IN THE

United States Court of Appeals

FOR THE FIFTH CIRCUIT

Case No. 23-10362

Alliance for Hippocratic Medicine, *et al.*,
Plaintiffs-Appellees,
v.

U.S. Food & Drug Administration, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court for the
Northern District of Texas, Amarillo Division
Civil Action No. 2:22-CV-223-Z

BRIEF OF OVER 100 REPRODUCTIVE HEALTH, RIGHTS, AND JUSTICE ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS AND THE MOTIONS FOR STAY PENDING APPEAL

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PARTIES

Amici curiae certify that they have no outstanding shares or debt securities in the hands of the public, and they have no parent companies. No publicly held company has a 10% or greater ownership interest in any of the *amici curiae. Amici curiae* are unaware of any persons with any interest in the outcome of this litigation other than the signatories to this brief and their counsel, and those identified in the party and *amicus* briefs filed in this case.

Dated: April 11, 2023

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INTEREST OF *AMICI* AND SUMMARY OF ARGUMENT[1]

Amici are over 100 reproductive health, rights, and justice organizations, as well as other organizations with a strong interest in access to reproductive care. Several *amici* have directly seen the importance of medication abortion to individuals' health and bodily autonomy, as well as mifepristone's efficacy and safety as a tool for achieving those goals. These *amici* have a unique window into the benefits mifepristone provides and the immense challenges people would face if the decision below takes effect. And all of these organizations are well-suited to serve as *amici*, as they have an interest in ensuring that all individuals have access to reproductive healthcare services and the resources necessary to support autonomy. In addition, several *amici* represent abortion providers and patients and have experience litigating cases involving plaintiffs and their experts; they are well-versed in the scientific evidence offered by the parties. A complete list of *amici* can be found in the Appendix.

The district court ordered an unprecedented stay of the FDA's longstanding approval of mifepristone, threatening millions of people's access to time-sensitive medication essential to reproductive health based on faulty and discredited data. *See* Memorandum Opinion and Order, *Alliance for Hippocratic Med. v. U.S. FDA*, No.

[1] No party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and no person other than *amici*, its members, or its counsel contributed money intended to fund preparing or submitting the brief.

22-cv-00223-Z (N.D. Tex. Apr. 7, 2023), ECF No. 137 [hereinafter Order]. In granting plaintiffs' motion for a stay, the district court effectively made itself, not the agency, the expert evaluator of drug safety, cherry-picking from debunked data to opine about the purported dangers of medication abortion. The court maintained that the FDA's 2000 approval of mifepristone ignored "safety concerns," suggesting that the agency acquiesced to "political pressure to forego its proposed safety precautions." *Id*. at 57. Despite the fact that the challenged approval has been in effect for over twenty years, the court—citing nothing more than plaintiffs' assertions in their brief—declared that medication abortion causes "physical and emotional trauma," "mental and monetary costs," and death. *Id*. at 61-62.

The decision contravenes basic tenets of administrative law and principles of Article III jurisdiction. It is also contrary to the immense wealth of medical evidence demonstrating conclusively that medication abortion is one of the safest medication regimens in the United States and around the world. The FDA approved mifepristone over twenty years ago in recognition of the fact that it is safe, effective, and medically necessary. This evidence is even more compelling today, as decades of study and practice have confirmed mifepristone's efficacy and safety. The district court's decision, relying on self-serving anecdotal data and discredited expert testimony, flies in the face of both this conclusive and rigorous scientific evidence and the proper role of a district court reviewing agency decision-making.

The decision below will have immediate and life-threatening consequences. Since its approval, more than five million people in the United States have used mifepristone for medication abortion and miscarriage management, and the two-drug medication abortion regimen approved by the FDA now accounts for 53% of all abortions in the United States. Today, with abortion access already severely restricted nationwide, mifepristone's availability is critically important. If the decision below takes effect, people even in states where abortion remains legal or protected will be denied access to mifepristone, imperiling access to abortion and jeopardizing the health of persons unable to timely obtain care. Neither science nor law supports this result, and this Court should issue the requested emergency relief.

ARGUMENT

I. Mifepristone Is Safe, Effective, and Widely Used.

Mifepristone is one of two medications (along with misoprostol) that are most used to terminate an early pregnancy—often referred to as medication abortion. Medication abortion is central to reproductive healthcare today. Thousands of people in the United States use mifepristone each year, and over twenty years of evidence reinforces the FDA's conclusion that medication abortion with mifepristone is undeniably safe and effective.[2] Medication abortion has become the most common

[2] *See A Private Choice for Early Abortion*, Danco, https://www.earlyoptionpill.com/ (last visited Apr. 11, 2023) (brand-name mifepristone has been used by over 5 million patients in the U.S.);

method of abortion in the United States, both because of its safety and efficacy and because many patients prefer it.[3]

