nos. 23-235, 23-236

In the

Supreme Court of the United States

U.S. FOOD & DRUG ADMINISTRATION, ET AL.,
PETITIONERS,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
RESPONDENTS.

DANCO LABORATORIES, L.L.C.,
PETITIONER,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
RESPONDENTS.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF OF PHYSICIANS FOR REPRODUCTIVE HEALTH AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

Physicians for Reproductive Health ("PRH") is a doctor-led nonprofit that seeks to ensure meaningful access to comprehensive reproductive health services, including contraception and abortion. 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 nearly 500 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

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

attest that mifepristone is a safe and effective[2] drug and is critical to offering high-quality comprehensive reproductive health care to patients.

SUMMARY OF ARGUMENT

For nearly 25 years, mifepristone has been an essential medication used in full-spectrum reproductive health care in the United States. Mifepristone is prescribed on a regular basis by providers nationwide and around the world and is viewed as the standard of care in many procedures, obstetric care, medication abortion, and miscarriage management.

Ignoring the wealth of scientific evidence supporting the safety and efficacy of mifepristone, the District Court in this case purported to "stay" the medication's decades-old FDA approval following a motion seeking injunctive relief. When a Fifth Circuit panel upheld the District Court's order in part by invalidating certain regulatory changes the U.S. Food & Drug Administration ("FDA") had made since 2016, this Court granted emergency relief, issuing a stay that extends through the final resolution of this

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[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, Vol. 10, June 2022, at 1, 3, 4 (citing MARE Guidelines).

appeal.[3] The Fifth Circuit affirmed the portion of the District Court's order that suspends (i) the FDA's 2016 changes to mifepristone's approved conditions of use and (ii) the FDA's 2021 decision to eliminate the drug's in-person dispensing requirement. In doing so, it reinstated medically unnecessary and burdensome restrictions on mifepristone that were properly removed by the FDA in 2016 and 2021. Should the District Court's order, as modified by the Fifth Circuit's ruling, ever go into effect, the impact would be devastating.

The regulatory changes that the modified preliminary injunction would reinstate will limit patients' access to a safe and effective course of medical care. In largely upholding the District Court's order, the Fifth Circuit ignored the vast body of peer-reviewed evidence and real-life experiences of providers and patients when it wrongly asserted that mifepristone can have "dangerous side effects" and may cause "serious complications[.]"[4] Decades of rigorous, detailed studies and the experience of over five million patients who have used mifepristone in the United States since 2000, when the FDA first approved mifepristone, confirm the safety and efficacy of mifepristone for use in medication abortion

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[3] *Danco Laboratories, LLC v. Alliance for Hippocratic Medicine,* 143 S. Ct. 1075 (U.S. Apr. 21, 2023) (No. 22A901) (Mem.) and *Food & Drug Administration v. Alliance for Hippocratic Medicine,* 143 S. Ct. 1075 (U.S. Apr. 21, 2023) (No. 22A902) (Mem.).

[4] *Alliance for Hippocratic Medicine v. U.S. Food & Drug Administration*, 78 F.4th 210, 238, 240 (5th Cir. 2023) [hereinafter "Fifth Circuit Opinion"].

care and for miscarriage management. Studies also confirm that mifepristone is safe and effective when prescribed via telehealth and mailed directly to patients.

The experiences of PRH's providers are consistent the medical evidence. Many of PRH's providers routinely prescribe and administer mifepristone. As qualified medical professionals with training in multiple medical specialties including obstetrics, gynecology, family medicine, pediatrics, and emergency medicine, these providers are in the unique position to offer first-hand perspectives and experience on the safety and efficacy of mifepristone and to explain why access to mifepristone is critical, the ways that limiting access to mifepristone would disrupt the standard of care nationwide, and how providers share information and obtain informed consent from patients electing a course of treatment involving mifepristone.[5] As described herein, PRH providers attest that mifepristone is safe and effective. Restricting access to mifepristone will hurt patients by limiting their ability to select a safe and

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[5] 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.

effective treatment that is medically sound and that best fits their needs.

