Nos. 23-235, 23-236

IN THE

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL., Petitioners,

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DANCO LABORATORIES, L.L.C.,

Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL., Respondents.

ON WRITS OF CERTIORARI TO THE U.S. COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF OF THE WOMEN'S BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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INTERESTS OF AMICUS CURIAE1

The Women's Bar Association of the District of Columbia (WBA-DC) is one of the oldest women's bar associations in the country. Since 1917, the WBA-DC has advocated for the advancement of women and historically oppressed communities and upheld its mission to maintain the honor and integrity of the legal profession, promote the administration of justice, advance and protect the interests of women lawyers, promote their mutual improvement, and encourage a spirit of friendship. In support of its mission, the WBA-DC participates as *amicus curiae* before this Court and other courts throughout the nation to advocate for the rights of historically oppressed minorities, including women.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The Fifth Circuit elevates allegations of highly speculative, if not nonexistent, injuries to a handful of doctors over real evidence of the harms its decision will inflict on millions of women and society as a whole. The injuries alleged by Respondent Doctors (the "Doctors") are neither "actual" nor "imminent" but instead are based on an improbable chain of possibilities. The Doctors themselves do not prescribe mifepristone, and nothing requires them to do so. And

¹ Pursuant to Supreme Court Rule 37.6, no counsel for a party authored the brief in whole or in part, and no party, counsel for a party, or any person other than *amicus curiae* and their counsel made a monetary contribution intended to fund the preparation or submission of the brief.

they have a federal right to refuse to provide any abortion-related treatment.

On the other hand, restricting access to mifepristone will force women to seek out more invasive and potentially dangerous methods to terminate their pregnancies. Should women be unsuccessful in that regard and forced to carry their pregnancies to term, the unnecessary restrictions on access to mifepristone resulting from the Fifth Circuit's decision will impose on women much higher risks of experiencing medical complications, prolonged economic hardship, and even death. These harms will particularly and disproportionately affect our most vulnerable, including Black and indigenous women, low-income women, and women living in rural areas. And safe haven laws do not relieve the harms to women and others created by restricting mifepristone access. The Fifth Circuit decision and its resulting harms cannot be allowed to stand.

ARGUMENT

I. The Fifth Circuit Inappropriately Credited The Doctors' Speculative Injury Allegations And Erred In Finding Standing.

The Doctors failed to allege a cognizable legal harm and therefore do not have standing to sue. The Doctors' theory is: When they treat women experiencing complications from mifepristone, they must perform or complete an abortion or engage in procedures that facilitate an abortion. Pet. App. 24a. Some claim this violates their moral beliefs. Pet. App. 24a. Others claim it "diverts time and resources away from their ordinary patients," inflicts emotional distress, or risks exposing them to malpractice claims and increased insurance costs. Pet. App. 24a, 31a.

But these speculative and illusory claims are insufficient to show Article III standing. To have standing, the Doctors must demonstrate that: (i) they have suffered an injury in fact that is "concrete," "particularized," and "actual or imminent;" (ii) the injury was likely caused by the defendant; and (iii) the injury would likely be redressed by judicial relief. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). The Doctors have failed to meet that test.

The Doctors' tenuous claims rely on hypothetical patients suffering unforeseen complications that are neither "actual" nor "imminent." *Id.* A threatened injury must be "certainly impending to constitute injury in fact"—"allegations of possible future injury are not sufficient." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). But the Doctors have not alleged facts showing they have been forced to treat any patients under circumstances resulting in the harms they claim. *See* Pet. App. 20a-22a. None of the declarations relied on by the Fifth Circuit, for example, show that any of the Doctors objected to providing care for any patient, much less that such treatment caused the claimed harms to them or their medical practices.

Nor have they shown that it is "likely" or "predictable" that such patients would be treated by the Doctors in this case. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2566 (2019). The Doctors are not required to prescribe mifepristone. And, under the Church Amendments, they have a federal right to refuse to provide any abortion-related treatment if such treatment "would be contrary to [their] religious beliefs or moral convictions." 42 U.S.C. §§ 238n, 300a-7(b)(1). This statute even protects the Doctors from employment discrimination if they refuse to perform or assist in any abortion, removing any pressure they might feel to provide this treatment. 42 U.S.C. §§ 238n, 300a-7(c). The Doctors' brief opposing certiorari is telling in this respect. Despite responding at length to the government's arguments on standing, the Doctors failed even to mention the Church Amendments or to provide any explanation of why the federal conscience protections are insufficient to protect them from providing the abortion services they claim are at the root of the harm they have suffered as a result of the FDA's actions on mifepristone. Br. in Opp'n 19-39.

