Nos. 22A901, 22A902

IN THE
Supreme Court of the United States

DANCO LABORATORIES, LLC,
APPLICANT,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,

U.S. FOOD & DRUG ADMINISTRATION, ET AL.,
APPLICANTS,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,

On Application for Stay of Preliminary Injunction Pending Appeal

BRIEF OF OVER 200 REPRODUCTIVE HEALTH, RIGHTS, AND JUSTICE ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF APPLICANTS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

OTHER AUTHORITIES

INTRODUCTION AND INTEREST OF *AMICI CURIAE*[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 safety, cherry-picking from debunked data and anecdotes to opine about the 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

[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.

precautions." *Id.* at *27. Despite the fact that the challenged approval has been in effect for over twenty years, the court—citing nothing more than plaintiffs' assertions in their brief—declared that medication abortion causes "physical and emotional trauma," "mental and monetary costs," and death. *Id.* at *29.

Rather than stay this erroneous decision in its entirety, the Fifth Circuit compounded the problem. The panel, in a 2-1 decision, enjoined the 2016 and 2023 Risk Evaluation and Mitigation Strategies (REMS), as well as the 2019 abbreviated new drug application (ANDA) despite serious jurisdictional and merits flaws and without any real evaluation of the nationwide harm such an injunction will cause. *See Alliance for Hippocratic Med. v. U.S. FDA*, No. 23-10362, __ F.4th __, 2023 WL 2913725, at *21 (5th Cir. Apr. 12, 2023) [hereinafter Panel Decision]. As a result of the Fifth Circuit's decision, *all* existing doses of the branded mifepristone would currently be mislabeled, and the previously approved generic version—which made the drug accessible to many more patients than the more costly branded version—would no longer be approved for use. *See* U.S. FDA's Stay Application at 38. Moreover, the FDA estimates that it will take the agency months to modify mifepristone's labeling to bring it back into compliance with this decision. *Id.* And if this Court declines to stay the Fifth Circuit's decision now, and a later court order ultimately reinstates the conditions of the FDA's Mifeprex approval as of 2023, all of these sponsors would need to begin the process *all over again*. All the while, the untold thousands of people who need mifepristone for life-saving reproductive care will face immense hurdles to obtaining it, while the providers will face tremendous legal uncertainty as to whether they can prescribe and administer it.

Amici write to explain how both decisions are contrary to the conclusions 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 stay the district court's decision in its entirety. The FDA approved mifepristone over twenty years ago in recognition of the fact that it is safe, effective, and medically necessary, and that evidence has only grown more compelling with time, as decades of study and practice have confirmed mifepristone's efficacy and safety. The decisions below rely 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 they fly in the face of both this conclusive scientific evidence and the proper role of courts reviewing agency decision-making.

Permitting even part of district court's decision to take effect will immediately 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 stayed, people even in states where abortion remains legal or protected could find themselves unable to timely access mifepristone, imperiling access to abortion and jeopardizing the health and autonomy of persons unable to timely obtain care. 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.

By contrast, the utterly hypothetical harm alleged by the plaintiffs is decidedly *not* imminent—it does not even meet the legal standard for Article III standing, much less the type of irreparable harm that could outweigh the nationwide damage the decision below will inflict. Neither science nor law supports this result, and this Court should issue the requested emergency relief.

ARGUMENT

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

Mifepristone is one of two medications (along with misoprostol) that are most used to terminate an early pregnancy—often referred to as medication abortion. Medication abortion is central to reproductive healthcare today. Thousands of people in the United States use mifepristone each year, and over twenty years of evidence reinforces the FDA's conclusion that medication abortion with mifepristone is undeniably safe and effective.[2] Medication abortion has become the most common method of abortion in the United States, both because of its safety and efficacy and because many patients prefer it.[3]

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[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).