By limiting access to mifepristone, the rulings of the lower courts would jeopardize patient health rather than protect it. If the stay is upheld, patients may be restricted in accessing, or may even be entirely unable to receive, necessary medical care. Equally concerning, patients may experience or may be placed at a greater risk of harm that could have been avoided by a treatment plan incorporating mifepristone. For example, patients who cannot obtain a treatment plan incorporating mifepristone may opt to carry their pregnancies to term rather than undergo a procedural abortion, even if their pregnancies pose medical risks. Carrying any pregnancy to term may present medical complications and risks that could have otherwise been circumvented.

Additionally, restricting access to mifepristone impedes patient autonomy and places providers in untenable positions. Patients have a right to make decisions about their medical care. To protect this autonomy, providers are ethically obligated to inform their patients of the risks and benefits of different courses of treatment and to honor a patient's decision on which course of treatment is best for them. However, this right is curtailed when providers cannot offer to a patient a course of treatment incorporating mifepristone, even if such care is medically appropriate, considered the standard of care, and the benefits and risks are adequately communicated to and understood by the patient. Under these circumstances, providers are placed in

the ethically challenging position of being unable to legally present their patients with all potential evidence-based treatments.

Overall, the Fifth Circuit's description of the status quo bears no resemblance to how medication is actually regulated by the FDA and would throw the provision of medication abortion and miscarriage management care in the United States into chaos. If this Court allows the District Court's order, as modified by the Fifth Circuit's decision, to go into effect, it will harm reproductive health and patient autonomy, as well as force providers into positions in which the law requires them to deprive patients of access to a safe and effective treatment option. For all these reasons, as discussed further below, this Court should reverse the Fifth Circuit's decision affirming the portions of the District Court's order.

ARGUMENT

I. Restricting Access to Mifepristone Will Limit Patient Options and Harm Patient Health

The safety and effectiveness of mifepristone have been overwhelmingly and consistently confirmed. The FDA first approved mifepristone in 2000 after years of study for use in combination with misoprostol to terminate a pregnancy, *i.e.*, a method of medication abortion. Since then, for over two decades, patients have often elected for medication abortions over procedural options. In recent years, medication abortion accounted for over 50% of

abortions performed in the United States.[6] Providers also commonly prescribe mifepristone in combination with misoprostol to manage miscarriages and pregnancy loss.[7]

Under the guise of protecting patient well-being, the Fifth Circuit's order would restrict access to mifepristone under the rational that significant "serious adverse events" affecting patient health can occur.[8] The medical evidence and judgment of highly-trained providers demonstrate that this contention is patently false.

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

Scores of high-quality 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 pass the uterine contents on their own.

First, medical studies and PRH provider experiences confirm how safe mifepristone is as a

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[6] Rachel Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, Guttmacher Institute (Dec. 1, 2022 Update) (quantifying medication abortions in the U.S. in 2020 and 2022).

[7] American College of Obstetricians and Gynecologists ("ACOG"), *Practice Bulletin No. 200*, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2021).

[8] Fifth Circuit Opinion, 78 F.4th at 239-40.

course of treatment for both medication abortion and miscarriage management. The medical evidence plainly demonstrates that the "data" and anecdotal accounts of mifepristone use submitted by Respondents and relied upon by the courts below are not indicative of how safe mifepristone use is.[9] 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.[10] 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 over 19,000 medication abortion patients taking mifepristone either at home or before a physician.[11] 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

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[9] *See, e.g.*, Fifth Circuit Opinion, 78 F.4th at 230-31.

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

[11] *See* Daniel Grossman & 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).

abortion is extremely low.[12] Dr. Aishat Olatunde, a PRH fellow who practices in Pennsylvania and who prescribes mifepristone on a routine basis, reports that mifepristone is "extremely safe" and that she has "never witnessed an adverse reaction to mifepristone in [her] practice."

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.[13]

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[12] *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, 273 (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 Sciences, Engineering and Medicine, *The Safety and Quality of Abortion Care in the United States*, at 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.") (alterations added).

[13] *See* FDA Center for Drug Evaluation and Research, *Medical Review Application Number 020687Orig1s020 (Mifepristone)*, at 1, 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.").