The Emergency Medical Treatment and Labor Act, 42 U.S.C. § 1395dd, does not require a different result, as that statute does not displace the Religious Freedom and Restoration Act, 42 U.S.C. § 2000bb-1(b), and would require such treatment only if it was the least restrictive means to save the patient's life, *see Austin v. U.S. Navy SEALs 1-26*, 142 S. Ct. 1301, 1305 (2022) (mem.) (Alito, J., dissenting) (explaining that the government has a "compelling interest in minimizing any serious health risk").

The Doctors' theory therefore, at best, relies on a "highly attenuated chain of possibilities," *Clapper*, 568 U.S. at 410. A patient must be prescribed mifepristone by a doctor who selects that treatment to meet the patient's medical needs. The patient must then develop statistically anomalous complications and seek care from a *different* doctor—one of the Doctors in this suit. The patient's complications must be of the exceedingly rare type that requires emergency abortion care. And the Doctor must be forced to perform those emergency services despite having a federal right to refuse to do so. If such an improbable string of events were sufficient to support standing, it "would make a mockery" of this Court's standing doctrine. *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009). And yet that is precisely the position the Doctors ask this Court to accept.

Paradoxically, the remedy the Doctors seek is more likely to *increase* the mental and emotional distress they allege in support of their standing. If mifepristone is removed from the market, more women may face medical complications related to abortions. Although misoprostol on its own is safe and effective, adding mifepristone reduces side effects. Compare Ruvani Jayaweera et al., Medication Abortion Safety and Effectiveness With Misoprostol Alone, JAMA Network Open (Oct. 27.2023), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2811114 (showing a success rate of misoprostol alone as 98.1%), with Luu Doan Ireland et al., Medical Compared with Surgical Abortion for Effective Pregnancy Termination in the First Trimester, 126 Obstetrics & Gynecology 22 (2015) (showing a success rate of 99.6% when mifepristone is taken in combination with misoprostol). Without mifepristone, the Doctors could confront more instances of abortion-related complications.

The Doctors nonetheless further claim that mifepristone has interfered with their medical practices by increasing the number of patients who have required medical care, costing them time and money. Br. in Opp'n 35. But it is unclear how this is an "economic harm." Pet. App. 31a. The Doctors do not allege that patients with mifepristone complications fail to pay their medical bills or that doctors are somehow compensated less for treating these patients. They assert only that patients who have complications from medication abortions require "more time and attention" than the "typical OB/Gyn patient." Pet. App. 25a (quoting Dr. Harrison Declaration ¶ 30). But *any* patient with complications related to pregnancy fits that mold. And any patient in any hospital diverts resources from other patients. The Doctors do not suffer and cannot allege a cognizable legal harm simply because they treat patients.

Likewise, there is no basis for the claim that the Doctors will have greater exposure to malpractice claims or higher insurance premiums if mifepristone is kept on the market. In their declarations, the Doctors did not assert that the complications from mifepristone increased their risk of facing malpractice claims or higher insurance premiums. Instead, the declarants stated that they faced an increased risk whenever they treated a patient with whom they had no "existing patient relationship or prior knowledge of the patient's medical history." All. for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-cv-00223-Z, Dkt. No. 1-53 (N.D. Tex. Nov. 18, 2022) (Declaration of Dr. Shaun Jester) at p. 5 ¶ 20; see also id. at Dkt. No. 1-50 (Declaration of Dr. Tyler Johnson) at p. 5 ¶ 15 (stating that they are in "higher risk situations" when they "treat women in emergency situations without crucial information"); id. at Dkt. No. 1-6 (Declaration of Dr. Jeffrey Barrows) at p. 5 ¶¶ 2223 (stating that doctors are in "riskier, emergen[cy] medical situations" when patients are treated by "hospitalists and emergency department physicians who have no prior history with these patients"). But this would be true of *any* new emergency room patient, whether treated for an ectopic pregnancy, a broken bone, or a gunshot wound. Under the Doctors' theory, any doctor would have standing to challenge the repeal of gun laws to avoid the costs of treating gunshot victims with no prior relationship with the hospitalists and emergency room doctors or to challenge reform of product liability regulations on the theory that more patients will arrive at hospitals with complicated injuries after severe accidents.

