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 Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF 237 REPRODUCTIVE HEALTH, RIGHTS, AND JUSTICE ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

Lindsay C. Harrison
Counsel of Record
Peggy Xu
JENNER & BLOCK LLP
1099 New York Ave. NW, Suite 900
Washington, DC 20001
(202) 639-6000
lharrison@jenner.com

Counsel for Amici Curiae

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INTEREST OF *AMICI CURIAE*[1]

Amici are almost 240 reproductive health, rights, and justice organizations, as well as other organizations with a strong interest in access to reproductive care. *Amici* represent organizations with a presence in all fifty states, and include clinics, health centers, advocacy organizations, religious groups, research institutes, and more. Together, *amici* serve and represent the interests of a diverse range of populations across the country. A complete list of *amici* can be found in the attached Appendix.

Many *amici* are clinics and healthcare providers who are directly impacted by the decisions below. They have seen firsthand 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* write to explain how the decisions below are contrary to their experience and the overwhelming consensus of the scientific and medical community that medication abortion is one of the safest medication regimens in the United States and around the world.

Amici also have a unique window into mifepristone's benefits and the immense challenges people would face if access to mifepristone were restricted. In the

[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici* certify that 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.

experience of *amici*, limiting access to mifepristone would have devastating consequences.

Amici urge this Court to reverse the judgment of the Fifth Circuit.

SUMMARY OF ARGUMENT

The FDA approved mifepristone over twenty years ago based on substantial evidence of its safety and efficacy for use in early termination of pregnancy. That evidence, now bolstered by decades of study and practice, has only grown more compelling with time.

The Fifth Circuit's decision ignores the overwhelming consensus of the scientific and medical community that medication abortion is one of the safest medication regimens in the United States and around the world. Moreover, the decision imposes harsh limits on access to mifepristone that will have dramatic and far-reaching 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 accounts for most abortions in the United States today. Now, with abortion access already severely restricted nationwide, mifepristone's availability is critically important.

Restrictions on mifepristone would have widespread detrimental consequences. The Fifth Circuit's decision reimposes a burdensome in-person dispensing requirement and narrows the types of medical professionals who can become certified prescribers. As a

result of these restrictions, even people in states where abortion remains legal and protected could find themselves unable to timely access mifepristone, imperiling access to abortion and jeopardizing the health and autonomy of those denied care. Clinics and providers—including several *amici*—could find themselves unable to effectively provide competent and much-needed medical care.

Far from protecting patient health, the Fifth Circuit's decision will have severe and damaging consequences unsupported by law or science. The decision should be reversed.

ARGUMENT

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

Mifepristone is one of two medications (along with misoprostol) used in the most common method for terminating early pregnancy in the United States—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]

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[2] *See A Private Choice for Early Abortion*, Danco, https://www.earlyoptionpill.com/ (last visited Jan. 24, 2024) (brand-name mifepristone has been used by over 5 million patients in the U.S.); Kaiser Family Found., *The Availability and Use of*

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.[3]

In 2016, after mifepristone had been approved and in use for sixteen years, the FDA made two evidence-based modifications to mifepristone's conditions of use. First, it updated Mifeprex's labeling to increase the gestational age limit from forty-nine to seventy days, reduced the number of in-person clinic visits to one, changed the dosing of Mifeprex and misoprostol, and allowed for the prescription of the drug by a broader set of healthcare providers. Second, the FDA updated the risk evaluation and mitigation strategy ("REMS") for mifepristone to relax reporting requirements for certain adverse events and to allow non-physicians to become certified prescribers.

In making these changes, the FDA relied on a wealth of updated data—including over eighty high-quality studies involving hundreds of thousands of women—underscoring mifepristone's safety without these impediments.[4] The FDA also drew from no fewer than

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Medication Abortion (Sept. 28, 2023), http://bit.ly/3n0LUme (2.75 million people between 2000 and 2016 used brand-name mifepristone for an abortion).

[3] 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).

