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 200 REPRODUCTIVE HEALTH, RIGHTS, AND JUSTICE ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PARTIES

The undersigned counsel of record certifies that *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. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Except as stated below, *amici curiae* certify that they have no outstanding shares or debt securities in the hands of the public, and they have no parent companies. Except as stated below, no publicly held company has a 10% or greater ownership interest in any of the *amici curiae.*

- Endora's parent company is Open Collective Foundation. No publicly traded corporation owns 10% or more of its stock.
- I Need an A.com's parent company is A Team Tech LLC. No publicly traded corporation owns 10% or more of its stock.
- Patient Forward's parent company is NEO Philanthropy. No publicly traded corporation owns 10% or more of its stock.
- The Lawyering Project is fiscally sponsored by Tides Foundation. No publicly traded corporation owns 10% or more of its stock.
- Whole Woman's Health's parent company is The Booyah Group, LLC. No publicly traded corporation owns 10% or more of its stock.

Dated: May 1, 2023

/s/ Jessica Ring Amunson
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INTEREST OF *AMICI* AND SUMMARY OF ARGUMENT[1]

Amici are over 200 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. 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. Other *amici* are clinics and healthcare providers, who are directly impacted by the decisions below. 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. *See* Memorandum Opinion and Order, *Alliance for Hippocratic Med. v. U.S. FDA*, No. 22-cv-00223-Z, __ F. Supp. 3d __, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023) [hereinafter Order]. In granting that stay, the district court effectively substituted itself for the agency as the expert evaluator of drug approval, cherry-picking from debunked data and anecdotes to opine about the

[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.

purported dangers of medication abortion. The court maintained that the FDA's actions ignored "safety concerns," suggesting that the agency acquiesced to "political pressure to forego its proposed safety precautions." *Id*. at *27. Despite the fact that the challenged approval has been in effect for over twenty years and has, in that time, enjoyed an indisputable safety record conclusively demonstrating that the drug is safe and effective, 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 *29.

Rather than stay this erroneous decision in its entirety, a divided panel of this Court rolled back the clock on the FDA's scientific evaluations of mifepristone, enjoining the agency's 2016 evidence-based updates to the mifepristone labeling; 2016 and 2021 determinations to eliminate certain outdated and burdensome elements of its Risk Evaluation and Mitigation Strategy (REMS) for mifepristone; and 2019 approval of an abbreviated new drug application (ANDA) for mifepristone. *See Alliance for Hippocratic Med. v. U.S. FDA*, No. 23-10362, 2023 WL 2913725, at *21 (5th Cir. Apr. 12, 2023) [hereinafter Panel Decision]. The Supreme Court subsequently stayed the district court's order in full pending appeal, with only two Justices noting their dissent. *See* Order on Application for Stay, *Danco Labs., LLC v. Alliance for Hippocratic Med.*, Nos. 22A901 & 22A902, 2023 WL 3033177 (U.S. Apr. 21, 2023).

Amici write to explain how the district court's decision is contrary to the conclusion of the scientific and medical community that medication abortion is one of the safest medication regimens in the United States and around the world, and to explain the devastating consequences if the Court does not reverse the district court's decision and reject plaintiffs' specious claims of injury. The FDA approved mifepristone over twenty years ago in recognition of the fact that it is safe, effective, and medically necessary; that evidence has only grown more compelling with time, as decades of study and practice have confirmed mifepristone's efficacy and safety. The decision below relies on self-serving anecdotal data and discredited testimony, while declining to engage with the rigorous—and plentiful—scientific data supporting the FDA's decisions. And it flies in the face of both this conclusive scientific evidence and the proper role of courts reviewing agency decision-making. Before this Court, too, plaintiffs have sought to rely on that very same purported expert analysis; but this Court should reject these contentions as lacking any scientific basis.

Affirming even part of the district court's decision will erect unnecessary burdens to mifepristone access. 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 ready availability is critically important. If the decision is not reversed, people even in states where abortion remains legal or protected could find themselves unable to timely access mifepristone, imperiling access to abortion and miscarriage care and jeopardizing patients' health and autonomy. And clinics and providers—such as several *amici*—could find themselves unable to effectively provide competent medical care given the new legal uncertainty the decision below creates. Neither science nor law supports this result, and this Court should reverse the decision below.