The FDA approved mifepristone in 2000 after a thorough, nearly five-year scientific review determined it was safe for widespread use. Mifepristone had already been approved in multiple countries across the world before being approved for use in the United States.[4] The FDA updated the evidence-based regimen on the drug's label in 2016, reflecting an increase in the gestational age limit from 49 to 70 days, a reduction in the number of in-person clinic visits to one, and the prescription of the drug by a broader set of healthcare providers, relying on new data underscoring mifepristone's safety without these impediments.[5]

In its 2016 approval, the FDA relied on no fewer than 12 independent clinical studies, collectively representing "well over 30,000 patients," and conclusively showing "serious adverse events" at rates "generally far below 1.0%."[6] *Hundreds* of additional high-quality studies conducted since mifepristone's 2000 approval show the same. Mifepristone has been used in over 600 published clinical trials and

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Kaiser Family Found., *The Availability and Use of Medication Abortion* (Feb. 24, 2023), http://bit.ly/3n0LUme (2.75 million people between 2000 and 2016 used brand-name mifepristone for an abortion).

[3] *Id.*; Pak Chung Ho, *Women's Perceptions on Medical Abortion*, 74 Contraception 11 (2006).

[4] U.S. FDA, Medical Officer's Review of NDA 20-687, at 2 (Nov. 1999), https://bit.ly/3TSM77p; *see* Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. Med. 57 (2022).

[5] *See* FDA Ctr. for Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 5, 14-17 (Mar. 29, 2016) ("2016 Approval"), https://bit.ly/3n5zUzZ.

[6] *Id.* at 1, 50, 56.

discussed in nearly 800 medical reviews.[7] Indeed, after reviewing all available science, the National Academies of Sciences, Engineering, and Medicine ("National Academies"), a universally respected non-partisan advisory institution, concluded that abortion by any method is extremely safe, and the risks of medication abortion are "similar in magnitude to the reported risks of serious adverse effects of commonly used prescription and over-the-counter medications," such as "antibiotics and NSAIDS"[8] (non-steroidal anti-inflammatory drugs, such as ibuprofen and aspirin)—medications millions of people take daily.[9]

Mifepristone carries extremely low risks of complication or negative health consequences. It also has an exceedingly low rate of major adverse events, such as hospitalization or serious infection. The FDA's 2016 approval cited a host of studies showing that the rate of major adverse events was roughly 0.3%,[10] with multiple studies reporting even lower rates of infection (such as 0%, 0.014%, and 0.015%[11]). The risk of death hovers around zero (only 13 recorded deaths even possibly related to medication abortion, or roughly 0.00035%)[12]—less than the risk of complications

[7] Based on a review of publications on PubMed.
[8] Nat'l Acads. of Sci., Eng'g. & Med., *The Safety and Quality of Abortion Care in the United States* 45, 56-68, 79 (2018) ("National Academies Report"), http://nap.edu/24950.
[9] Pamela Gorczyca et al., *NSAIDs: Balancing the Risks and Benefits*, U.S. Pharmacist (Mar. 17, 2016), http://bit.ly/3YLbw3x.
[10] 2016 FDA Approval, *supra* note 5, at 56.
[11] *Id.* at 54.
[12] ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report: "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018,"* Univ. of Cal., S.F.: Issue Brief, 1 (Apr. 2019), https://bit.ly/3Tqn1fY; *see also* 2016 FDA Approval, *supra* note 5, at 8, 47-51.

from the use of Viagra[13] or getting one's wisdom teeth removed.[14] Moreover, the FDA has noted that the very same complications can arise during a miscarriage or procedural abortion[15] and "the physiology of pregnancy may be a more plausible risk factor" than mifepristone for rare serious infections following use.[16]

Just as importantly, mifepristone *works*. Studies show that mifepristone, combined with misoprostol, has a 99.6% success rate in terminating pregnancies.[17] A misoprostol-only regimen is also safe and effective, but it can have more side effects, and some studies suggest it has a lower success rate.[18]

Instead of citing any of this authoritative data, the district court, "improperly substitut[ing] its judgment for that of the agency," relied on articles and scholars that have been debunked. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2570 (2019). For

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[13] Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 JAMA Network 590 (Feb. 2, 2000) (Viagra associated with 4.9 deaths per 100,000 prescriptions).

[14] ANSIRH, *Safety of Abortion in the United States*, Univ. of Cal., S.F.: Issue Brief # 6, 1, 1-2 (Dec. 1, 2014), https://bit.ly/3JmawgA (wisdom tooth complication rate is roughly 7%, compared to 2.1% of abortions; complication for tonsillectomies is approximately 4x higher than abortions).

[15] U.S. FDA., Mifeprex Prescribing Information 1, 2, 5 (revised Mar. 2016), https://bit.ly/3Z0kGJy; *see id.* at 16 ("[R]arely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, [procedural] abortion, medical abortion, or childbirth").

[16] Janet Woodcock, M.D., Director, Ctr. for Drug Eval. & Res., to Donna Harrison, M.D., et al., Denying Citizen Petition Asking the FDA to Revoke Approval of Mifeprex 25-26 n.69 (Mar. 29, 2016), http://bit.ly/3KhGAEl.