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

eighty-five different studies and papers, collectively representing "well over 30,000 patients" and conclusively showing "[s]erious adverse events" at rates "generally far below 1.0%."[5] *Hundreds* of additional high-quality studies conducted since mifepristone's 2000 approval show the same. To date, mifepristone has been used in over 600 published clinical trials and discussed in over 800 medical reviews.[6] 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"[7] (non-steroidal anti-inflammatory drugs, such as ibuprofen and aspirin)—medications millions of people take daily.[8]

Mifepristone carries extremely low risks of complications 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 modifications to mifepristone's conditions of use cited a host of studies showing that the rate of major

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

[6] Based on a review of publications on PubMed, the National Institute of Health's sponsored database of research studies.

[7] 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.

[8] Pamela Gorczyca et al., *NSAIDs: Balancing the Risks and Benefits*, 41 U.S. Pharmacist 24 (2016), http://bit.ly/3YLbw3x.

adverse events was roughly 0.3%,[9] with multiple U.S. studies reporting even lower rates of infection (such as 0%, 0.014%, and 0.015%[10]). The risk of death hovers around zero, with only thirteen recorded deaths even possibly related to medication abortion, or roughly 0.00035%[11]—less than the risk of complications from the use of Viagra[12] or getting one's wisdom teeth removed.[13] Moreover, the FDA has noted that the very same complications can arise during a miscarriage or procedural abortion[14] and "the physiology of pregnancy may be a more plausible risk factor" than mifepristone for rare serious infections following use.[15] Indeed, the FDA has concluded that side effects such as "bleeding, infections, or other problems,"[16] which the Fifth Circuit

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[9] 2016 FDA Approval, *supra* note 4, at 56.

[10] *Id.* at 54.

[11] 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 4, at 8, 47-51.

[12] 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).

[13] 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).

[14] U.S. FDA, Mifeprex Prescribing Information 1, 2, 5, 15 (revised Mar. 2016), https://bit.ly/3Z0kGJy.

[15] Letter from Janet Woodcock, M.D., Director, Ctr. for Drug Eval. & Rsch., to Donna Harrison, M.D., et al., *Denying Citizen Petition Asking the FDA to Revoke Approval of Mifeprex* 1, 25 n.69 (Mar. 29, 2016), http://bit.ly/3KhGAEl.

[16] U.S. FDA, *supra* note 14, at 16.

associated with mifepristone use, Pet. App. 7a, can accompany "a miscarriage, [procedural] abortion, medical abortion, or childbirth."[17] These complications are therefore both rare *and* not specific to mifepristone.

Instead of citing any of this authoritative data, the courts below, "improperly substitut[ing] [their] judgment for that of the agency," relied on articles and scholars that have been debunked, as well as off-point anecdotal "evidence" that runs directly counter to the peer-reviewed studies the FDA relied upon. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2570 (2019). At the district court, for example, the court relied on a study by Dr. Priscilla Coleman, Pet. App. 123a-124a, that 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), *summarily vacated sub nom. Box v. Planned Parenthood of Ind. & Ky., Inc.*, 141 S. Ct. 184 (2020). The district court also 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 relevant to longevity"), *with*

[17] *Id.*

Pet. App. 123a-124a (citing different Reardon & Coleman study).

The Fifth Circuit only amplified the district court's use of unreliable sources. In finding that the physician plaintiffs had standing, the Fifth Circuit relied on several declarations for the supposed burden on physicians stemming from mifepristone. *See* Pet. App. 19a-24a. These declarations are decontextualized and convey thinly-supported anecdotes that have little bearing on or relation to the scientific literature on mifepristone. And several of these declarants—including Dr. Skop, Dr. Harrison, and Dr. Wozniak—have been repeatedly discredited by various courts.[18] *See, e.g.*, *Planned Parenthood of Sw. & Cent. 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*

[18] Moreover, isolated anecdotal evidence from a handful of physicians cannot outweigh the extensive research and clinical data underlying the FDA's actions. *See United States v. Playboy Ent. Grp., Inc.*, 529 U.S. 803, 819 (2000) (faulting the government for relying on "anecdotal evidence to support its regulation"). And it is certainly not an adequate basis for the court to "substitute[] its judgment for that of the agency." *Dep't of Com.*, 139 S. Ct. at 2570.

grounds, 344 So. 3d 637 (Fla. 1st Dist. Ct. App. 2022), *review granted*, No. SC22-1050, 2023 WL 356196 (Fla. Jan. 23, 2023); *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."); *Whole Woman's Health All. v. Rokita*, 553 F. Supp. 3d 500, 528 (S.D. Ind. 2021) (although "Dr. Nancy Goodwine-Wozniak testified, . . . regarding certain concerns," "these 'concerns' were not anchored in any referenced medical research or literature or even her own personal experiences"), *vacated*, No. 21-2480, 2022 WL 2663208 (7th Cir. July 11, 2022).