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

The FDA approved mifepristone in 2000 after a thorough, nearly five-year scientific review determined it was safe for widespread use. Mifepristone had already been approved in multiple countries across the world before being approved for use in the United States.[4] The FDA updated the evidence-based regimen on the drug's label in 2016, reflecting an increase in the gestational age limit from 49 to 70 days, a reduction in the number of in-person clinic visits to one, and the prescription of the drug by a broader set of healthcare providers, relying on updated data (inclusive of over 80 high-quality studies studying hundreds of thousands of women) underscoring mifepristone's safety without these impediments.[5]

In its 2016 approval, the FDA relied on no fewer than 12 independent clinical studies, collectively representing "well over 30,000 patients," and conclusively showing "serious adverse events" at rates "generally far below 1.0%."[6] *Hundreds* of additional high-quality studies conducted since mifepristone's 2000 approval show the same. Mifepristone has been used in over 600 published clinical trials and discussed in nearly 800 medical reviews.[7] Indeed, after reviewing all available science, the National Academies of Sciences, Engineering, and Medicine ("National Academies"), a universally respected non-partisan advisory institution, concluded that abortion by any method is extremely safe, and the risks of medication abortion are "similar in magnitude to the

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[4] U.S. FDA, Medical Officer's Review of NDA 20-687, at 2 (Nov. 1999), https://bit.ly/3TSM77p; *see* Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. Med. 57 (2022).
[5] *See* FDA Ctr. for Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 5, 14-17 (Mar. 29, 2016) ("2016 FDA Approval"), https://bit.ly/3n5zUzZ.
[6] *Id.* at 1, 50, 56.
[7] Based on a review of publications on PubMed.

reported risks of serious adverse effects of commonly used prescription and over-the-counter medications," such as "antibiotics and NSAIDS"[8] (non-steroidal anti-inflammatory drugs, such as ibuprofen and aspirin)—medications millions of people take daily.[9]

Mifepristone carries extremely low risks of complication or negative health consequences. It also has an exceedingly low rate of major adverse events, such as hospitalization or serious infection. The FDA's 2016 approval cited a host of studies showing that the rate of major adverse events was roughly 0.3%,[10] with multiple studies reporting even lower rates of infection (such as 0%, 0.014%, and 0.015%[11]). The risk of death hovers around zero (only 13 recorded deaths even possibly related to medication abortion, or roughly 0.00035%)[12]—less than the risk of complications from the use of Viagra[13] or getting one's wisdom teeth removed.[14] Moreover, the FDA has noted that the very same complications can arise during a miscarriage or procedural abortion[15] and "the physiology of pregnancy may be a more plausible risk factor" than mifepristone for rare

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[8] Nat'l Acads. of Sci., Eng'g. & Med., *The Safety and Quality of Abortion Care in the United States* 45, 56-68, 79 (2018) ("National Academies Report"), http://nap.edu/24950.
[9] Pamela Gorczyca et al., *NSAIDs: Balancing the Risks and Benefits*, U.S. Pharmacist (Mar. 17, 2016), http://bit.ly/3YLbw3x.
[10] 2016 FDA Approval, *supra* note 5, at 56.
[11] *Id.* at 54.
[12] ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report: "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018*," Univ. of Cal., S.F.: Issue Brief, 1 (Apr. 2019), https://bit.ly/3Tqn1fY; *see also* 2016 FDA Approval, *supra* note 5, at 8, 47-51.
[13] Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 JAMA Network 590 (Feb. 2, 2000) (Viagra associated with 4.9 deaths per 100,000 prescriptions).
[14] ANSIRH, *Safety of Abortion in the United States*, Univ. of Cal., S.F.: Issue Brief # 6, 1, 1-2 (Dec. 1, 2014), https://bit.ly/3JmawgA (wisdom tooth complication rate is roughly 7%, compared to 2.1% of abortions; complication for tonsillectomies is approximately 4x higher than abortions).
[15] U.S. FDA, Mifeprex Prescribing Information 1, 2, 5 (revised Mar. 2016), https://bit.ly/3Z0kGJy.

serious infections following use.[16] Indeed, the FDA has concluded that side effects such as "bleeding, infections, or other problems,"[17] which the Fifth Circuit associated with mifepristone use, Panel Decision, 2023 WL 2913725, at *6, can accompany "a miscarriage, [procedural] abortion, medical abortion, or childbirth."[18] These complications are therefore both exceedingly 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). *Amici* discuss just a few of the many examples from the decisions below.