[17] Luu Doan Ireland et al., *Medical Compared with Surgical Abortion for Effective Pregnancy Termination in the First Trimester*, 126 Obstetrics & Gynecology 22 (2015), http://bit.ly/42jHK9n. Studies have also shown that self-managed medication abortion is just as effective. *See, e.g.*, 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—Ams. 1 (2022), https://bit.ly/3TumJ7H.

[18] Kaiser Family Found., *supra* note 2.

example, Dr. Coleman's study purporting to show the mental health consequences of abortions has been rejected by nearly every court to consider it and has "been almost uniformly rejected by other experts in the field." *Planned Parenthood of Ind. & Ky., Inc. v. Comm'r, Ind. State Dep't of Health*, 273 F. Supp. 3d 1013, 1036 (S.D. Ind. 2017), *aff'd*, 896 F.3d 809, 826, 830 (7th Cir. 2018) (noting Coleman's "much maligned" research), *vacated sub nom. Box v. Planned Parenthood of Ind. & Ky., Inc.*, 141 S. Ct. 184 (2020). The very study on which the district court relied has been discounted as "riddled with serious methodological errors," as it "included women who had *at any time* experienced a mental health problem in their lives, without distinguishing between mental health problems occurring before the abortion and those occurring after." *Whole Woman's Health All. v. Rokita*, No. 18-cv-1904, 2021 WL 650589, at *5 (S.D. Ind. Feb. 19, 2021) (quoting study). Indeed, "the journal in which one of these studies was published later disavowed the study's findings based on the authors' flawed methodology." *Id.* at *6.

The district court cited several additional authors whose work has been rejected by other courts. *Compare, e.g., Planned Parenthood of Wis., Inc. v. Schimel*, 806 F.3d 908, 922 (7th Cir. 2015) (critiquing Reardon & Coleman study because it "measured long-term mortality rates rather than death resulting from an abortion, and also failed to control for socioeconomic status, marital status, or a variety of other factors related to longevity"), *with* Order at 11 (citing Reardon study); *compare*

also Okla. Coal. for Reproductive Just. v. Cline, 441 P.3d 1145, 1155-57 & n.31 (Okla. 2019) (discounting study on alleged adverse events after medication abortion), *with* Order at 45 n.38 (citing same study).

Each of plaintiffs' other experts relies on research that has been rejected as unreliable and contrary to scientific consensus in case after case. *See, e.g.*, *MKB Mgmt. Corp. v. Burdick*, 855 N.W.2d 31, 68 (N.D. 2014) ("Dr. Harrison's opinions lack scientific support, tend to be based on unsubstantiated concerns, and are generally at odds with solid medical evidence."); *Am. Med. Ass'n v. Stenehjem*, 412 F. Supp. 3d 1134, 1150-51 (D.N.D. 2019) (Delgado's "abortion reversal" theory is "devoid of scientific support," "an unproven medical and scientific theory," and "a very controversial and medically-uncertain procedure"); *Planned Parenthood of Sw. & Central Fla. v. Florida*, No. 2022 CA 912, 2022 WL 2436704, at *13 (Fla. Cir. Ct. July 5, 2022) ("Dr. Skop has no experience in performing abortions; admitted that her testimony on the risks of certain abortion complications was inaccurate and overstated, or based on data from decades ago; admitted that her views on abortion safety are out of step with mainstream, medical organizations; and provided no credible scientific basis for her disagreement with recognized high-level medical organizations in the United States."), *rev'd on other grounds*, 344 So. 3d 637 (Fla. 1st Dist. Ct. App. 2022), *review granted*, No. SC22-1050, 2023 WL 356196 (Fla. Jan. 23, 2023).

More broadly, studies seeking to show that abortion carries negative physical and mental health consequences have repeatedly been deemed by members of the scientific community to be counter to the evidence. The National Academies concluded that "much of the published literature on" the topics of "abortion's [negative] effects" on health and well-being "fails to meet scientific standards for rigorous, unbiased research."[19] When considering only "high-quality research" that met scientific standards, that research showed that "having an abortion does not increase a woman's risk of secondary infertility, pregnancy-related hypertensive disorders, abnormal placentation …, preterm birth, breast cancer, or mental health disorders."[20] Despite this scientific consensus, the district court below—with the benefit of *neither* the FDA's expertise *nor* any live expert testimony—relied on just such debunked research to inaccurately maintain that after abortions, people "experience shame, regret, [and] anxiety." Order at 11.[21]

Given mifepristone's demonstrated safety, it is unsurprising that the drug is used in roughly 53% of all abortions in the United States.[22] Indeed, mifepristone is