It is little surprise that both the district court and the Fifth Circuit struggled to find reputable scientific data with which to bolster their conclusions. The scientific and medical community has repeatedly found no evidence to support the assertions that abortion carries negative physical and mental health consequences. 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 decisions below—with the

[19] National Academies Report, *supra* note 7, at 152.
[20] *Id.* at 152-53.

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. . . ." Pet. App. 123a.

Mifepristone, in large part due to its safety and efficacy, is used in the majority of all abortions in the United States.[21] Indeed, mifepristone is not only used to provide medication abortion, but also is regularly prescribed for the management and treatment of miscarriages,[22] which can be life-threatening without adequate treatment.[23] Even for people carrying a pregnancy to term, mifepristone can be used to reduce bleeding or life-threatening hemorrhaging during certain serious pregnancy complications.[24]

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

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

[23] *See* ACOG Practice Bulletin No. 200, *Early Pregnancy Loss*, e197, e203 (Nov. 2018, reaff'd 2021), https://bit.ly/3LJ1lta; 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 González & Ashley Gold, *Abortion Pill Demand Soaring Following Roe's Demise*, Axios (July 19, 2022), http://bit.ly/3FAIP2I.

[24] *See* Yanxia Cao et al., *Efficacy of Misoprostol Combined with Mifepristone on Postpartum Hemorrhage and Its Effects on*

Just as importantly, mifepristone works. Studies show that mifepristone, combined with misoprostol, has a 99.6% success rate in terminating pregnancies.[25] 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.[26] Again, instead of engaging with existing scholarship about the efficacy of mifepristone, the Fifth Circuit relied exclusively in its stay decision on a patient agreement form warning patients of potential risks from mifepristone to extrapolate that "hundreds of thousands of women" might eventually have had to seek procedural abortions from emergency physicians after taking mifepristone. Pet. App. 218a, 220a. But the patient agreement form does not say this. Instead, it says that "about 2 to 7 out of 100 women who use this treatment" may need to "talk with [their] provider" about "a surgical procedure" if the medication does not work.[27] It does not say that these patients will need emergency care. And there is simply no evidence that hundreds of thousands of women have required emergency care due to mifepristone—not since the modifications of the REMS in 2016 or 2023, or since mifepristone was initially approved in 2000. Surely if such evidence existed, the plaintiffs—who so readily

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Coagulation Function, 13 Int. J. Clin. Exp. Med. 2234 (2020), https://bit.ly/3ZXywhb.

[25] *See* 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.

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

[27] *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG* (Jan. 2023), https://perma.cc/MJT5-35LF.

invoked junk science to support their claims about mifepristone—would have entered it into the record below.

The Fifth Circuit ignored the evidence showing that mifepristone is an essential component of reproductive healthcare today. Over the last nearly twenty-five years of use, mifepristone 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. The FDA modified the REMS in 2016 and in 2023 precisely because of the overwhelming evidence of mifepristone's safety. There is no legitimate reason to turn back the clock on science and restrict mifepristone's availability now—and doing so will cause enormous harm.

II. The Consequences Of Restricting Access To Mifepristone Will Be Immediate And Severe.

The decisions below imperil the health and safety of millions of people. If patients cannot readily access 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 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, other people of color, people with low incomes, LGBTQ+ people, young people, immigrants, people with disabilities, and people living at the intersection of those identities.

Unlike procedural abortions, patients can undergo medication abortions in private, at a place of their choosing, and with the support of their immediate network.[28] Medication abortions also allow people to forgo physical contact and vaginal insertions, an option that may be particularly important for, among other people, survivors of sexual violence.