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. Millions of people in the United States have used mifepristone, and over twenty years of evidence reinforces the FDA's conclusion that medication abortion with mifepristone is undeniably safe and effective.[2] Medication abortion is the most common method of

[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.); 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).

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

Mifepristone is also recommended by leading medical authorities like the American College of Obstetricians and Gynecologists ("ACOG") as part of a safe and effective medication regimen for miscarriage care, with high-quality research indicating that use of mifepristone "may significantly improve treatment efficacy."[4] Indeed, mifepristone is regularly prescribed for the management and treatment of miscarriages,[5] which can be life-threatening without adequate treatment.[6] For people carrying a pregnancy to term, mifepristone can also be used to reduce bleeding or life-threatening hemorrhaging during certain serious pregnancy complications.[7]

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

[3] *Id.*; Pak Chung Ho, *Women's Perceptions on Medical Abortion*, 74 Contraception 11 (2006).
[4] ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, reaff'd 2021), https://bit.ly/3LJ1lta.
[5] *See* Mara Gordon & Sarah McCammon, *A Drug that Eases Miscarriages is Difficult for Women to Get*, NPR (Jan. 10, 2019), http://bit.ly/42lU7l8.
[6] *See* ACOG, *supra* note 4; 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.
[7] *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.

for use in the United States.[8] The FDA updated the evidence-based regimen in 2016, allowing the prescription of the drug by a broader set of healthcare providers and altering the drug's labeling to reflect an increase in the gestational age limit from 49 to 70 days and a reduction in the number of in-person clinic visits to one, relying on updated data (inclusive of over 80 high-quality studies studying hundreds of thousands of women) underscoring mifepristone's safety without these impediments.[9]

Hundreds of high-quality studies conducted since mifepristone's 2000 approval confirm mifepristone's safety. Indeed, mifepristone has been used in over 600 published clinical trials and discussed in nearly 800 medical reviews.[10] Moreover, 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

[8] 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).
[9] *See* FDA Ctr. for Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 5, 14-17 (Mar. 29, 2016) ("2016 FDA Approval"), https://bit.ly/3n5zUzZ.
[10] Based on a review of publications on PubMed.

medications," such as "antibiotics and NSAIDS"[11] (non-steroidal anti-inflammatory drugs, such as ibuprofen and aspirin)—medications millions of people take daily.[12]

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%.[13] The risk of death hovers around zero (only 13 recorded deaths even possibly related to medication abortion, or roughly 0.00035%)[14]—less than the risk of complications from use of Viagra[15] or wisdom teeth removal.[16] The FDA has noted that side effects such as "bleeding, infections, or other problems" can arise any time the pregnant uterus is emptied, whether through "a miscarriage, [procedural] abortion, medical abortion, or childbirth"[17]; that there is no evidence that these serious complications are *caused* by mifepristone; and that "the physiology of pregnancy may be a more plausible risk

[11] 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.
[12] Pamela Gorczyca et al., *NSAIDs: Balancing the Risks and Benefits*, U.S. Pharmacist (Mar. 17, 2016), http://bit.ly/3YLbw3x.
[13] 2016 FDA Approval, *supra* note 9, at 56.
[14] 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 9, at 8, 47-51.
[15] Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 JAMA Network 590 (Feb. 2, 2000) (4.9 deaths per 100,000 prescriptions).
[16] 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% for abortions).
[17] U.S. FDA, Mifeprex Prescribing Information 15-16 (revised Mar. 2016), https://bit.ly/3Z0kGJy.

factor" than mifepristone for rare serious infections following use.[18] These complications are therefore both exceedingly rare *and* not specific to mifepristone.

Instead of citing any of this authoritative data, the court below, "improperly substitut[ing] [its] 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). *Amici* discuss just a few of the many examples to illuminate precisely how unreliable plaintiffs' purported experts are.

The district court relied on a study by Dr. Priscilla Coleman purporting to show the mental health consequences of abortions. Order, 2023 WL 2825871, at *5. But that study 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). One court described the study 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

[18] 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.

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, 2023 WL 2825871, at *5 (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 after being presented with overwhelming countervailing evidence), *with* Order, 2023 WL 2825871, at *22 n.38 (citing same study).