[19] National Academies Report, *supra* note 8, at 152.
[20] *Id.* at 152-53.
[21] The court's reliance on these studies is of a piece with the court's use of anti-abortion rhetoric rather than scientific terminology to describe medication abortion. *See, e.g.*, Order at 2 & n.1 (calling fetuses "unborn human[s]"); *id.* at 2 (dubbing people who have elected to have an abortion "post-abortive"); *id.* at 2-3 (calling physicians providing abortion "abortionists" while calling plaintiffs "doctors").
[22] *See* Rachel K. Jones et al., *Medication Abortion Now Accounts for More than Half of All US Abortions*, Guttmacher Inst. (Feb. 24, 2022), http://bit.ly/3FA740X.

not only used to provide medication abortion, but also is regularly prescribed for the management and treatment of miscarriages,[23] which can be life-threatening without adequate treatment.[24] Even for people carrying a pregnancy to term, mifepristone can be used to reduce bleeding or life-threatening hemorrhaging during certain serious pregnancy complications.[25]

Mifepristone is thus an essential component of reproductive healthcare today. Over the last nearly 25 years of use, it has been proven by reliable scientific sources to be safe and effective, while experts and sources seeking to show its risks have been routinely discredited. There is no legitimate reason to suspend mifepristone's approval now—and doing so will impose enormous harm.

II. The Consequences of Suspending Mifepristone's FDA Approval Will Be Immediate and Severe.

The decision below imperils the health and safety of millions of people. Without mifepristone, people in need of abortions may be forced to seek out procedural abortions, or may be forced to carry pregnancies to term against their

[23] *See* Mara Gordon & Sarah McCammon, *A Drug that Eases Miscarriages is Difficult for Women to Get*, NPR (Jan. 10, 2019), http://bit.ly/42lU7l8.

[24] *See* ACOG Practice Bulletin No. 200, *Early Pregnancy Loss*, e197, e203 (Nov. 2018, reaff'd 2021); Pam Belluck, *They Had Miscarriages, and New Abortion Laws Obstructed Treatment*, N.Y. Times (July 17, 2022), https://nyti.ms/3Jwb7N1; Rosemary Westwood, *Bleeding and in Pain, She Couldn't Get 2 Louisiana ERs to Answer: Is It a Miscarriage?*, NPR (Dec. 29, 2022), http://bit.ly/40ji4I1; *see also* Oriana Gonzalez & Ashley Gold, *Abortion Pill Demand Soaring Following Roe's Demise*, Axios (July 19, 2022), http://bit.ly/3FAIP2I.

[25] *See* Yanxia Cao et al., *Efficacy of Misopristol Combined with Mifepristone on Postpartum Hemorrhage and Its Effects on Coagulation Function*, 13 Int. J. Clin. Exp. Med. 2234 (2020), https://bit.ly/3ZXywhb.

will. While procedural abortion is also safe, many patients seek medication abortion because it can be easier to access, particularly for patients in communities facing the most obstacles to care, including Black, Indigenous, and other people of color, those with low incomes, LGBTQ+ people, young people, immigrants, people with disabilities, and those living at the intersection of those identities. Medication abortion actively reduces sometimes insurmountable barriers to patients, because many states allow patients to take the medications at home following a consultation with a healthcare provider. This permits them to undergo the process in privacy, at a place of their choosing, and with the support of their immediate network.[26] And it allows people to forgo physical contact and vaginal insertions, which may be particularly important for survivors of sexual violence and people experiencing gender dysphoria. The district court invoked the history of eugenics to justify restrictions on people's access to bodily autonomy; but forcing people to carry pregnancies to term against their will is the more apt analogy to eugenic control.[27]

Having an abortion at home also may provide safety benefits to both patients and providers. Telehealth can eliminate the exposure risks inherent in in-person clinic visits, particularly in light of the persistent and escalating violence and

[26] *See* Charlotte Kanstrup et al., *Women's Reasons for Choosing Abortion Method: A Systematic Literature Review*, 46 Scandinavian J. Pub. Health 835 (2018), http://bit.ly/3yQkSRd; Ho, *supra* note 3.

[27] *See generally* Melissa Murray, *Race-ing* Roe*: Reproductive Justice, Racial Justice, and the Battle for* Roe v. Wade, 134 Harv. L. Rev. 2025, 2036-37 (2021).

harassment at clinics known to provide abortion.[28] It can also reduce wait times[29] and remove barriers to healthcare due to travel costs.[30]

Eliminating mifepristone will exacerbate the current reproductive healthcare crisis, as it constitutes over half of current abortions. The prohibition of abortion care in over a dozen states—and more expected—has dramatically increased demand in states with abortion clinics, leading to overwhelmed providers, longer wait times and delays, and more complicated logistics for patients.[31] The ever-shrinking number of clinics already have to provide care for a dramatic increase in patients.[32] For example, post-*Dobbs*, the three Wichita, Kansas clinics have an average service population of 1.8 million (meaning that they are the closest abortion facility for 1.8 million women *each*).[33] Not one of these three facilities has an opening in the next

[28] *See* Press Release, Nat'l Abortion Fed'n, *National Abortion Federation Releases 2021 Violence and Disruption Report* (June 24, 2022), http://bit.ly/3mVsTS2 (reporting steady increase in harassment and violence at abortion clinics over 45-year period); U.S. Dep't of Just., *Recent Cases on Violence Against Reproductive Health Care Providers* (last updated Oct. 18, 2022), http://bit.ly/3JQlmwR.