The Fifth Circuit's decision, however, makes medication abortion substantially harder to access by limiting the ability of patients to obtain mifepristone through telehealth appointments or by mail—despite the fact that this method of delivery protects both patients and providers. Telehealth or the delivery of mifepristone by mail can eliminate the risks inherent in in-person clinic visits, particularly in light of the persistent and escalating violence and harassment at clinics known to provide access to abortion.[29] It can also reduce wait times[30] and remove barriers to healthcare due to travel costs and scheduling burdens, including the

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[28] *See* Press Release, Nat'l Abortion Fed'n, *Violence Against Abortion Providers Continues to Rise Following Roe Reversal, New Report Finds* (May 11, 2023), http://bit.ly/42aBQYv (reporting a sharp increase in violence and disruption against abortion clinics and providers in states "that are protective of abortion rights"); U.S. Dep't of Just., *Recent Cases on Violence Against Reproductive Health Care Providers*, http://bit.ly/3JQlmwR (last updated May 30, 2023).

[29] *See* Press Release, *supra* note 28.

[30] Liam J. 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/.

need to take time off from work or find care for children or other dependents.[31]

Preserving access to mifepristone through telehealth and by mail is also crucial in light of an historic increase in pregnancy criminalization, or the practice of punishing pregnant people for actions or events interpreted as harmful to their own pregnancies.[32] Over the past two decades, criminal arrests of individuals for pregnancy-related reasons—such as substance abuse during pregnancy or self-managed abortion—has skyrocketed.[33] Nearly 85% of these criminal arrests involve charges against pregnant people who are deemed "legally 'indigent.'"[34] Whether or not a pregnant patient has committed any wrongdoing, the threat of prosecution is often enough to prevent pregnant people from actively seeking the medical care they need, particularly if that care requires meeting in-person with a physician.[35] Given this rise in pregnancy

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

[32] *Criminalizing Pregnancy: Policing Pregnant Women Who Use Drugs in the USA*, Amnesty Int'l (May 23, 2017), https://bit.ly/3vLaMCV.

[33] Purvaja S. Kavattur et al., *The Rise of Pregnancy Criminalization: A Pregnancy Justice Report*, Pregnancy Just. (Sept. 2023), https://bit.ly/3HvY3GE (finding that, between 2006 and 2022 alone, three times as many criminal arrests of pregnant persons took place in half as many years as the previous period studied).

[34] *Id.*

[35] *Opposition to Criminalization of Individuals During Pregnancy and the Postpartum Period*, Am. Coll. Obstetricians & Gynecologists (Dec. 2020), https://bit.ly/428sA6Y.

criminalization, the Fifth Circuit's reimposition of an in-person dispensing requirement can be especially harmful.

Restricting mifepristone's use will also exacerbate the current reproductive healthcare crisis. Currently, the mifepristone-misoprostol medication abortion regimen accounts for over half of abortions.[36] The prohibition of abortion care in over a dozen states will likely dramatically increase demand for abortion in states where abortion is legal and supported, leading to overwhelmed providers, longer wait times and delays, and more complicated logistics for patients.[37] The ever-shrinking number of clinics already have to provide care for a dramatic increase in patients.[38] 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*).[39] Only one of these three facilities has an opening in the next two weeks.[40] The lone Cincinnati clinic, with an average service population of 1.4 million women, has no openings in the next two weeks.[41] Even a two-week wait

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[36] *See* Rachel K. Jones et al., *supra* note 21.

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

[38] *See* Caitlin Myers et al., *Abortion Access Dashboard*, https://bit.ly/3uc3qI0 (last updated Sept. 1, 2023) (noting that there has been a 28% increase in women per abortion facility since March 1, 2022).

[39] *Id.* 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.

[40] Myers et al., *supra* note 38.

[41] *Id.*

can quite literally be the determining factor in whether an individual can legally receive abortion care.[42]

This already-overwhelmed system of abortion provision will be even further strained if the main method for abortion provision becomes more limited. Currently, roughly 10% of "U.S. counties have an abortion provider that offers either procedural or medication abortion" (or both); in roughly 2% of U.S. counties, the only option is medication abortion.[43] If medication abortion were put functionally out of reach, 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."[44]

In fact, of the "762 brick-and-mortar abortion facilities" in the United States, 40% provide *exclusively* medication abortion.[45] In 2020, 100% of abortions in Wyoming were performed with medication abortion.[46] The numbers are even more dramatic given how many people live in 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