Beginning at the district court, the court relied on a study by Dr. 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,"

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[16] Janet Woodcock, M.D., Director, Ctr. for Drug Eval. & Res., to Donna Harrison, M.D., et al., Denying Citizen Petition Asking the FDA to Revoke Approval of Mifeprex 25-26 n.69 (Mar. 29, 2016), http://bit.ly/3KhGAEl.
[17] U.S. FDA, *supra* note 15, at 16.
[18] *Id.*

as it "included women who had *at any time* experienced a mental health problem in their lives, without distinguishing between mental health problems occurring before the abortion and those occurring after." *Whole Woman's Health All. v. Rokita*, No. 18-cv-1904, 2021 WL 650589, at *5 (S.D. Ind. Feb. 19, 2021) (quoting study). Indeed, "the journal in which one of these studies was published later disavowed the study's findings based on the authors' flawed methodology." *Id.* at *6.

The district court cited several additional authors whose work has been rejected by other courts. *Compare, e.g.*, *Planned Parenthood of Wis., Inc. v. Schimel*, 806 F.3d 908, 922 (7th Cir. 2015) (critiquing Reardon & Coleman study because it "measured long-term mortality rates rather than death resulting from an abortion, and also failed to control for socioeconomic status, marital status, or a variety of other factors related to longevity"), *with* Order, 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), *with* Order, 2023 WL 2825871, at *22 n.38 (citing same study).

The Fifth Circuit amplified the district court's use of unreliable sources. In finding that the physician plaintiffs had standing, the court relied on four declarations for the supposed burden on physicians stemming from mifepristone. Panel Decision, 2023 WL 2913725, at *5. 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. One declaration came from Dr. Skop, whose "expertise" has been

regularly discredited.[19] *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 Fifth Circuit noted patients' purported "torrential" bleeding, citing in part a declaration from Dr. Harrison. Panel Decision, 2023 WL 2913725, at *7; *see also* PI Appendix at 170, *Alliance for Hippocratic Med.*, No. 22-cv-223 (N.D. Tex. Nov. 18, 2022), ECF No. 8 (Harrison declaration averring that people who take mifepristone experience "intense side effects … including cramping and heavy bleeding") [hereinafter PI App.]. But Dr. Harrison, too, has been found to be unreliable. *See, e.g.*, *MKB Mgmt. Corp. v.*

[19] 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.

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."); *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).

The Fifth Circuit also relied on Dr. Francis, quoting her statement about a patient with heavy bleeding after purportedly obtaining mifepristone from a website. Panel Decision, 2023 WL 2913725, at *6. But the Fifth Circuit *omitted* Dr. Francis's admission that the patient "was told that the drugs would come from India." PI App. at 194. The omitted sentence—which the Fifth Circuit replaced with ellipses—completely undermines the reliance on Dr. Francis's anecdote (which, in any event, is not evidence). It calls into question whether the patient actually obtained mifepristone or some other, non-FDA-approved drug from India. And it demonstrates that the same patient would experience the same consequence with the Fifth Circuit's order in place. Indeed, many

more patients are likely to turn to imported medication if they face unnecessary barriers to obtaining FDA-approved and regulated mifepristone.[20]

Like Dr. Francis, Dr. Wozniak, also cited in the Fifth Circuit's decision, offered no studies or data. She claims to "know" that women suffering complications from medication abortion lie to their doctors and say they are experiencing miscarriages. PI App. at 218. But she cites nothing more than her own personal opinion—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 the district court and Fifth Circuit struggled to find reputable scientific data with which to bolster their conclusions. Studies seeking to show that abortion carries negative physical and mental health consequences have repeatedly been deemed by members of the scientific community to be counter to the actual scientific evidence. The National Academies concluded that "much of the published literature on" the topics of "abortion's [negative] effects" on health and well-being "fails to meet

[20] Allison McCann, *Inside the Online Market for Overseas Abortion Pills*, N.Y. Times (Apr. 13, 2023), https://bit.ly/3KYAsB0 (overseas "sellers stand only to gain from efforts to restrict medication abortion").

scientific standards for rigorous, unbiased research."[21] 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."[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.