[29] Liam Caffery et al., *Telehealth Interventions for Reducing Waiting Lists and Waiting Times for Specialist Outpatient Services: A Scoping Review*, 22 J. Telemed. Telecare 504 (2016), https://pubmed.ncbi.nlm.nih.gov/27686648/.

[30] Abid Haleem et al., *Telemedicine for Healthcare: Capabilities, Features, Barriers, and Applications*, 2 Sens. Int'l 100117 (2021), https://bit.ly/3nrY2No.

[31] Jesse Philbin et al., *10 States Would Be Hit Especially Hard by a Nationwide Ban on Medication Abortion Using Mifepristone*, Guttmacher Inst. (Feb. 2023), http://bit.ly/3JuKPKZ.

[32] *See* Caitlin Myers et al., *Abortion Access Dashboard* (last updated Mar. 23, 2023), http://bit.ly/3KFOck7 (noting that there has been a 32% increase in women per abortion facility since March 1, 2022).

[33] Caitlin Myers et al., *About the Abortion Access Dashboard: Data and Methodology*, http://bit.ly/3KiYoOc (last accessed Apr. 8, 2023). This brief mirrors the language used in the sources reviewed, which largely focus on cisgender women, but *amici* stress that this decision will affect all people with uteruses.

two weeks.[34] Similarly, the lone Cincinnati clinic, with an average service population of 957,700 women, has no openings in the next two weeks.[35]

This already-overwhelmed system of abortion provision will be even further strained if the main method of abortion provision is restricted or banned. Currently, roughly 10% of U.S. counties have an abortion provider that offers either procedural or medication abortion (or both); in roughly 2% of counties, the only option is medication abortion.[36] Without medication abortion, therefore, only 8% of counties would offer any kind of abortion, and access to abortion would be compromised—or eliminated altogether—in about one in five counties that currently have an abortion provider.[37] Of the 762 brick-and-mortar abortion facilities in the United States, 40% provide *exclusively* medication abortion.[38] In 2020, 100% of abortions in Wyoming were performed with medication abortion.[39] The numbers are even more dramatic given how many people live in those counties that rely on medication abortion. Roughly 2.4 million women of reproductive age live in the 2% of counties where medication abortion is the only option.[40] Without mifepristone, these millions

[34] Myers, *supra* note 32.
[35] *Id.*
[36] Philbin, *supra* note 31.
[37] *Id.*
[38] Caitlin Myers et al., *What If Medication Abortion Were Banned?* (Apr. 7, 2023), http://bit.ly/3GsvtGl.
[39] Allison McCann & Amy Schoenfeld Walker, *Where Restrictions on Abortion Pills Could Matter Most in the U.S.*, N.Y. Times (Apr. 7, 2023), https://nyti.ms/41kNjTl.
[40] Philbin, *supra* note 31.

of women (who live in states where abortion is legal and, indeed expressly protected in many) could live in a county that does not offer abortion or dramatically restricts it, along with the roughly 49% of U.S. women who already face that reality.[41] And 10.5 million women of childbearing age could experience an increase in travel time to their nearest provider.[42]

The numbers are particularly stark in some states. Take Maine, for example (a state that is *protective* of abortion rights). There, without medication abortion, "[t]he share of counties with an abortion provider would drop from 88% to as low as 19%."[43] And even if existing providers switch to misoprostol-only regimes, removing access to mifepristone will upend care delivery, imposing burdensome information costs on patients and providers to navigate an increasingly complex and uncertain legal landscape.

People living in these counties and states could therefore be forced to travel long distances to try to access abortions. At least 62 clinics have been shuttered since the end of June 2022, and travel time to obtain abortion has increased significantly across the United States.[44] In a 2019 paper, economists estimated that overturning

[41] *Id.* (Currently, roughly 55% of U.S. women live in a county with an abortion provider; without mifepristone, that number will drop to roughly 51%).
[42] Myers, *supra* note 38.
[43] Philbin, *supra* note 31; *see also* Myers, *supra* note 38 (Maine would lose 86% of its abortion facilities, California 60%, Connecticut 56%, Washington 51%, and Vermont 50%).
[44] *See* Marielle Kirstein et al., *100 Days Post-*Roe*: At Least 66 Clinics across 15 US States Have Stopped Offering Abortion Care*, Guttmacher Inst. (Oct. 6, 2022), http://bit.ly/3JtdekK.