The President and CEO of PRH, Dr. Jamila Perritt, notes that the global health community outside of the U.S. widely views mifepristone as safe and effective even beyond ten weeks, and the World Health Organization recommends that mifepristone can be safely used beyond ten weeks. *See* World Health Organization, *Self-Managing Recommendation 50: Self-Management of Medical Abortion In Whole or In Part at Gestational Ages <12* ch. 3, section 3.6.2 (last visited Jan. 24,

To put its safety in perspective, mifepristone has a lower complication rate than many other FDA-approved drugs widely available across the United States with fewer restrictions.[14] Dr. Nisha Verma, a PRH fellow who practices in Georgia, notes that virtually all FDA-approved drugs, such as acetaminophen (*e.g.*, Tylenol), sildenafil citrate (*e.g.*, Viagra), and penicillin, have some risk of serious adverse events, yet these drugs are available on the market and are frequently administered. While evidence-based studies and provider observations demonstrate that mifepristone poses less risk of complication than those common drugs,[15]

2024); *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 91-99 (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* ANSIRH, Issue Brief, *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone U.S. Post-Marketing Adverse Events Summary through 6/30/2021*," at 3 (Nov. 2022) (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).

[15] *See supra* note 14.

mifepristone access is burdened by numerous medically unnecessary restrictions. The Fifth Circuit's decision would further exacerbate those disproportionate restrictions. In short, studies and the real-world experience of providers are clear: restricting access to mifepristone on safety grounds is unwarranted. 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 for a serious complication after medication abortion.

Similarly, mifepristone is a safe and beneficial option for patients who experience pregnancy loss and prefer to take prescribed medication or 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.[16] 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

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

likelihood of success than treatment with misoprostol alone.[17]

For second and third trimester pregnancy loss, mifepristone can be used to induce labor and accelerate the process of vaginal delivery for those who want and need it, which reduces the likelihood of adverse medical complications compared to non-use.[18] 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[19] inside increases risk of hemorrhage, of infection, and of needing subsequent intervention."[20] Similarly, in the experience of Dr. Michael Belmonte, a PRH fellow who has practiced in

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[17] *See* Courtney Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 N. Engl. J. Med. 2161, 2168-69 (June 2018) (additionally finding that pretreatment of mifepristone resulted in a higher likelihood of successful management of first-trimester pregnancy loss).

[18] *See* ACOG & Society for Maternal-Fetal Medicine, *Management of stillbirth*, *ACOG Obstetric Care Consensus No. 10*, 135(3) Obstetric Care Consensus e110, e122 (2020).

[19] The term "fetus" is used to refer to the embryonic development stage for the period following eight weeks after the last menstrual period through the point of delivery. *See* ACOG, *Guide to Language and Abortion*, at 2 (Sept. 2023).

[20] *See also* Marike Lemmers et al., *Medical Treatment for Early Fetal Death (Less Than 24 Weeks)*, Cochrane Database Systematic Reviews, at 25 (June 17, 2019) (finding that the addition of mifepristone was more effective in inducing complete miscarriage).

Colorado and the District of Columbia, 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 (removal of the uterus) — risks that can be reduced by administering mifepristone.

Second, in addition to mifepristone's safety, medical studies and PRH provider experiences confirm mifepristone is effective as a treatment for both medication abortion and miscarriage management. In 1995, before the FDA approved mifepristone in the United States, a French study showed that the overall rate of success when mifepristone is administered in medication abortion is 95.5%.[21] 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 United States found that 96.4% of patients successfully ended their pregnancies without the need for intervention.[22] 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%.[23]

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[21] 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).

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

[23] *See* Gatter et al., *supra* note 12, at 271.

The same is true regarding the efficacy of mifepristone as used in miscarriage management. Studies confirm that for patients experiencing a miscarriage, administering mifepristone before misoprostol is more effective for miscarriage management than administering misoprostol alone, and it reduces the need for a subsequent procedure.[24]

High quality care for medication abortion and miscarriage management will be impacted if access to mifepristone is 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.[25] Dr. Carolyn Sufrin, a PRH fellow who practices in Maryland, observes that in her practice, "mifepristone added to misoprostol increases the success of medication management, and decreases

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[24] *See, e.g.*, Justin J. Chu et. al, *Mifepristone and Misoprostol Versus Misoprostol Alone for the Management of Missed Miscarriage (MifeMiso): A Randomised Double-Blind, Placebo-Controlled Trial*, 396 Lancet 770, 774, 776 (Aug. 2020); *see also* Schreiber, *supra* note 17, at 2161, 2168-69.