In upholding most of the district court's injunction, the motions panel of this Court similarly erred in relying on anecdotes in declarations from discredited anti-abortion physicians. As a preliminary matter, no declarant says that they have personally researched these issues, and no declaration reflects actual studies or peer-

reviewed scholarly works. But even taking them on their own terms, these declarations cannot be credited.[19]

One declaration came from Dr. Skop, whose "expertise" has been regularly discredited. *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 grounds*, 344 So. 3d 637 (Fla. 1st Dist. Ct. App. 2022), *review granted*, No. SC22-1050, 2023 WL 356196 (Fla. Jan. 23, 2023); *Planned Parenthood S. Atl. v. Wilson*, 527 F. Supp. 3d 801, 811 (D.S.C. 2021) ("Skop's opinion is at odds with actual data from South Carolina" (quotation marks omitted)), *voluntarily dismissed without prejudice*, 2022 WL 2905486 (D.S.C. July 22, 2022).

Next, the panel noted patients' purported "torrential" bleeding, citing in part a declaration from Dr. Harrison. Panel Decision, 2023 WL 2913725, at *7. But Dr.

[19] Of course, even if these declarations were reliable, which these and a host of similar cases show they are not, *amici* note that isolated anecdotal evidence from a handful of pro-life physicians is not an adequate substitute for neutral clinical studies. *See United States v. Playboy Ent. Grp., Inc.*, 529 U.S. 803, 819 (2000) (faulting government for relying on "anecdotal evidence to support its regulation"). And it is *certainly* not an adequate basis for the court to "substitute[e] its judgment for that of the agency." *Dep't of Com.*, 139 S. Ct. at 2570.

Harrison, too, has been found to be unreliable. *See, e.g.*, *MKB Mgmt. Corp. v. Burdick*, 855 N.W.2d 31, 68 (N.D. 2014) ("Dr. Harrison's opinions … appear to be shaped primarily by the position she is advocating at the moment. … [They also] lack scientific support, tend to be based on unsubstantiated concerns, and are generally at odds with solid medical evidence."); *Little Rock Fam. Planning Servs. v. Rutledge*, 397 F. Supp. 3d 1213, 1268, 1273 (E.D. Ark. 2019) ("Dr. Harrison cites no source material or scientific studies in support of [her] assertion[s]."), *aff'd in part, appeal dismissed in part, and remanded*, 984 F.3d 682 (8th Cir. 2021), *summarily vacated*, 142 S. Ct. 2894 (2022). Indeed, at least one court has explicitly rejected Dr. Harrison's concerns of "increased risk of bleeding" from mifepristone, in light of "several studies that show that only 1.6 out of every 1000 patients experienced *any* significant adverse events." *Okla. Coal.*, 441 P.3d at 1156-57. That court concluded—contrary to Dr. Harrison's contentions—"the evidence shows that there are *no* significant health-related problems which occur by utilizing the [post-2016] protocol." *Id.* at 1158 (emphasis added).

Dr. Wozniak, another of plaintiffs' physicians, also offered no studies or data. She claims that women suffering complications due to "the irresponsible administration" of mifepristone experience complications that occupy physicians' time to manage. Panel Decision, 2023 WL 2913725, at *9. But she cites nothing to back up this assertion—again, as courts have previously noted. *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 26632080 (7th Cir. July 11, 2022). And Dr. Wozniak's declaration neither contains nor describes *any* sort of evidence of this supposed phenomenon, much less evidence sufficient to contradict the hundreds of peer-reviewed studies and medical reviews demonstrating the absence of serious adverse effects.