Mifepristone, in large part due to its safety and efficacy, is used in roughly 53% of all abortions in the United States.[23] Indeed, mifepristone is not only used to provide medication abortion, but also is regularly prescribed for the management and treatment of miscarriages,[24] which can be life-threatening without adequate treatment.[25] Even for people carrying a pregnancy to term, mifepristone can be used to reduce bleeding or life-threatening hemorrhaging during certain serious pregnancy complications.[26]

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[21] National Academies Report, *supra* note 8, at 152.
[22] *Id.* at 152-53.
[23] *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.
[24] *See* Mara Gordon & Sarah McCammon, *A Drug that Eases Miscarriages is Difficult for Women to Get*, NPR (Jan. 10, 2019), http://bit.ly/42lU7l8.
[25] *See* ACOG Practice Bulletin No. 200, *Early Pregnancy Loss*, e197, e203 (Nov. 2018, reaff'd 2021); Pam Belluck, *They Had Miscarriages, and New Abortion Laws Obstructed Treatment*, N.Y. Times (July 17, 2022), https://nyti.ms/3Jwb7N1; Rosemary Westwood, *Bleeding and in Pain, She Couldn't Get 2 Louisiana ERs to Answer: Is It a Miscarriage?*, NPR (Dec. 29, 2022), http://bit.ly/40ji4I1; *see also* Oriana Gonzalez & Ashley Gold, *Abortion Pill Demand Soaring Following Roe's Demise*, Axios (July 19, 2022), http://bit.ly/3FAIP2I.
[26] *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.

Just as importantly, mifepristone *works*. Studies show that mifepristone, combined with misoprostol, has a 99.6% success rate in terminating pregnancies.[27] 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.[28] Again, instead of engaging with this scholarship, the Fifth Circuit relied *exclusively* 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. Panel Decision, 2023 WL 2913725, at *5. But the patient agreement form does not say this, and no data supports it. Instead, the patient form 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.[29] 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 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.

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[27] 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.

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

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

The Fifth Circuit 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 Restricting Access To Mifepristone Will Be Immediate And Severe.

The decision below imperils the health and safety of millions of people. Unless this Court steps in with an immediate stay, providers and patients will be left trying to understand the changes that the courts below imposed overnight to a regulatory system in place for decades, putting the provision of care into chaos and exacerbating the reproductive healthcare system, already strained in light of *Dobbs*. The Principal Deputy Commissioner of the FDA has submitted an affidavit explaining the FDA's view that, under the Fifth Circuit's decision, Mifeprex will be deemed misbranded and mislabeled until the sponsor submits a supplemental application that is approved by the FDA; that most prescribers would need to become recertified; and that until the drug is appropriately labeled it cannot be distributed in interstate commerce. U.S. FDA Stay Appendix at 113a-16a. As a result, without this Court's intervention, the prescribing and distribution of Mifeprex will grind to a halt, throwing the current reproductive healthcare landscape into chaos. And when combined with the other potential consequences of the decision—such as reducing the number of people authorized to prescribe the medication,

stripping the approval of the generic, and eliminating telemedicine—this will create dire consequences for patients and physicians.

If patients cannot easily 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, and other people of color, those with low incomes, LGBTQ+ people, young people, immigrants, people with disabilities, and those living at the intersection of those identities. Medication abortion actively reduces sometimes insurmountable barriers to patients, because many states allow patients to take the medications at home following a consultation with a healthcare provider so patients may undergo the process in private, at a place of their choosing, and with the support of their immediate network.[30] And it allows people to forgo physical contact and vaginal insertions, an option that may be particularly important for survivors of sexual violence and people experiencing gender dysphoria.

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

[30] *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.

known to provide abortion.[31] It can also reduce wait times[32] and remove barriers to healthcare due to travel costs.[33]

Restricting mifepristone's use will exacerbate the current reproductive healthcare crisis, as it constitutes over half of current abortions. The prohibition of abortion care in over a dozen states—and more expected—has dramatically increased demand in states with abortion clinics, leading to overwhelmed providers, longer wait times and delays, and more complicated logistics for patients.[34] The ever-shrinking number of clinics already have to provide care for a dramatic increase in patients.[35] 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*).[36] Not one of these three facilities has an opening in the next two weeks.[37] Similarly, the lone Cincinnati clinic, with an average service population of 957,700 women,

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

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

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

[34] 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.

[35] *See* Caitlin Myers et al., *Abortion Access Dashboard*, http://bit.ly/3KFOck7 (last accessed Apr. 14, 2023) (noting that there has been a 32% increase in women per abortion facility since March 1, 2022).

[36] Caitlin Myers et al., *About the Abortion Access Dashboard: Data and Methodology*, http://bit.ly/3KiYoOc (last accessed Apr. 14, 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.