Moreover, pregnancy and birth complications are likely to *rise* if access to mifepristone is restricted, leading to unwanted pregnancies. Pregnancy is *more* hazardous to a pregnant person's health than having an abortion. *Infra* Section II.A.² Medication abortions are safer than routine procedures like colonoscopies and tonsillectomies. *Id.* In fact, in response to increasing costs of medical malpractice insurance, some states impose a mandatory fee on all physicians to support obstetrics and gynecology physicians facing litigation. For example, in Florida, the Florida Birth-Related Neurological Injury Compensation Association (NICA) imposes a \$250 fee on "all Florida

² See HealthDay News, Abortion Remains Medically Safe for U.S. Women (Nov. 24, 2021), https://healthlibrary.brighamand-womens.org/RelatedItems/6,1655538532.

physicians," and another fee is imposed against hospitals.³ Fla. Stat. Ann. §§ 766.302–316. For obstetrics and gynecology physicians, the annual fee is \$5,000 per provider.⁴ These fees are used "to pay for the care of children with certain birth-related neurological injuries specified by law."⁵ If an injury is covered by NICA, "the child and his or her family are not entitled to compensation through malpractice lawsuits." Id. Virginia has a similar law, the Virginia Birth-Related Neurological Injury Compensation Act, with similar fees. Va. Code §§ 38.2-5000–5021. It is therefore speculative at best that the malpractice rates of the Doctors will increase causing them irreparable harm. Even if that were the result, it is no different than the additional increase in such rates and expenses imposed by pregnancies.

There will be enormous consequences if the Court grants standing to the Doctors in this case. If the Doctors' alleged injuries were deemed sufficient for Article III standing, then any physician who disagrees with or morally objects to the effects of any drug will have standing to challenge that medication. For example, some physicians may object on moral grounds

³ Fla. Birth-Related Inj. Comp. Ass'n, *Non-Participating Physicians*, https://www.nica.com/medical-providers/non-participating-physicians.

⁴ Fla. Birth-Related Inj. Comp. Ass'n, *OBGYN'S: Frequently Asked Questions*, https://www.nicaofficial.org/obgyns/faq.html#:~:text=What%20does%20it%20cost%20to,credit %20on%20their%20malpractice%20insurance.

⁵ Fla. Birth-Related Inj. Comp. Ass'n, *Non-Participating Physicians*, https://www.nica.com/medical-providers/non-participating-physicians.

to contraceptive medication. Under the Doctors' theory, any doctor harboring such objections would have standing to oppose FDA action with respect to any birth control medication—even though those medications have been approved and prescribed for decades. Nor would such a theory be logically limited to doctors. Physician assistants and nurses too would have standing to challenge any action on a federally approved contraceptive medication. Such challenges would significantly complicate medical care and lead to exponential delays in patient access to safe and medically efficacious drugs. At a time when the FDA's approval process has been criticized for involving long delays, see, e.g., Conor Friedersdorf, The Death Toll of Delay, The Atlantic (Aug. 23, 2021), granting standing to every medical professional to challenge FDA approval will exacerbate those delays.

The law protects physicians from having to provide care to which they object on moral grounds. But no law allows a physician to dictate, based on religious or moral views, the medically safe care that another physician can provide. The Fifth Circuit's decision stretches standing doctrine beyond its limits. If affirmed, the cost would be borne not just by the courts that would be forced to hear a deluge of claims but also by patients who would be deprived of a safe and important form of reproductive health care.

II. The Fifth Circuit Decision Fails To Address The Suffering It Will Impose On Women And The Harms It Will Impose On Society.

While giving credence to the alleged injuries of the Doctors, the Fifth Circuit failed to take account of the harms its decision will impose on women and society at large.

Many women, including women throughout the legal profession, continue to confront significant barriers and setbacks to career advancement and quality of life if they lack control over the timing and size of their families. *Amicus* members have personally benefited from access to abortion and relied on the guarantee of bodily autonomy to advance their own careers and to promote the position of women in the legal field as a whole. Restrictions on access to mifepristone perpetuate barriers to women's advancement and hinder efforts to provide equal opportunities to all. The Fifth Circuit gave short shrift to that reality and to other harms that result from unwanted pregnancies.

A. Millions Of Women Will Suffer If Access To Mifepristone Is Restricted.

Allowing the Fifth Circuit to roll back evidencebased improvements to the rules on the prescription of mifepristone profoundly harms women.

Over the past decade, medication abortion has become an increasingly common way in which women have exercised the choice to determine the timing and size of their families—and, indeed, their quality of life. In 2021, the most recent year for which the CDC reported abortion-related data, 53% of abortions were early medication abortions (i.e., nonsurgical abortions at 9 weeks' gestation or less).⁶ In areas that broke down the data by weeks of gestation and method type, medication abortions accounted for an even greater share—70.6% of abortions at 6 weeks' gestation or less and 61.6% of abortions at 7 to 9 weeks' gestation. Kortsmit et al., *supra*, at 7. Overall, these numbers reflect a 137% increase in early medication abortions between 2012 and 2021. *Id.* at 6–7. And, as of 2020, the vast majority of medication abortions—more than 98%—were provided using the two-step mifepristonemisoprostol regimen. Rachel K. Jones, Marielle Kirstein & Jesse Philbin, *Abortion Incidence and Service Availability in the United States*, 2020, 54 Persps. on Sexual & Reprod. Health 128, 130 (2022).