It is little surprise that both plaintiffs and the district court below struggled to find reputable scientific data with which to bolster their arguments and conclusions. Studies seeking to show that abortion carries negative health consequences have repeatedly been criticized by members of the scientific community as counter to the actual scientific evidence. The National Academies concluded that much of the literature alleging "abortion's [negative] effects" on health and well-being "fails to meet scientific standards for rigorous, unbiased research."[20] 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,

[20] National Academies Report, *supra* note 11, at 152.

breast cancer, or mental health disorders."[21] The American Psychological Association, too, has emphatically rejected the notion that abortion is associated with increased psychological problems.[22] 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, 2023 WL 2825871, at *5.[23]

Just as importantly, mifepristone *works*. Studies show that mifepristone, combined with misoprostol, has a 99.6% success rate in terminating pregnancies.[24] 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.[25] Although plaintiffs invoke mifepristone's patient agreement form to misleadingly suggest that hundreds of thousands of women will need emergency care after taking mifepristone, there is

[21] *Id.* at 152-53.
[22] Zara Abrams, *The Facts About Abortion and Mental Health*, Am. Psychological Ass'n (updated Apr. 21, 2023), https://bit.ly/3AKhDvq.
[23] The court's reliance on these studies is of a piece with the court's adoption of anti-abortion rhetoric rather than scientific terminology to describe the medical procedure at issue. *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").
[24] 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.
[25] Kaiser Family Found., *supra* note 2.

simply no evidence of widespread need for emergency care due to mifepristone—not since it was approved in 2000, nor since the adoption of the 2016 or 2023 REMS. Surely if such evidence existed, the plaintiffs would have entered it into the record below.

The district court ignored the evidence showing that mifepristone is an essential component of reproductive healthcare today. Over the last nearly 25 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 2016 and 2023 REMS were adopted precisely because of the overwhelming evidence of its safety. There is no legitimate reason to restrict mifepristone's availability 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 will. While procedural abortion is also very safe, medication abortion offers unique and important benefits for many patients. Some patients prefer medication abortion because it allows them to pass the pregnancy in private, at a place of their choosing, and with the support of their immediate network, in a process similar to

miscarriage.[26] Medication abortion also allows patients to forgo physical contact and vaginal insertions, an option that may be particularly important for survivors of sexual violence and people experiencing gender dysphoria. And, critically, medication abortion is often easier to access than procedural abortions, which are offered by a smaller percentage of U.S. abortion providers; frequently require multi-week wait times for an appointment; and necessarily require patients to travel to a health care provider for in-person care, with all of the attendant costs and burdens of transportation, childcare, and time off work.

By contrast, in many states (and consistent with the FDA's well-founded determination in 2021 to eliminate the REMS in-person dispensing requirement), medically eligible patients can now safely access medication abortion through telemedicine without ever needing to leave their home. Having an abortion at home may provide benefits to both patients and providers. Telehealth can enable patients to avoid harassment from protesters at clinics known to provide abortion.[27] It can

[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* Press Release, Nat'l Abortion Fed'n, *National Abortion Federation Releases 2021 Violence and Disruption Report* (May 19, 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.

also reduce wait times[28] and remove barriers to healthcare due to travel costs.[29]

Because medication abortion reduces barriers to time-sensitive health care, its availability is particularly critical 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.

Eliminating mifepristone from the market will exacerbate the current reproductive healthcare crisis, as medication abortion constitutes over half of current abortion care. The prohibition of abortion in over twelve 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.[30] The ever-shrinking number of clinics already have to provide care for a dramatic increase in patients.[31] For example, post-*Dobbs*, the three Wichita, Kansas clinics have an average service population of 1.8 million (meaning

[28] 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://bit.ly/3lGze3O.
[29] Abid Haleem et al., *Telemedicine for Healthcare: Capabilities, Features, Barriers, and Applications*, 2 Sens. Int'l 100117 (2021), https://bit.ly/3nrY2No.
[30] 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.
[31] *See* Caitlin Myers et al., *Abortion Access Dashboard*, http://bit.ly/3KFOck7 (last accessed May 1, 2023) (noting that there has been a 32% increase in women per abortion facility since March 1, 2022).

that they are the closest abortion facility for 1.8 million women *each*).[32] Not one of these three facilities has an opening in the next two weeks.[33] Similarly, the lone Cincinnati clinic, with an average service population of 957,700 women, has no openings in the next two weeks.[34] Even a two-week wait can quite literally be the determining factor in whether an individual can legally receive abortion care.[35]

This already-overwhelmed system of abortion provision will be even further strained if the main method of abortion provision is restricted or banned, including by reverting mifepristone's labeling and REMS to their pre-2016 status. 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] 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.[37] Of the 762 brick-and-mortar abortion facilities in the United States, 40% provide *exclusively* medication