Roe would lead to a "249 mile increase in travel distance" to an abortion provider, which would prevent 93,546–143,561 people from accessing abortion care.[45] A 2021 study forecasts a similar trend, showing that an increase in travel distance from 0 to 100 miles is estimated to prevent 20.5% of women seeking an abortion from reaching a provider.[46] Studies show that requiring people to travel prevents a substantial number from reaching providers at all.[47] Increases in travel distances by as few as 25 miles decreased abortion rates by 10%, and increases by 50 miles decreased abortion rates by 18%.[48]

Increased travel adds not only logistical barriers, but also added material costs, including the risk of adverse employment consequences. As a result, banning mifepristone could erect burdensome socioeconomic barriers for communities that are already underinsured and medically underserved.[49] Many people in the United States—disproportionately people of color—lack paid leave. Nationally, people of color are significantly less likely to have access to paid leave, with 40.8% of Black

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[45] Caitlin Myers, Rachel Jones & Ushma Upadhyay, *Predicted Changes in Abortion Access and Incidence in a Post-*Roe *World*, 100 Contraception 367 (2019).
[46] Caitlin Myers, *Measuring the Burden: The Effect of Travel Distance on Abortions and Births*, IZA Inst. Labor Econ. (IZA DP No. 14556, Discussion Paper Series, 2021), https://bit.ly/400IEWr; *see also* Jason M. Lindon et al., *How Far Is Too Far? New Evidence on Abortion Clinic Closures, Access, and Abortions*, 55 J. Human Res. 1137 (2020) (finding "substantial and nonlinear effects of travel distance on abortion rates: an increase in travel distance from 0-50 miles to 50-100 miles reduces abortion rates by 16 percent").
[47] Jason Lindon et al., *supra* note 46, at 1217.
[48] *Id.*
[49] Rachel K. Jones et al., *COVID-19 Abortion Bans and Their Implications for Public Health*, 52 Persps. on Sexual & Reprod. Health 65, 66 (2020), https://bit.ly/40aI0pc.

and 23.2% of Hispanic employees having access, compared to 47.4% of white employees.[50] Studies show that people without paid sick days are three times more likely to delay or forego medical care, including reproductive healthcare, and that people frequently cite lost wages as one of the largest obstacles to their seeking an abortion.[51] Delayed access to abortion also significantly increases the cost and availability of care.[52] Moreover, although second-trimester abortion remains a very safe procedure, the health risks associated with abortion increase with the weeks of pregnancy,[53] and the availability of providers who offer such procedures decreases. As a result, some of those unable to travel may risk life-threatening obstetrical emergencies.

And finally, the decision below could force countless people to carry a pregnancy to term, which will worsen health-outcome disparities, cause socioeconomic hardship, and decrease wellbeing. Studies show that people denied the ability to terminate their pregnancies may face increased long-term risks. Pregnancy and birth pose much higher health risks than abortion and are associated

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[50] Ann P. Bartel et al., *Racial and Ethnic Disparities in Access to and Use of Paid Family and Medical Leave: Evidence from Four Nationally Representative Datasets*, U.S. Bureau of Lab. Stats. (Jan. 2019), http://bit.ly/3yS0dMK.

[51] Nat'l P'ship for Women & Families, *Paid Sick Days Enhance Women's Abortion Access and Economic Security* (May 2019), http://bit.ly/3n6hLC8.

[52] Jenna Jerman & Rachel K. Jones, *Secondary Measures of Access to Abortion Services in the United States, 2011 and 2012: Gestational Age Limits, Cost, and Harassment*, 24-4 Women's Health Issues e419, e421-22 (2014), https://bit.ly/3ZQF0hX.

[53] *See* Bonnie Scott Jones & Tracy A. Weitz, *Legal Barriers to Second-Trimester Abortion Provision and Public Health Consequences*, 99 Am. J. Pub. Health 623, 623 (2009).

with chronic pain lasting up to five years after birth.[54] People denied abortions are also nearly 400% more likely to have a household income below the poverty level, and 300% more likely to be unemployed.[55] People denied the ability to terminate their pregnancies are also more likely to remain in contact with violent intimate partners,[56] and are likely to suffer from mental, emotional, and physical trauma.[57] Forcing a person to carry a pregnancy to term, moreover, can have negative consequences for that person's children, as they are more likely to live below the poverty line, have lower child development scores, and enjoy poorer maternal bonding.[58]

Giving birth, too, carries serious health risks. According to a recent Centers for Disease Control and Prevention report, the maternal mortality rate has risen since

[54] Lauren J. Ralph et al., *Self-reported Physical Health of Women Who Did and Did Not Terminate Pregnancy After Seeking Abortion Services*, 171 Annals Internal Med. 238 (2019), http://bit.ly/40lsl6o.

[55] *See* 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 (2018), http://bit.ly/3TpwpjT.

[56] Sarah C.M. Roberts et al., *Risk of Violence from the Man Involved in the Pregnancy After Receiving or Being Denied an Abortion*, 12 BMC Med. 1, 1-7 (2014), http://bit.ly/3Zf1R5T.