[37] Myers, *supra* note 35.

has no openings in the next two weeks.[38] Even a two-week wait can quite literally be the determining factor in whether an individual can legally receive abortion care.[39]

This already-overwhelmed system of abortion provision will be even further strained if the main method of 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 counties, the only option is medication abortion.[40] 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.[41] Of the 762 brick-and-mortar abortion facilities in the United States, 40% provide *exclusively* medication abortion.[42] In 2020, 100% of abortions in Wyoming were performed with medication abortion.[43] 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.[44] 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

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[38] *Id.*
[39] *See* Patricia Mazzei et al., *DeSantis Signs Six-Week Abortion Ban in Florida*, N.Y. Times (Apr. 14, 2023), https://bit.ly/3KGakcM.
[40] Philbin, *supra* note 34.
[41] *Id.*
[42] Caitlin Myers et al., *What If Medication Abortion Were Banned?* (Apr. 7, 2023), http://bit.ly/3GsvtGl.
[43] 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.
[44] Philbin, *supra* note 34.

roughly 49% of U.S. women who already face that reality.[45] And 10.5 million women of childbearing age could experience an increase in travel time to their nearest provider.[46]

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%."[47] And even if existing providers switch to misoprostol-only regimes, removing access to mifepristone will upend care delivery, imposing burdensome information costs on patients and providers to navigate an increasingly complex and uncertain legal landscape.

People living in these counties and states could therefore be forced to travel long distances to try to access abortions. At least 62 clinics have been shuttered since the end of June 2022, and travel time to obtain abortion has increased significantly across the United States.[48] 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 accessing abortion care.[49] A 2021 study forecasts a similar trend, showing that an increase in travel distance from 0 to 100 miles is estimated to prevent 20.5% of women seeking an abortion from reaching a provider.[50] Studies show

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[45] *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%).
[46] Myers, *supra* note 42.
[47] Philbin, *supra* note 34; *see also* Myers, *supra* note 42 (Maine would lose 86% of its abortion facilities, California 60%, Connecticut 56%, Washington 51%, and Vermont 50%).
[48] *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.
[49] Caitlin Myers, Rachel Jones & Ushma Upadhyay, *Predicted Changes in Abortion Access and Incidence in a Post-*Roe *World*, 100 Contraception 367 (2019).
[50] 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.

that requiring people to travel prevents a substantial number from reaching providers at all.[51] 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%.[52]

Increased travel adds not only logistical barriers, but also added material costs, including the risk of adverse employment consequences. As a result, lack of access to mifepristone could erect burdensome socioeconomic barriers for communities that are already underinsured and medically underserved.[53] 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.[54] Studies show that people without paid sick days are three times more likely to delay or forego medical care, including reproductive healthcare, and that people frequently cite lost wages as one of the largest obstacles to their seeking an abortion.[55] Delayed access to abortion also significantly increases the cost and availability of care[56]—particularly worrisome given

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ly/400IEWr; *see also* Jason M. Lindon et al., *How Far Is Too Far? New Evidence on Abortion Clinic Closures, Access, and Abortions*, 55 J. Human Res. 1137 (2020) (finding "substantial and nonlinear effects of travel distance on abortion rates: an increase in travel distance from 0-50 miles to 50-100 miles reduces abortion rates by 16 percent").

[51] Jason Lindon et al., *supra* note 50, at 1217.

[52] *Id.*

[53] 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.

[54] 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.

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

[56] 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.

that a large share of people seeking abortions have low incomes and are least equipped to handle increased economic burdens.[57] Moreover, although second-trimester abortion remains a very safe procedure, the health risks associated with abortion increase with the weeks of pregnancy,[58] and the availability of providers who offer such procedures decreases. As a result, some of those unable to travel may risk life-threatening obstetrical emergencies.

And finally, the decision below could force countless people to carry a pregnancy to term, which will worsen health-outcome disparities, cause socioeconomic hardship, and decrease wellbeing. Studies show that people denied the ability to terminate their pregnancies may face increased long-term risks. Pregnancy and birth pose much higher health risks than abortion and are associated with chronic pain lasting up to five years after birth.[59] 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.[60] People denied the ability to terminate their pregnancies are also more likely to remain in contact with violent intimate partners,[61] and are likely to suffer from mental, emotional, and physical

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[57] 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 ("75% of abortion patients were poor or low-income in 2014").

[58] *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).

[59] 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.

[60] *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.