[25] *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, 2403 (May 2020) ("Although misoprostol alone can be used to expel pregnancy tissue, combining it with mifepristone increases its efficacy for both abortion and miscarriage.").

the likelihood of a procedure" after a miscarriage, meaning that all fetal tissue is passed and further treatment is unnecessary.

In sum, the medical evidence available at the time mifepristone was initially approved by the FDA is consistent with the additional evidence available in 2016 and 2021 (when the FDA implemented changes to the mifepristone regulatory framework), as well as today: mifepristone is proven to be safe and effective for medication abortion up to (at a minimum) ten weeks gestation, as well as for miscarriage management and management of fetal demise later in pregnancy. Over two decades of medical evidence and provider experience supports the FDA's approval and subsequent changes to the risk evaluation and mitigation strategies (REMS), and this Court should not allow the lower courts to second-guess the expert judgment of the FDA.

B. The In-Person Dispensing Requirement for Mifepristone Does Not Increase or Promote Safety

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 when prescribed through telehealth appointments.[26] In fact, the experience of the COVID-19 pandemic demonstrates that mifepristone is as

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[26] *See e.g.*, Grossman & Grindlay, *supra* note 11, at 780-81 (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.

safe when prescribed through telehealth and mailed directly to patients as it is when distributed directly by a physician or other health care provider in a health-care setting.[27] Telehealth patients also have the same access to continuous care as in-person patients. For example, Dr. Sufrin schedules a follow-up appointment after any patient uses mifepristone — whether seen via telehealth or at an in-person appointment. At that appointment, she reviews a "standardized, evidence-based set of screening questions" with the patient "to assess whether both the clinician and the patient think they passed the pregnancy." She also performs a "general review of systems to check for fever, chills, abnormal pain or bleeding." In the exceedingly rare case that any concerns arise during a telehealth follow-up visit, Dr. Sufrin schedules an in-person appointment or advises the patient to go to the emergency room, as needed. Dr. Verma, who has provided telehealth abortion care in the past, explains that care continued throughout and after a telehealth medication abortion: "For all our patients undergoing medication abortion through telehealth, we did an initial screening, talked them through the whole process, and also made sure they had a helpline to call 24/7 if any questions or issues arose," as well as scheduled a follow-up appointment.

The Fifth Circuit merits panel, like the District Court, relies on Respondents' cherry-picked anecdotes

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[27] Ushma D. Upadhyay et al., *Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic*, 4(8) JAMA Network Open, at 2 (Aug. 2021) (no patients reporting adverse events in a study of fully remote medication abortion using mifepristone).

about patients experiencing ectopic pregnancies to call attention to a scenario that the FDA allegedly did not consider when it lifted the in-person office visit requirement for accessing mifepristone. The Fifth Circuit's ruling states that without an in-person visit, a patient with an ectopic pregnancy may never know that the embryo is growing in their fallopian tube, and that taking mifepristone may put their life in danger by causing fallopian tube rupture.[28] This represents a gross misunderstanding of ectopic pregnancy. Ectopic pregnancies (which are very rare) are medical emergencies whether or not a patient takes mifepristone. A patient who seeks mifepristone via a telehealth visit is screened by a provider using evidence-based screening tools for symptoms of ectopic pregnancy and is directed to seek emergency treatment, rather than mifepristone, if those symptoms are present. Dr. Sufrin advises, "if someone has an ectopic pregnancy that is not detected through screening questions, and they take mifepristone, we still advise them that they could have an ectopic pregnancy and tell them the signs of when they need emergency care." She notes that while mifepristone "does not treat an ectopic pregnancy," it "does not cause an ectopic to rupture either." 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 then directed those patients to appropriate care. Ever since the approval of mifepristone, providers have been required to be able to screen for ectopic

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[28] Fifth Circuit Opinion, 78 F.4th at 231.

pregnancy. All medical providers who treat early pregnancy are trained in diagnosing ectopic pregnancies. Because providers can safely dispense mifepristone outside of the in-person setting, while appropriately screening for ectopic pregnancies, this concern over ectopic pregnancies is not a medical basis to override the FDA's 2021 decision to eliminate the in-person dispensing requirement.

C. 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 adequately take into consideration the material impact on patient health if mifepristone access is restricted. Dr. Perritt explains that limiting access to mifepristone will not just reduce patient options for abortion care; for some patients, it will eliminate abortion as an option entirely. This is because other methods of medication abortion, like misoprostol-alone regimens, may not be as available, and because procedural abortion is not medically appropriate or available for everyone.