[57] Diana Greene Foster et al., *A Comparison of Depression and Anxiety Symptom Trajectories Between Women Who Had an Abortion and Women Denied One*, 45 Psych. Med. 2073 (2015), https://bit.ly/42lMXgF.

[58] Diana Greene Foster et al., *Effects of Carrying an Unwanted Pregnancy to Term on Women's Existing Children*, 205 J. Ped. 183 (2019), http://bit.ly/3n9gzO4; 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 Ped. 1053 (2018), http://bit.ly/3JNziI1.

2018.[59] While the maternal mortality rate in 2018 was 17.4 deaths per 100,000 live births, in 2021 that number spiked to 32.9 deaths per 100,000 live births.[60] And these risks are not distributed evenly across communities. At every turn, the risks of both pregnancy and birth are higher for people who face barriers to healthcare.[61] Pregnant people of color are more likely to experience early pregnancy loss or miscarriage, the treatment for which can include procedural or medication abortion.[62] Moreover, Black women are three to four times more likely than white women to die a pregnancy-related death in the United States,[63] and Indigenous women are 2.3 times more likely than white women.[64] Notably, hospitals that predominantly serve Black patients—where about 75% of Black women give birth—provide comparatively lower-quality maternal care.[65]

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[59] Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, Nat'l Ctrs. for Health Stats. (Mar. 2023), https://bit.ly/3M0PCqA.
[60] *Id.* at 3.
[61] *See* 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 (2016), http://bit.ly/3TurNcd.
[62] Lyndsey S. Benson et al., *Early Pregnancy Loss in the Emergency Department*, 2 J. Am. Coll. Emergency Physicians Open, e12549 n.29 (2021), https://bit.ly/3ZXy9TP.
[63] Elizabeth A. Howell, *Reducing Disparities in Severe Maternal Morbidity and Mortality*, 61 Clinical Obstetrics & Gynecology 387 (2018), https://bit.ly/42rRn5V; *see also* Claire Cain Miller et al., *Childbirth is Deadlier for Black Families Even When They're Rich, Expansive Study Finds*, N.Y. Times (Feb. 12, 2023), http://bit.ly/3YUiHqt.
[64] Emily E. Petersen, et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths—United States, 2007-2016*, CDC (Sept. 6, 2019), http://bit.ly/3Km7UQv.
[65] *See* Cecilia Lenzen, *Facing Higher Teen Pregnancy and Maternal Mortality Rates, Black Women Will Largely Bear the Brunt of Abortion Limits*, Tex. Trib. (June 30, 2022), http://bit.ly/3lsuVZu.

Mifepristone, as the most common method of abortion in the country, and the safest and most accessible means of obtaining an abortion for many people, is key to avoiding harmful outcomes and empowering people of all backgrounds to make decisions for themselves and their families. Depriving people of mifepristone would deny many people who are *not* seeking an abortion safe and effective medical care for miscarriage and even after giving birth. It would also place increased strain on the ever-shrinking number of healthcare providers offering abortions, making abortion more logistically difficult nationwide (not just where it has been outlawed already). And crucially, it could put abortion functionally out of reach for potentially millions of people—even those who live in states where abortion remains legal. Pregnant people could thus be forced to make an untenable choice: spend time and money, risk losing one's job, and navigate the logistical hurdles of traveling for an abortion, or be forced to carry a pregnancy to term against one's will, with all the attendant physical and financial consequences.

There is no basis in fact or law for this result, given mifepristone's demonstrated safety, efficacy, and indeed necessity in today's reproductive healthcare landscape. And the result is especially inappropriate where a district court substituted faulty "science," and unreliable "experts," for nearly twenty-five years of the FDA's scientific assessment of a safe and effective medication. There is simply no reason to deprive individuals of mifepristone's life-saving use now.

CONCLUSION

The Court should grant the motions for stay pending appeal.

April 11, 2023

Respectfully submitted,

/s/ Jessica Ring Amunson

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APPENDIX

List of *Amici Curiae*

Center for Reproductive Rights
New York, NY

American Civil Liberties Union
New York, NY

Planned Parenthood Federation of America
Washington, DC

A Woman's Choice Clinics: Jacksonville, Charlotte, Greensboro, Raleigh
Jacksonville, FL; Charlotte, NC; Greensboro, NC; Raleigh, NC