[32] Caitlin Myers et al., *About the Abortion Access Dashboard: Data and Methodology*, http://bit.ly/3KiYoOc (last accessed May 1, 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.
[33] Myers, *supra* note 31.
[34] *Id.*
[35] *See* Patricia Mazzei et al., *DeSantis Signs Six-Week Abortion Ban in Florida*, N.Y. Times (Apr. 14, 2023), https://bit.ly/3KGakcM.
[36] Philbin, *supra* note 30.
[37] *Id.*

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 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 some portion of existing medication abortion providers switch to misoprostol-only regimes, removing access to mifepristone will upend care

[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 30.
[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 30; *see also* Myers, *supra* note 38 (Maine would lose 86% of its abortion facilities, California 60%, Connecticut 56%, Washington 51%, and Vermont 50%).

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] Studies show that requiring people to travel prevents a substantial number from reaching providers at all.[45] A 2021 study forecast 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] Another study showed that 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%.[47]

Increased travel adds not only logistical barriers, but also material costs, including the risk of adverse employment consequences. As a result, limiting mifepristone access could erect burdensome socioeconomic barriers for communities that are already underinsured and medically underserved.[48] Many

[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.
[45] Jason M. Lindon et al., *How Far Is Too Far? New Evidence on Abortion Clinic Closures, Access, and Abortions*, 55 J. Human Res. 1137, 1217 (2020).
[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.
[47] Lindon et al., *supra* note 45.
[48] 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.

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.[49] 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.[50] Delayed access to abortion also significantly increases the cost and decreases the availability of care[51]—particularly worrisome given that a large share of people seeking abortions have low incomes and are least equipped to handle increased economic burdens.[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 people may then need to travel outside of

[49] 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.

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

[51] 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.

[52] 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 (June 2017), https://bit.ly/3GE5KdW.

[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).

their communities to access care, some may experience life-threatening obstetrical emergencies, and some may not be able to access care at all.

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 face increased long-term risks across numerous measures of health and well-being. 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.[54] They are also more likely to remain in contact with violent intimate partners,[55] and are likely to suffer from mental, emotional, and physical trauma.[56] 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.[57]

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[54] *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.

[55] 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.

[56] 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.

[57] 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.

Giving birth, too, carries serious health risks. Pregnancy and birth pose much higher health risks than abortion and are associated with chronic pain lasting up to five years after birth.[58] According to a recent Centers for Disease Control and Prevention report, the maternal mortality rate has risen since 2018.[59] The United States has long had the highest maternal mortality rate among wealthy countries, with no signs of improvement.[60] 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.[61] 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.[62] Pregnant people of color are more likely to experience early pregnancy loss or miscarriage, the treatment for which can include procedural or medication abortion.[63] Moreover, Black women are three to four times more likely than white

[58] 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.
[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] Eugene Declercq & Laurie Zephyrin, *Maternal Mortality in the United States: A Primer*, Commonwealth Fund (Dec. 2020), https://bit.ly/3niymD7.
[61] *Id.* at 3.
[62] *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.
[63] 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.

women to die a pregnancy-related death in the United States,[64] and Indigenous women are 2.3 times more likely than white women.[65] Notably, hospitals that predominantly serve Black patients—where about 75% of Black women give birth—provide comparatively lower-quality maternal care.[66]

Mifepristone, as a component of 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 also deny scores of people who are *not* seeking an abortion an important aspect of medical care for miscarriage and for complications that might occur 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 render abortion essentially unattainable in some parts of the country—even within states where abortion remains legal. Pregnant people could

[64] 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.

[65] Emily E. Petersen, et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths—United States, 2007-2016*, CDC (Sept. 6, 2019), http://bit.ly/3Km7UQv.

[66] *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.

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.