It therefore is no surprise that with critical technological advancements, increased access to medication abortion, whether through telemedicine or otherwise, is more pressing than ever. *See* Society of Family Planning, #WeCount Report — April 2022 to March 2023 at 3 (June 15, 2023) (observing a significant increase in abortions provided by virtual clinic telehealth providers in recent years). Women may seek out telemedicine to obtain a medication abortion for a variety of reasons, including the inability to afford an in-clinic abortion, fear that a partner or family member would find out if they tried to go to a clinic,

⁶ Katherine Kortsmit et al., CDC, Abortion Surveillance — United States, 2021, 72 Morbidity & Mortality Wkly. Rep. 1, 6 (2023), https://www.cdc.gov/mmwr/volumes/72/ss/pdfs/ss7209a1-H.pdf; see also Rachel K. Jones et al., Medication Abortion Now Accounts for More than Half of All US Abortions, Guttmacher Inst. (Dec. 1, 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

too long of a distance to the nearest clinic, and an inability to take time off work or school to go to a clinic. See Abigail R. A. Aiken, Jennifer E. Starling & Rebecca Gomperts, Factors Associated with Use of an Online Telemedicine Service to Access Self-Managed Medical Abortion in the US, 4 JAMA Network Open 1, 4 (2021). Normalizing the use of telemedicine to deliver medication-abortion care and meet this need entails no parade of horribles. To the contrary, it has been widely studied and endorsed.

For example, the World Health Organization (WHO) has recommended telemedicine as one way for trained health workers to deliver medication-abortion services in whole or in part. World Health Org., Abortion Care Guideline 95 (2022), https://iris.who.int/bitstream/handle/10665/349316/9789240039483eng.pdf (relying on a systematic review of studies spanning Bangladesh, Cambodia, Egypt, Indonesia, Canada, Peru, and the United States). In support of this recommendation, WHO specifically noted that "[i]n studies comparing telemedicine with in-person" medication-abortion services, "there was no difference between the two groups in rates of successful abortion or ongoing pregnancies," and that "[r]eferrals for surgical intervention were fewer among women who used telemedicine." Id.

Illustrating just how well-accepted and safe mifepristone is, WHO goes one step further, recommending self-managed medication abortion at up to 12 weeks' gestation as yet another alternative to in-person care. *Id.* at 98–99. That recommendation is grounded in the evidence. The first U.S. study on selfmanaged medication abortion using the two-step mifepristone-misoprostol regimen found it to be safe and effective. Abigail R. A. Aiken et al., Safety and Effectiveness of Self-Managed Medication Abortion Provided Using Online Telemedicine in the United States: A Population Based Study, 10 Lancet Reg'l Health – Americas 1, 4, 6 (2022). It showed a 0.8% rate of overall adverse events for self-managed medication abortions at less than 10 weeks' gestation. Id.; see also Dana M. Johnson et al., Safety and Effectiveness of Self-Managed Abortion Using Misoprostol Alone Acquired from an Online Telemedicine Service in the United States, 55 Persps. on Sexual & Reprod. Health 4 (2023) (noting safety of self-managed medication abortion using misoprostol alone).

Given the safety and efficacy of mifepristone even in telemedicine and self-managed abortion settings—the Fifth Circuit's decision restricting access to mifepristone does far more harm than good on a number of fronts.

For one, restricting access to mifepristone may force those seeking abortions to pursue more invasive or potentially dangerous procedures. Experience has borne this out. Past abortion restrictions have led those seeking abortions to depend on more self-managed methods. Granted, some of those methods are generally safe and effective, such as taking mifepristone in combination with misoprostol outside of a clinical setting. See Nisha Verma & Daniel Grossman, Self-Managed Abortion in the United States, 12 Current Obstetrics & Gynecology Reps. 70, 72 (2023); Abigail R. A. Aiken et al., Requests for Self-Managed Medication Abortion Provided Using Online Telemedicine in 30 US States Before and After the Dobbs v Jackson Women's Health Organization *Decision*, 328 JAMA 1768 (2022).