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[42] *See* Patricia Mazzei et al., *DeSantis Signs Six-Week Abortion Ban in Florida*, N.Y. Times (Apr. 13, 2023), https://bit.ly/3KGakcM.
[43] Philbin, *supra* note 37.
[44] *Id.*
[45] Caitlin Myers et al., *What If Medication Abortion Were Banned?* (Apr. 10, 2023), http://bit.ly/3GsvtGl.
[46] 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.

legal option.[47] Without easy access to mifepristone, these millions of women (who live in states where abortion is legal and, in many cases, expressly protected) could find themselves in counties where abortion is functionally inaccessible, along with the roughly 49% of U.S. women who already face that reality.[48] And 10.5 million women of childbearing age could experience an increase in travel time to their nearest provider.[49]

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%."[50] 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.

If access to mifepristone were limited or eliminated, people living in these counties and states could be forced to travel long distances to try to access abortions. At least sixty-six clinics have been shuttered since the end of June 2022, and travel times to obtain an abortion

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[47] Philbin, *supra* note 37.

[48] *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%).

[49] *What If Medication Abortion Were Banned?*, *supra* note 45.

[50] Philbin, *supra* note 37; *see also What If Medication Abortion Were Banned?*, *supra* note 45 (Maine would lose 86% of its abortion facilities, California 60%, Connecticut 56%, Washington 51%, and Vermont 50%).

have increased significantly across the United States.[51] Research shows that requiring people to travel for an abortion prevents a substantial number from reaching providers at all. In a 2019 paper, economists estimated that overturning *Roe* would lead to a "249 mile increase in travel distance" to an abortion provider, which would "prevent 93,546–143,561 [people] from obtaining abortion care."[52] A 2024 study forecasts a similar trend, estimating that an increase in travel distance from 0 to 100 miles will prevent 19.4% of women seeking an abortion from reaching a provider.[53]

Increased travel adds not only logistical barriers, but also added material costs, including the risk of adverse employment consequences. As a result, reduced access to mifepristone could erect burdensome socioeconomic barriers for communities that are already underinsured

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[51] *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.

[52] Caitlin Myers, Rachel Jones & Ushma Upadhyay, *Predicted Changes in Abortion Access and Incidence in a Post-*Roe *World*, 100 Contraception 367, 372-73, (2019); *see also* Gianna Melillo, *Post Roe, travel times to abortion clinics more than tripled: study*, Hill (Nov. 1, 2022), https://bit.ly/48Izxye.

[53] Caitlin Myers, *Forecasts for a post-Roe America: The effects of increased travel distance on abortions and births*, 43 J. Pol'y Analysis & Management 39, 39 (2024), https://bit.ly/48GfBfb; *see also* Jason M. Lindo 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[%]").

and medically underserved.[54] 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 and 23.2% of Hispanic employees having access, compared to 47.4% of white employees.[55] 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 seeking an abortion.[56] Delayed access to abortion also significantly increases the cost and availability of care[57]—particularly worrisome given that a large share of people seeking abortions have low incomes and are the least equipped to handle increased economic burdens.[58] Moreover, although second-trimester abortion remains

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[54] 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.

[55] 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.

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

[57] *Id.*; 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.

[58] Jenna Jerman et al., *Barriers to Abortion Care and Their Consequences for Patients Traveling for Services: Qualitative Findings from Two States*, 49 Persp. Sex. Reprod. Health 95 (2017), https://bit.ly/3GE5KdW ("75% of abortion patients were poor or low-income in 2014").

a safe procedure, the health risks associated with abortion increase with each subsequent week of pregnancy,[59] 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.

For many patients, the decision below will do more than delay a potential abortion: It could force countless people to carry a pregnancy to term against their will, which will worsen health-outcome disparities, cause socioeconomic hardship, and decrease wellbeing. One recent study found that state abortion bans have caused a 2.3% increase in births (or about 32,000 annual births), and that nearly a *quarter* of women who would have otherwise sought an abortion were forced to carry their pregnancies to term.[60] The implications of this trend for patient health are dire. Research shows 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 with chronic pain lasting up to five years after birth.[61] People denied abortions are also nearly 400%

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[59] *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), https://bit.ly/49p6G1Z.