Abortion Care Network
Washington, DC

All* Above All Action Fund
Washington, DC

American Civil Liberties Union of Texas
Houston, TX

American Humanist Association
Washington, DC

Ancient Song
New York, NY

Avow Texas
Austin, TX

AWAKE TN
Nashville, TN

Blue Mountain Clinic
Missoula, MT

Catholics for Choice
Washington, DC

Central Conference of American Rabbis
New York, NY

Chicago Abortion Fund
Chicago, IL

Chicago Foundation for Women
Chicago, IL

CHOICES Center for Reproductive Health
Memphis, TN

Coalition of Labor Union Women, AFL-CIO
Washington, DC

Cobalt Advocates
Denver, CO

Collective Power for Reproductive Justice
Amherst, MA

COLOR Latina
Denver, CO

Columbia NOW
Columbia, SC

Community Catalyst
Boston, MA

Desert Star Family Planning
Phoenix, AZ

Desert Star Institute for Family
Phoenix, AZ

Expanding Medication Abortion Access Project
Washington, DC

Florida NOW—National Organization for Women
Deland, FL

Frontera Fund
McAllen, TX

Fund Texas Choice
Austin, TX

Gender Justice
Saint Paul, MN

Gender Justice League
Seattle, WA

Girls for Gender Equity
New York, NY

Greater Seattle Business Association
Seattle, WA

Guttmacher Institute
Washington, DC

Health Justice MD
Phoenix, AZ

Ibis Reproductive Health
Cambridge, MA

If/When/How: Lawyering for Reproductive Justice
Oakland, CA

In Our Own Voice: National Black Women's Reproductive Justice Agenda
Washington, DC

Indigenous Women Rising
Albuquerque, NM

Ipas: Partners for Reproductive Health
Chapel Hill, NC

Jane's Due Process
Austin, TX

Jewish Women International
Washington, DC

Just the Pill
Minneapolis, MN

Lambda Legal
New York, NY

LatinoJustice PRLDEF
New York, NY

Lawyering Project
New York, NY

Legal Momentum: The Women's Legal Defense and Education Fund
New York, NY

Lift Louisiana
New Orleans, LA

Louisiana Coalition for Reproductive Freedom
Baton Rouge, LA

Maine Family Planning
Augusta, ME

Medical Students for Choice
Philadelphia, PA

Men of Reform Judaism
New York, NY

Michigan Voices
Detroit, MI

NARAL Pro-Choice America
Washington, DC

National Abortion Federation
Washington, DC

National Center for Law and Economic Justice
New York, NY

National Center for Lesbian Rights
San Francisco, CA

National Council of Jewish Women
Washington, DC

National Education Association
Philadelphia, PA

National Employment Law Project
Washington, DC

National Family Planning & Reproductive Health Association
Washington, DC

National Health Law Program
Washington, DC

National Institute for Reproductive Health
New York, NY

National Latina Institute for Reproductive Justice
New York, NY

National Organization for Women—Seattle
Seattle, WA

National Partnership for Women & Families
Washington, DC

National Women's Law Center
Washington, DC

National Women's Liberation
Gainesville, FL

National Women's Political Caucus
Washington, DC

New Era Colorado
Denver, CO

Northwest Health Law Advocates
Seattle, WA

Nurses for Sexual and Reproductive Health
St. Paul, MN

Oklahoma Call for Reproductive Justice
Oklahoma City, OK

Oregon Affiliate of the American College of Nurse-Midwives
Corvallis, OR

PAI
Washington, DC

Palmetto State Abortion Fund
Columbia, SC

Patient Forward
Sedona, AZ

People for the American Way
Washington, DC

Positive Women's Network—USA
Oakland, CA

Possible Health
New York, NY

Power to Decide
Washington, DC

Pregnancy Justice
New York, NY

Pro-Choice Arizona
Phoenix, AZ

Pro-Choice Montana
Helena, MT

Pro-Choice North Carolina
Durham, NC

Pro-Choice Washington
Seattle, WA

Reproaction
Washington, DC

Reproductive Equity Now
Boston, MA

Reproductive Health Access Project
New York, NY

Reproductive Health Initiative for Telehealth Equity & Solutions
New York, NY

Rhia Ventures
San Francisco, CA

SIECUS: Sex Ed for Social Change
Washington, DC

SisterSong: The National Women of Color Reproductive Justice Collective
Atlanta, GA

South Asian SOAR
New York, NY

SPARK Reproductive Justice NOW
Atlanta, GA

State Innovation Exchange
Madison, WI

Tennessee Freedom Circle
Nashville, TN

Texas Equal Access Fund
Dallas, TX

The Women's Centers: CT, GA, NJ & PA
Hartford, CT; Atlanta, GA; Cherry Hill, NJ; Philadelphia, PA

UltraViolet
New York, NY

Union for Reform Judaism
New York, NY

URGE: Unite for Reproductive & Gender Equity
Washington, DC

Washington State NOW—National Organization for Women
Tacoma, WA

We Testify
Washington, DC

West Alabama Women's Center
Tuscaloosa, AL

Wild West Access Fund of Nevada
Reno, NV

Whole Women's Health Alliance
Charlottesville, VA

Women of Reform Judaism
New York, NY

Women's Law Project
Philadelphia, PA

10,000 Women Louisiana
Baton Rouge, LA

CERTIFICATE OF COMPLIANCE

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/s/ Jessica Ring Amunson

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of April, 2023 a true and correct copy of the foregoing Brief was served via the court's CM/ECF system.

/s/ Jessica Ring Amunson