But other self-managed methods are significantly less effective and more dangerous. Women left with no other choice in light of the Fifth Circuit's decision, including women experiencing intimate partner violence or human trafficking, may resort to drastic measures in an effort to terminate their pregnancies. See Haleigh P. Ferro et al., Disproportionate Impact of Abortion Restriction: Implications for Emergency Department Clinicians, 69 Am. J. Emergency Med. 160, 161-62 (2023). These measures may include ingesting alcohol, castor oil, and bleach, engaging in traumatic physical activity such as falling down stairs, inserting unsterile objects or liquids into the body, and attempting to physically dislodge the fetal mass via strong compressions on the abdomen. Id. at 162.

Still other self-managed methods, such as ingesting botanicals, herbs, and vitamins, are less extreme. See Aiken et al., Safety and Effectiveness of Self-Managed Medication Abortion, supra, at 2. But many of these methods can nonetheless be ineffective. And they can be harmful when they mislead the person seeking to terminate the pregnancy into thinking they are no longer pregnant, when in fact they still are. See Verma & Grossman, supra, at 72. That, too, may result in a delay that leads to an eventual surgical abortion. To be clear, while surgical abortions are generally safe, they are undoubtedly a more invasive procedure that could be avoided with sufficient access to medication abortion. Women who cannot access in-clinic abortion care also may be forced to carry their pregnancies to term against their choice and contrary to their own interests, placing them at an even higher risk of experiencing medical complications and economic hardship.

Pregnancy and childbirth are far riskier for women than abortion and are associated with increased levels of hypertension, gestational diabetes, preeclampsia, and eclampsia. See CDC, Data on Selected Pregnancy Complications in the United States (2019); U.S. Dep't of Health & Human Servs., Nat'l Instit. of Health, Am I at Risk for Gestational Diabetes? (2012); U.S. Dep't of Health & Human Servs., Off. on Women's Health, Pregnancy Complications (2019). In fact, carrying a pregnancy to term carries a risk of death 14 times higher than for early abortion. Elizabeth G. Raymond & David A. Grimes, The Comparative Safety of Legal Induced Abortion and Childbirth in the United States, 119 Obstetrics & Gynecology 215, 216-18 (2012). And these risks have become more pronounced in recent years. Between 2019 and 2021, maternal-mortality rates *increased* by almost 60%, with Black women continuing to face a much higher risk of maternal death. Donna L. Hovert, CDC, Maternal Mortality Rates in the United States, 2021 (Mar. 2023). Moreover, pregnancy and childbirth complications have been on the rise, increasing 31.5% between 2014 and 2018. Blue Cross Blue Shield, Trends in Pregnancy and Childbirth Complications in the U.S. 1 (2020).

Take, for example, hemorrhaging, a life-threatening complication that could arise in the course of both abortion and childbirth. In one study, national rates of hemorrhage postpartum—one of the leading causes of preventable maternal death-were five times higher than rates of hemorrhage reported in the study of self-managed medication abortion. Aiken et al., Safety and Effectiveness of Self-Managed Medication Abortion, supra, at 7. In another study, a higher percentage of women who were unable to access abortion and forced to carry their pregnancies to term reported potentially life-threatening conditions, including postpartum hemorrhage, compared to women who were able to obtain an abortion. Caitlin Gerdts et al., Side Effects, Physical Health Consequences, and Mortality Associated with Abortion and Birth After an Unwanted Pregnancy, 26 Women's Health Issues 55, 55, 58 (2016). Moreover, the disproportionate impact on Black women is clear: Black women are at "approximately 5 times higher risk for death" due to postpartum hemorrhage compared to White women. Cynthia Gyamfi-Bannerman et al., Postpartum Hemorrhage Outcomes and Race, 219 Am. J. Obstetrics & Gynecology 185.e1, 185.e6 (2018).

Limiting the safe and effective means by which women can choose to end pregnancies early means increasing the potential for more women to experience these health risks, some of which are life-threatening.

If that were not enough, women denied an abortion and forced to carry their pregnancies to term are more likely to experience economic hardship for years afterward, compared to women who are able to terminate their pregnancies. Diana Greene Foster et al., Socioeconomic Outcomes of Women who Receive and Women who Are Denied Wanted Abortions in the United States, 108 Am. J. Pub. Health 407, 412–13 (2018). Women forced to carry their pregnancies to term are less likely to be able to pay for basic living expenses, such as food, housing, and transportation. Diana Greene Foster et al., Comparison of Health, Development, Maternal Bonding, and Poverty Among Children Born After Denial of Abortion vs After Pregnancies Subsequent to an Abortion, 172 JAMA Pediatrics 1053, 1058 (2018). And their likelihood of incurring unpaid debts that are 30 days past due, as well as experiencing evictions and bankruptcies, increases substantially. Sarah Miller, Laura R. Wherry & Diana Greene Foster, The Economic Consequences of Being Denied an Abortion, 15 Am. Econ. J. 394 (2023). That is a particular cause for concern when viewed in context: As it is, 75% of abortion patients are low-income, and 49% live below the poverty line. Jenna Jerman, Rachel K. Jones & Tsuyoshi Onda, Guttmacher Inst., Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008 at 1 (2016). Thus, the need for more accessible mifepristone is particularly acute for low-income women. Indeed, one study found that a higher proportion of the population living below the poverty line in a given county correlated with greater demand for telemedicine services providing medication abortion. Aiken, Starling & Gomperts, *supra*, at 9.