[60] Margot Sanger-Katz & Claire Cain Miller, *How Many Abortions Did the Post-Roe Bans Prevent?*, N.Y. Times (Nov. 22, 2023), https://nyti.ms/3HvEAWC.

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

more likely to have a household income below the poverty level, and are much more likely to be unemployed.[62] People denied the ability to terminate their pregnancies are also more likely to remain in contact with violent intimate partners,[63] and are more likely to suffer from mental, emotional, and physical trauma.[64] 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 experience poorer maternal bonding.[65]

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

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[62] *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.

[63] 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.

[64] 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.

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

since 2018.[66] 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.[67] 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.[68] Pregnant people of color are more likely to experience early pregnancy loss or miscarriage, the treatment for which can include procedural or medication abortion.[69] Moreover, Black women are three to four times more likely than white women to die a pregnancy-related death in the United States,[70] and Indigenous women are 2.3 times more likely to die a pregnancy-related death than white women.[71] Notably,

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[66] Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, Nat'l Ctrs. for Health Stats. (Mar. 2023), https://bit.ly/3M0PCqA.

[67] *Id.* at 3.

[68] *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.

[69] Lyndsey S. Benson et al., *Early Pregnancy Loss in the Emergency Department, 2006-2016*, 2 J. Am. Coll. Emergency Physicians Open e12549 ¶ 1.1 (2021), https://bit.ly/3ZXy9TP.

[70] 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.

[71] Emily E. Petersen et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths—United States, 2007-2016*, 68 MMWR Morbidity Mortal Weekly Rep. 762 (Sept. 6, 2019), http://bit.ly/3Km7UQv.

hospitals that predominantly serve Black patients—where about 75% of Black women give birth—provide comparatively lower-quality maternal care.[72] The number of obstetric units has also declined precipitously in the past decade. Between 2011 and early 2023, 217 hospital obstetric units have shut down, creating "maternity care deserts" that disproportionately leave Black patients and patients in rural counties without care.[73]

Mifepristone, used in 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 for their families. The Fifth Circuit's decision, which could functionally put mifepristone out of reach for many, would also deny scores of people who are *not* seeking an abortion safe and effective medical care for miscarriage and even after giving birth. It would 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 render abortion essentially unattainable for some—even for 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

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[72] *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.

[73] Amy Roeder, *Maternity Ward Closures Exacerbating Health Disparities*, Harv. T.H. Chan Sch. Pub. Health (Dec. 13, 2023), https://bit.ly/3Ssryzq.

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.

Finally, should this Court suspend the FDA's post-2015 modifications to mifepristone's conditions of use, all branded mifepristone would currently be mislabeled, and the FDA and the drug's sponsors would be required to bring the drug back into compliance with the Fifth Circuit's decision. Moreover, even after compliance is achieved, the more restrictive pre-2016 conditions of use would unnecessarily impair access to mifepristone across the country. Turning back the clock to pre-2016 conditions of use would prevent patients from being able to obtain prescriptions from many qualified advanced-practice clinicians. And crucially, reinstating a harsh in-person dispensing requirement would limit patients' ability to procure mifepristone through telehealth or by mail. Given the costs and difficulties of visiting a clinic in-person—which often requires taking unpaid leave from work or finding substitute caregivers—the reality is that these restrictions will for many patients make mifepristone not just difficult to access but unattainable. This reality, and the evolving scientific data and consensus about mifepristone's safety, is part of what motivated the FDA to modify its conditions of use in 2016 and beyond.

There is no basis in science or in law for the Fifth Circuit's judgment, given mifepristone's demonstrated safety, efficacy, and indeed necessity in today's reproductive healthcare landscape. The decisions below are especially inappropriate where the courts

substituted faulty "science" and unreliable "experts" for nearly twenty-five years of the FDA's scientific assessment of a safe and effective medication. Courts should not be permitted to flout the overwhelming scientific consensus, as recognized by the FDA.

CONCLUSION

For the foregoing reasons, *amici* respectfully request that this Court reverse the decision below.

Respectfully submitted,

Lindsay C. Harrison
Counsel of Record
Peggy Xu
JENNER & BLOCK LLP
1099 New York Ave. NW, Suite 900
Washington, DC 20001
(202) 639-6000
lharrison@jenner.com

Counsel for Amici Curiae

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YWCA Kalamazoo
YWCA USA