Patients who cannot access needed 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.[29] Moreover, given the current restrictions

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[29] ACOG Committee Opinion No. 815, *Increasing Access to Abortion*, 136(6) Obstetrics & Gynecology, e107, e108 (Dec. 2020); Elizabeth Raymond & David Grimes, *The Comparative*

on abortion access across many states, 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 far greater risks to a patient's health than an abortion.[30]

There are also psychological risks associated with denying patients care. As a landmark longitudinal study established, patients who are denied abortions experience greater anxiety and depression symptoms, lower self-esteem, and lower life satisfaction than patients who receive an abortion.[31] Dr. Belmonte describes how providers at his hospital often witnessed the trauma faced by patients who experience difficulty accessing abortion care or who are foreclosed entirely from obtaining such care.

Moreover, reinstating the in-person dispensing requirement for mifepristone will further restrict access to medication abortion, which disproportionately harms patients whose access to

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Safety of Legal Induced Abortion and Childbirth in the United States, 119 Obstet. Gynecol. 215, 217 (2012).

[30] *See, e.g.*, Raymond & Grimes, *supra* note 29, 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).

[31] 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).

reproductive healthcare is already limited, like patients who live far from their providers. Dr. Verma explains that from the pandemic, we know that medication abortion is safe and just as effective when prescribed through telemedicine, 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 that required following an outdated FDA protocol from 2000 found that the law not only drastically restricted access to medication abortion, but also disproportionately impacted patients with low-incomes and those living farther from an open clinic.[32] An additional study, which examined the impact of a 2011 Ohio law that similarly required following the outdated FDA protocol from 2000, 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 practices.[33]

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[32] *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(2) J. Am. Obstet. Gynecol. 236.e1, 236.e7, 236.e8 (Aug. 2020).

[33] 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*, 13(8) PLOS Medicine, at 3 (Aug. 2016) (finding that medication abortion decreased 80% in Ohio from 2010 to 2014).

Recently, access to abortion care — both medication abortion and procedural abortion — has become either practically unavailable or dramatically less accessible in many states.[34] As a result, patients in states with limited or no access to abortion care may need to travel (sometimes far distances) to receive care.[35] 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 also strains providers and resources in states providing abortion access by increasing wait times at reproductive health care clinics. Dr. Verma discussed the many barriers patients must overcome before they can present for care, which can include finding a provider, securing child care, securing financial resources, and travel time. For example, Dr. Winchester observed that the wait in her clinic for a procedural abortion is currently about two and a half weeks. Dr. Belmonte witnessed wait times of up to six weeks at the hospital where he practiced in Colorado. 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 also force pregnant patients to jump through

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[34] 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).

[35] 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*, 113(4) Am. J. Public Health (Mar. 2023).

several hoops and make important medical decisions in an extremely limited time frame.

Several PRH doctors, including Dr. Winchester and Dr. Verma, note 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 allows 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 via telehealth is likely to harm patients and potentially remove the option of medication abortion. In sum, while the courts below decided to substitute their judgment for that of the FDA's expertise in concluding that the FDA's approved changes to the condition of use for mifepristone should be restricted in order to purportedly protect patients, the lower court orders will have the opposite result: they are likely to jeopardize and harm patient health.

II. Restricting Access to Mifepristone Impedes Patient Autonomy and Providers' Ethical Obligations

The Fifth Circuit's attempt to restrict FDA approval of studied and safe conditions of use of mifepristone limits the range of options providers can offer their patients, places providers in untenable positions, and impedes the provider-patient relationship. For over twenty years, providers have included the mifepristone-misoprostol regimen among the range of options for patients seeking abortion care and miscarriage management. As part of this, providers communicate the risks of each medically appropriate option, including treatment plans using mifepristone, providers and their patients consult on each plan, and the patient provides informed consent for their chosen treatment. However, if the District Court order, as modified, goes into effect, it may jeopardize providers' ability to provide mifepristone, even if it is the course of treatment the patient chooses after consultation with their provider and after providing informed consent. Providers should not be forced to withhold valid and safe medical options and should respect patient autonomy, where possible.