Restricting access to mifepristone also disproportionately affects women living in rural areas. As the American College of Obstetricians and Gynecologists has observed, "[r]estrictions and requirements of clinicians who provide abortions" and "restrictions on the use of telemedicine" disproportionately affect rural people's access to abortion. American College of Obstetricians and Gynecologists Committee on Health Care for Underserved Women, Increasing Access to Abortion: ACOG Committee Opinion No. 815, 136 Obstetrics & Gynecology e107, e112 (2020). That makes sense. Living far from an abortion provider can effectively make abortion inaccessible, as traveling long distances requires paying for transportation, taking time off work, and arranging for childcare. Jonathan M. Bearak, Kristen Lagasse Burke & Rachel K. Jones, Disparities and Change over Time in Distance Women Would Need to Travel to Have an Abortion in the USA: A Spatial Analysis, 2 Lancet Pub. Health e493, e498 (2017). These are burdens that can be insurmountable, especially for low-income women. And by that same logic, requiring multiple inperson follow-up visits, including to obtain misoprostol, is simply an exceptionally onerous ask. Cf. id. (pre-abortion in-person counseling requirements).

By the same token, many indigenous people encounter high barriers to accessing medication abortion. Tribal health facilities have faced extraordinary difficulties obtaining mifepristone. See Katherine Glaser & Jennifer Whitehair, Missing Mifepristone at Tribal Health Facilities Serving Native Americans, 104 Contraception 36, 37 (2021). That is all the more concerning given many Indian Health Service facilities are not equipped to provide any abortion services at all. Id.; Shaye Beverly Arnold, Reproductive Rights Denied: The Hyde Amendment and Access to Abortion for Native American Women Using Indian Health Service Facilities, 104 Am. J. Pub. Health 1892, 1892 (2014). One study noted that, for their tribal community in Arizona, the "nearest other source of healthcare is 75 miles away," which makes restricted access to mifepristone particularly harmful for

indigenous women living in rural areas. Glaser & Whitehair, *supra*, at 37.

The forward-looking steps the FDA has undertaken in recent years, including allowing distribution of mifepristone through retail pharmacies and easing requirements for in-person visits, are designed to help bridge some of these gaps in health care. And yet, this evidence-based progress in meeting women's healthcare needs will be all for naught, gutted, and undone by the Fifth Circuit's haphazard ruling.

Further compounding these harms, the final blow is the Fifth Circuit's choice of the remedy in this case. The Fifth Circuit's "stay" results in the temporary removal of Mifeprex (not to mention a more prolonged removal of generic mifepristone) from shelves while the drug is relabeled and brought into compliance. For however long that process takes—and Petitioners contend it will be an extended period of time—the Fifth Circuit's decision entirely divests women of an option to end pregnancy early through a safe and effective method of medication abortion.

B. Safe Haven Laws Do Not Remedy The Harms Of Denying Women Access To Safe And Effective Health Care.

The harms to women, contrary to what some have proposed, are, furthermore, not extinguished through the presence of safe haven laws. *See, e.g.*, Brief of Amici Curiae Women Injured by Abortion, *et al.* in Opposition to Stay, *U.S. Food & Drug Admin. v. All. for Hippocratic Med.*, Nos. 22A901, 22A902 (U.S. Apr. 17, 2023). Safe haven laws permit the anonymous relinquishment of infants in designated locations to authorized personnel without fear of criminal consequence for that abandonment. *See, e.g.*, D.C. Code §§ 4-1451.01–08 (Newborn Safe Haven). All 50 states and the District of Columbia have enacted such laws, each with different requirements and restrictions. The differences are numerous and include the categories of facilities that qualify as safe surrender sites, individuals authorized to surrender infants, obligations to preserve the anonymity of those relinquishing the infants, and other caretaking and administrative responsibilities of the acceptors. *See Infant Abandonment*, Guttmacher Inst. (last updated Sept. 1, 2023), https://www.guttmacher.org/state-policy/explore/infant-abandonment.

Critically, however, none of the safe haven laws alleviate the harms to women presented by the restriction of medication abortion. And they further present unique ethical, legal, and administrative concerns. Those concerns will become all the more serious if safe haven programs must be increasingly relied on to bear the burdens imposed by unwanted births on women and society broadly.