Finally, even partial suspension of FDA approval would cause grievous harm. The FDA has made clear that, should the court suspend all post-2015 changes to the mifepristone regimen, it would consider all branded mifepristone to currently be mislabeled, potentially making its interstate distribution illegal and meaning that all prescribers would need to become recertified—a costly and time-intensive process—and it would consider the generic mifepristone to be unapproved, impacting two-thirds of the mifepristone currently supplied for medication abortions.[67] As a result, prescribing mifepristone would functionally come to an immediate standstill. Even if providers were able to obtain medication to provide, such a decision would also create needless legal confusion and uncertainty as to what is and is not allowed—attempting to comply with such an unprecedented court order would bear no relationship to how drug regulation and evidence-based medicine work with respect to every other prescription drug. Confusion over which Patient

[67] *See* Brief for GenBioPro as Amicus Curiae Supporting Applicant, *Danco Labs. LLC. v Alliance for Hippocratic Med.*, No. 22A901, 2023 WL 3033177 (U.S. Apr. 21, 2023) , https://bit.ly/44fnTcd (noting that the only supplier of generic mifepristone in the United States supplies approximately two-thirds of the market).

Agreement Forms and Medication Guides apply, as well as whether recertification by providers is necessary, could chill the provision of care and would sow chaos, confusion, and distress throughout the country. Patients deserve to be able to access the care they need, when they need it, and physicians deserve to be able to make evidence-based medical decisions for their patients without fear of ill-defined liability.

There is no basis in science or law for the result below, given mifepristone's demonstrated safety, efficacy, and indeed necessity in today's reproductive healthcare landscape. And the result is 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. There is simply no reason to allow any part of the district court's decision to go into effect.

CONCLUSION

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

May 1, 2023

Respectfully submitted,

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APPENDIX

List of *Amici Curiae*

Center for Reproductive Rights

American Civil Liberties Union Foundation

Planned Parenthood Federation of America

A Better Balance

A Woman's Choice clinics in FL and NC

Abortion Freedom Fund

Abortion Fund of Arizona

Abortion Rights Fund of Western Mass

ACCESS REPRODUCTIVE JUSTICE

Access Health Group Ltd

Advancing New Standards in Reproductive Health (ANSIRH, UCSF)

Advocates for Youth

Alamo Women's Clinics of Illinois and New Mexico

All* Above All Action Fund

All Families Healthcare

American Civil Liberties Union of Texas

American Humanist Association

American Medical Student Association (AMSA)

Americans United for Separation of Church and State

Amplify Georgia Collaborative

Ancient Song

Apiary for Practical Support

Avow Texas

AWAKE TN

Birth in Color RVA

Black Women for Wellness

Black Women for Wellness Action Project

Blue Mountain Clinic

Bread and Roses Women's Health Center

Broward Women's Emergency Fund, Inc.

California Nurse-Midwives Association

California Women Lawyers

Cambridge Reproductive Health Consultants

carafem

CARE Colorado

Carolina Jews for Justice

Catholics for Choice

Center for Women's Health

Central Conference of American Rabbis

Chicago Abortion Fund

Chicago Foundation for Women

Choice Network

Cobalt

Collective Power for Reproductive Justice

COLOR Latina

Colorado Doula Project

Colorado Women's Bar Association

Columbia NOW, SC, National Organization for Women

Community Catalyst

Community Supported Abortion / Aborto Sostenido por la Comunidad

DC Abortion Fund

Desert Star Family Planning

Desert Star Institute for Family Planning

Desiree Alliance

El Pueblo

Elephant Circle

EMAA Project

Emergency Medical Assistance

Endora

Equinox Primary Care

Essential Access Health

Every Mother Counts

Faith Choice Ohio

Falls Church Healthcare Center

Family Planning Associates Medical Group

Feminist Women's Health Center

Florida Health Justice Project

Full Circle Health Center

Fund Texas Choice

Gender Justice

Gender Justice League

Girls for Gender Equity

Grand Strand Action Together

GSBA

Grandmothers for Reproductive Rights (GRR!)

Greenville Women's Clinic, PA

Guttmacher Institute

Healthy and Free Tennessee

Healthy Futures

Hope Clinic

Hope Medical

Houston Women's Reproductive Services

I Need an A.com

Ibis Reproductive Health

ICAN! (Illinois Contraceptive Access Now)

If/When/How: Lawyering for Reproductive Justice

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

Indigenous Women Rising

Innovations in Reproductive Health Access

International Action Network for Gender Equity & Law (IANGEL)

Ipas

Jane's Due Process

Jewish Women International

Juniper Midwifery

Just The Pill

Lambda Legal Defense and Education Fund., Inc.