A. Restricting Access to Mifepristone Interferes with Patient Autonomy

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.[36] However, patient autonomy is eroded 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 select 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 abortion and for miscarriage management allows patients to avoid medically unnecessary pelvic exams and instrumentation, 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.

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

Moreover, patients may elect to use mifepristone during a later miscarriage or in response to fetal demise because mifepristone 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 a demised fetus in 8 to 12 hours, and the patient can often go home the same day if they desire. Without mifepristone, patients in their second and third trimesters who miscarry and must vaginally deliver the demised fetus can be 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 may be forced to listen to crying babies and celebrations while they mourn their own loss.

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 miscarriage will exacerbate existing distrust in the medical system.[37] Dr. Koyama

[37] The District Court distorted the history of eugenics, *see Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration,* No. 22-CV-00223, 2023 WL 2825871, at *31 (N.D. Tex. Apr. 7, 2023), 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

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, the Fifth Circuit's ruling, which purports to flip a switch and send the provision of care back to 2015, is likely to cause (and add to pre-existing) mass confusion about what is lawful to prescribe and how to prescribe it — all of which will exacerbate the already existing harms outlined herein. Providers may be chilled as they fear legal risk for prescribing medication in a manner that is scientifically proven to be safe and effective — and has been approved by the FDA — but has nevertheless been targeted by court orders and injunctions. If the Fifth Circuit's opinion is affirmed, providers will be left to attempt to navigate the chaos that will ensue. In the weeks or months it will take patients and prescribers to sort out the regulatory nightmare that the Fifth Circuit's Opinion seeks to restore, patients will struggle to access care and, for some patients, certain treatment options will be foreclosed altogether.

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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. Forcing a patient to carry a pregnancy to term is making reproductive choices on a patient's behalf. PRH decries any comparison between its mission to provide reproductive healthcare and the eugenics movement.

Mifepristone has been available in the United States 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 overwhelming majority of studied patients are satisfied with their decision.[38] Patients should be able to select medical treatment that they determine, in consultation with their provider, is the most appropriate for their care.

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

Respondents believe that the risks of mifepristone cannot be adequately communicated to patients, and patients therefore cannot provide informed consent for a treatment plan incorporating mifepristone. Contrary to this belief, providers, relying on both their experience and evidence-based studies, discuss those risks with their patients when describing different medical options. With this information at their disposal, patients who elect a course of treatment incorporating mifepristone can provide informed consent.[39]

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[38] *See e.g.*, Aiken, *supra* note 2, at 1, 4-5, tbl. 4 (study finding that 95.5% of participants who provided information about their self-managed abortion felt they had made the right choice for them).

[39] *See ACOG Committee Opinion No. 819*, *Informed Consent and Shared Decision Making in Obstetrics and Gynecology*, e34, e35-e36 (Feb. 2021).

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.[40] Providers, who studied for an extended number of years to provide high quality care, are best positioned to determine what medical information, including potential risks, to discuss with their patients to ensure they have the relevant information necessary to make an informed decision on appropriate medical treatment.[41]

As discussed *supra* Section I.A., the consensus of the medical community is that mifepristone, as used in medication abortion up through at least 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 mifepristone are heavy bleeding, nausea, and abdominal pain.[42] 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

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[40] *See id.* at e36.

[41] *See also* American Medical Association Code of Medical Ethics, *Opinion 2.1.1, Informed Consent* (2017).

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

abortion up to ten weeks gestation.[43] For example, less than 1% of patients obtain an emergency intervention for excessive bleeding.[44] Dr. Verma, who has been providing abortion and miscarriage management for nine years, cannot recall the last time a patient had an adverse effect with mifepristone, because it is *that* uncommon in her practice.[45]

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

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[43] *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).

[44] *See* ACOG, *Practice Bulletin No. 225*, *Medication Abortion Up to 70 Days of Gestation* (Oct. 2020, *reaff'd* 2023).

[45] 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. *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, No. 22-CV-00223, 2023 WL 2825871, at *25 (N.D. Tex. Apr. 7, 2023). Dr. Amy Caldwell, an 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.

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 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 medical or scientific evidence that warrants judicial overturn of 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.

CONCLUSION

For all the reasons set forth herein, PRH respectfully asks the Court to reverse the Fifth Circuit's Opinion affirming the portions of the District Court's order.

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Respectfully submitted,

s/ Janice Mac Avoy

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