1. Safe Haven Laws In No Way Address The Harms To Women Presented By Forced Pregnancy.

As an initial matter, safe haven laws cannot substitute for abortion. No matter how well-intentioned or implemented, they do nothing to address the immediate circumstances of an unwanted pregnancy. By design, safe haven laws presuppose a pregnancy carried to term. Pregnancy, as addressed *supra*, places unique demands on the female body and creates additional economic costs. These harms to women, which extend past birth but begin and compound over the course of the pregnancy, cannot begin to be addressed by the option to surrender a baby after live delivery.

This should not be surprising, as safe haven laws were not enacted to address pregnancy but rather the adjacent yet distinct issues of infant abandonment and infanticide. See Rebecca F. Wilson et al., CDC, Infant Homicides Within the Context of Safe Haven Laws—United States, 2008–2017, 69 Morbidity & Mortality Wkly. Rep. 1385 (2020). In essence, the security afforded by safe haven laws to relinquishing parents aims to protect infants. Offering immunity for responsible abandonment can indeed provide incalculable relief for new mothers who would otherwise be faced with difficult and markedly worse choices. But these laws were not designed to meet the needs of women who do not want to be pregnant. Naturally, they fall short of doing so in many ways.

> 2. Relying On Safe Haven Laws To Address The Consequences Of Restricting Abortion Access Imposes Additional Social Harms.

Setting aside the rights of and harms to birth mothers, safe haven laws also present additional unanswered questions of legal rights and associated harms to broader society. Among the differences between safe haven laws is whether the non-birth parent must be notified when the birth parent relinquishes the infant, which is not required in a majority of states. While goals of total anonymity and immunity for infant abandonment may be better achieved without a notice requirement, scholars have criticized safe haven laws as promoting potential infringements on the rights of non-relinquishing parents. See, e.g., Dayna R. Cooper, Fathers Are Parents Too: Challenging Safe Haven Laws with Procedural Due Process, 31 Hofstra L. Rev. 877 (2003). Similarly, the anonymity protected by safe haven laws also impinges on an infant's right to, "as far as possible" "know and be cared for by his or her parents." U.N. Convention on the Rights of the Child art. 7, Nov. 20, 1989, 1577 U.N.T.S. 3. These questions, which are inherent and unavoidable consequences of key incentives of these laws, remain unaddressed by any court to date and persist as sources of potential social harm with impact proportional to the use of the systems.

Nor can these concerns of principle be dismissed in light of the practical effectiveness of safe haven programs. Indeed, research on the effectiveness of safe havens is wanting. Most states do not require promotion or education of their safe haven programs, allocate resources to track wellness or other outcomes of relinquished infants, or have established mechanisms for reporting these statistics. It is thus unclear whether any available data accurately reflects the impact of the programs, and it is difficult to gauge impact at all.

Where data is available, they raise questions as to whether safe haven laws are an effective solution for alleviating the concerns that they were implemented to address. Although widespread safe haven laws have coincided with a decline in infant homicides on the day of birth, infants are still more likely to die on their first days of life than any other point in their lifetimes by at least 5.4 times. *See* Wilson et al., *supra*.

Relatedly, the available data does not support the image of a country in which these programs are commonly used. The District of Columbia is one jurisdiction where the Child and Family Services Agency has published several Newborn Safe Haven Annual Reports. Since its policy was first enacted in 2009, one infant was reported relinquished in the decade of 2012-2022. See Newborn Safe Haven Temporary Act of 2009, D.C. Law 18-29; D.C. Child & Fam. Servs. Agency, Newborn Safe Haven Annual Reports 2012-2022,https://cfsa.dc.gov/service/safe-havens-newborns. In contrast, the District of Columbia reported over 4,400 abortions in 2020 alone. See Katherine Kortsmit et al., CDC, Abortion Surveillance — United States, 2020, 71 Morbidity & Mortality Wkly. Rep. 1 (2022).http://dx.doi.org/10.15585/mmwr.ss7110a1. This difference between the use of safe havens and abortions is reflected nationally as well. According to the National Safe Haven Alliance, around 4,700 infants have been relinquished since the enactment of the first safe haven law by the Texas legislature in See Our Cause, Nat'l Safe Haven All., 1999. https://www.nationalsafehavenalliance.org/our-

cause. Abortions, of which there are hundreds of thousands annually, outnumber the surrendered babies by several orders of magnitude. *See* Jeff Diamant & Besheer Mohamed, *What the Data Says About Abortion in the U.S.*, Pew Rsch. Ctr. (Jan. 11, 2023), https://www.pewresearch.org/short-

reads/2023/01/11/what-the-data-says-about-abortionin-the-u-s-2. These data are consistent with research showing that most women will not surrender a baby to adoption, despite being aware of that option, and instead become parents if they cannot obtain an abortion and are forced to carry an unwanted pregnancy to term. See Gretchen Sisson et al., Adoption Decision Making Among Women Seeking Abortion, 27 Women's Health Issues 136, 139 (2017).⁷