LatinoJustice PRLDEF

Lawyering Project

Legal Momentum, the Women's Legal Defense and Education Fund

Lift Louisiana

Lilith Care

Louisiana Coalition for Reproductive Freedom

Mabel Wadsworth Center

Maine Family Planning

Maitri Wellness

Mayday Health

Metro Area Modern Reproductive Care LLC

Men of Reform Judaism

Michigan Voices

Midwest Access Coalition

Midwives Alliance of Hawai'i

Miscarriage and Abortion Hotline

NARAL Pro-Choice America

National Black Midwives Alliance

National Center for Law and Economic Justice

National Center for Lesbian Rights

National Council of Jewish Women

National Education Association

National Employment Law Project

National Family Planning & Reproductive Health Association

National Health Law Program

National Hispanic Medical Association

National Indigenous Women's Resource Center

National Institute for Reproductive Health

National Latina Institute for Reproductive Justice

National Network of Abortion Funds

National Partnership for Women & Families

National Perinatal Association

National Women's Law Center

National Women's Liberation

National Women's Political Caucus

New Era Colorado

New Georgia Project

New York Abortion Access Fund (NYAAF)

New York Midwives

NOISE FOR NOW

North Dakota WIN Abortion Access Fund

North Seattle Progressives

Northland Family Planning Centers

Northwest Health Law Advocates

Nurses for Sexual and Reproductive Health (NSRH)

Oklahoma Call for Reproductive Justice

PAI

Palmetto State Abortion Fund

Partners in Abortion Care

Patient Forward

Pensacola Abortion Rights Task Force

People For the American Way

People Power United

Period Pills Project

Plan C

Positive Women's Network-USA

Possible Health, Inc.

Power to Decide

Pregnancy Justice

Presidential Women's Center

Pro-Choice Missouri

Pro-Choice North Carolina

Pro-Choice Ohio

Pro-Choice Washington

PUSH for Empowered Pregnancy

Queen's Bench Bar Association of the San Francisco Bay Area

Rapid Benefits Group Fund

Reclaim, Inc.

Red River Women's Clinic

Red Wine & Blue

REPRO Rising Virginia

Reproaction

Reproductive Equity Now

Reproductive Freedom Fund of New Hampshire

Reproductive Health Access Project

RHEDI (Reproductive Health Education in Family Medicine)

RHITES (Reproductive Health Initiative for Telehealth Equity & Solutions)

Reproductive Justice Action Collective

Reproductive Rights Coalition

Rhia Ventures

Robbinsdale Clinic, PA

Ryan Residency Training Program

Santa Barbara Women Lawyers

Seattle Chapter, National Organization for Women

SHERo Mississippi

Shout Your Abortion

SIECUS: Sex Ed for Social Change

South Asian SOAR

Southern Birth Justice Network

Southwestern Women's Options

SPARK Reproductive Justice NOW, Inc.

State Innovation Exchange (SiX)

Tennessee Freedom Circle

Texas Equal Access Fund

The Brigid Alliance

The National Abortion Federation

The National Women's Health Network

The Women's Centers: CT, GA, NJ & PA

The Womxn Project

Trust Women Foundation

Ubuntu Black Women's Wellness Collective

UCSF Bixby Center for Global Reproductive Health

UltraViolet

Union for Reform Judaism

Unitarian Universalist Association

Unite for Reproductive & Gender Equity (URGE)

URMC Family Planning Service

We Testify

West Alabama Women's Center

Whole Woman's Health (VA, MD, MN, IL, NM)

Whole Woman's Health Alliance (VA, MN, IN, TX)

Wild West Access Fund of Nevada

Women Lawyers On Guard Inc.

Women of Reform Judaism

Women's Health Specialists

Women's Law Project

Women's Reproductive Rights Assistance Project (WRRAP)

Women's Rights and Empowerment Network

2+ Abortions Worldwide

10,000 Women Louisiana

CERTIFICATE OF COMPLIANCE

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/s/ Jessica Ring Amunson

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of May, 2023 a true and correct copy of the foregoing Brief was served via the court's CM/ECF system.

/s/ Jessica Ring Amunson