The vast numerical difference in magnitude not only suggests that abortions serve real needs not addressed by safe havens but also raises the question of whether safe havens could, practically, support hundreds of thousands more infants than they do at present. Are safe haven programs adequately funded, operated, and publicized to handle and provide best outcomes in the face of an immense and sudden increase in cases? Beyond presenting challenges to gauging these programs recludes accurately extrapolating this solution's potential.

And yet, it is certain that an increase in the reliance on safe haven programs will lead directly to increased strain on the country's foster care system. Though the intake process differs by state and in some cases by local jurisdiction, most, if not all,

⁷ The harms flow both ways, as greater restrictions on access to abortion services have also been correlated with higher infant-mortality risk. Roman Pabayo et al., *Laws Restricting Access to Abortion Services and Infant Mortality Risk in the United States*, 17 Int'l J. Environ. Rsch. & Pub. Health 1 (2020).

relinquished infants travel through foster care or preadoptive homes on the path to adoption. At the same time, the number of licensed foster homes has not kept pace with demand, even dramatically decreasing in some states. See Total Licensed Foster Homes 2018-2023, Fostering Media Connections, https://www.fostercarecapacity.com/data/total-licensed-foster-homes. As investigated by numerous media outlets, the need has pushed states to create ad hoc group homes in settings such as hotels, offices, casinos, emergency rooms, and juvenile detention centers.⁸ It should be noted that any additional use of safe haven programs will contribute further pressure to an already-exhausted foster care system.

Even if the country could guarantee a foster home for every child in need, harms remain. Providing a child with a safe home prior to adoption can be a rewarding and transformative experience, and foster parents can profoundly change the lives of their foster

⁸ See, e.g., Neena Satija, For Troubled Foster Kids in Houston, Sleeping in Offices is "Rock Bottom," Texas Trib. (Apr. 20, https://www.texastribune.org/2017/04/20/texas-foster-2017). care-placement-crisis; Hannah Lawrence, Georgia Foster Care System in Crisis Due to Shortage of Foster Homes, WTVC (Feb. 15, 2017), https://newschannel9.com/news/local/georgia-fostercare-system-in-crisis-due-to-shortage-of-foster-homes; Paige Sutherland et al., Inside America's Critical Shortage of Foster Care Homes, WBUR (July 20, 2023), https://www.wbur.org/onpoint/2023/07/20/inside-americas-critical-shortage-of-fostercare-homes; Jazmin Orozco Rodriguez, Kids Housed in Casino Hotels? It's a Workaround as U.S. Sees Decline in Foster Homes, NPR (June 14, 2023), https://www.npr.org/sections/healthshots/2023/06/14/1181975688/foster-kids-in-casino-hotels-decline-in-foster-homes.

children for better. But the system is far from perfect. There are ample reports on foster care youth experiences of childhood homelessness, physical and sexual abuse, substance abuse, incarceration, and teen pregnancy. Research has also shown that foster care youth score lower on standardized testing and report lower earnings and employment rates as compared to their peers.⁹ Many of these struggles are further exacerbated among minority youth. It would be unrealistic to celebrate the second chance that safe haven laws provide without simultaneously recognizing that these risks could become any relinquished infant's reality.

The complexities presented here demonstrate that safe haven laws do not meaningfully alleviate the harms caused by unnecessarily restricting access to abortion. To be clear, *amicus* does not intend to argue for or against these laws generally; rather, *amicus* aims to present considerations to further define and contextualize them. In so doing, *amicus* hopes to present safe haven laws as policy solutions that are complex, nuanced, and ultimately directed at an entirely different social issue from abortion.

⁹ See U.S. Dep't of Health & Human Servs., Children's Bureau, Office of the Admin. for Children & Families, *Data and Statistics: NYTD*, https://www.acf.hhs.gov/cb/data-research/data-and-statistics-nytd; Huiling Feng et al., *Memo from CalYOUTH: Predictors of Homelessness at Age 21*, Chapin Hall at the Univ. of Chicago, https://www.chapinhall.org/wp-content/uploads/CY_PH_IB0520.pdf.

CONCLUSION

This Court should reverse the judgment of the Fifth Circuit.

Respectfully submitted,

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