[61] 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.

trauma.[62] 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.[63]

Giving birth, too, carries serious health risks. According to a recent Centers for Disease Control and Prevention report, the maternal mortality rate has risen since 2018.[64] 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.[65] 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.[66] Pregnant people of color are more likely to experience early pregnancy loss or miscarriage, the treatment for which can include procedural or medication abortion.[67] Moreover, Black women are three to four times more likely than white women to die a pregnancy-related death in the United

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[62] 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.

[63] 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.

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

[65] *Id.* at 3.

[66] *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.

[67] 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.

States,[68] and Indigenous women are 2.3 times more likely than white women.[69] Notably, hospitals that predominantly serve Black patients—where about 75% of Black women give birth—provide comparatively lower-quality maternal care.[70]

Mifepristone, as the most common method of abortion in the country, and the safest and most accessible means of obtaining an abortion for many people, is key to avoiding harmful outcomes and empowering people of all backgrounds to make decisions for themselves and their families. The decision below, which could functionally put mifepristone out of reach for many, would deny scores of people who are *not* seeking an abortion safe and effective medical care for miscarriage and even after giving birth. It would also place increased strain on the ever-shrinking number of healthcare providers offering abortions, making abortion more logistically difficult nationwide (not just where it has been outlawed already). And crucially, it could render abortion essentially unattainable—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 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.

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[68] 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.

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

[70] *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.

Finally, the Fifth Circuit's partial stay in no way eliminates the potential harm from the district court's decision. As a result of the Fifth Circuit's decision, the FDA considers all branded mifepristone to currently be mislabeled, making its interstate distribution illegal and meaning that all prescribers would need to become recertified—a costly and time-intensive process—and it considers the generic mifepristone to be unapproved. As a result, prescribing mifepristone may functionally come to an immediate standstill. The Fifth Circuit's decision creates needless legal confusion and uncertainty as to what is and is not allowed—and it is nearly impossible for physicians to apply because it bears no relationship to how drug regulation and evidence-based medicine *actually* work. Confusion over which Patient Agreement Forms and Medication Guides apply, as well as whether recertification by providers may be necessary could chill the provision of care and will 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, the Court should grant Applicants' emergency application for a stay.

Dated: April 14, 2023

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APPENDIX

List of *Amici Curiae*

Center for Reproductive Rights

American Civil Liberties Union

Planned Parenthood Federation of America

A Better Balance

A Woman's Choice of FL and NC

Abortion Access Front

Abortion Care Network

Abortion Freedom Fund

Abortion Fund of Arizona

Abortion On Demand

Abortion Rights Fund of Western Mass

ACCESS REPRODUCTIVE JUSTICE

Access Health Group Ltd

Advancing New Standards in Reproductive Health (ANSIRH)

Advocates for Youth

Alamo Women's Clinic of Albuquerque

Alamo Women's Clinic of Illinois

All* Above All Action Fund

All Families Healthcare

Allegheny Reproductive Health Center

American Civil Liberties Union of Texas

American Humanist Association

American Medical Student Association (AMSA)

American Society for Emergency Contraception

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 Gainesville

Broward Women's Emergency Fund

California Women Lawyers

Cambridge Reproductive Health Consultants

carafem

CARE Colorado

Carolina Jews for Justice

Catholics for Choice

Cedar River Clinics

Center for Advancing Innovative Policy

Center for Women's Health

Central Conference of American Rabbis

Chicago Abortion Fund

Chicago Foundation for Women

Choice Network

CHOICES Centers for Reproductive Health

Collective Power for Reproductive Justice

COLOR Latina

Columbia NOW-National Organization for Women

Community Catalyst

Desiree Alliance

DC Abortion Fund

Desert Star Family Planning

Desert Star Institute for Family Planning

EMAA Project

Emergency Medical Assistance

Endora

Essential Access Health

Every Mother Counts

Faith Choice Ohio

Feminist Women's Health Center

Florida Health Justice Project

Forward Midwifery

Full Circle Health Center

Fund Texas Choice

Gender Justice

Gender Justice League

Girls for Gender Equity

Grand Strand Action Together

GSBA

Greenville Women's Clinic, PA

Guttmacher Institute

Gynuity Health Projects

Healthy and Free Tennessee

Hope Clinic

Hope Medical

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

Indigenous Women Rising

Innovations in Reproductive Health Access

Ipas

Jane's Due Process

Jewish Women International

Juniper Midwifery

Just The Pill

Lambda Legal

LatinoJustice PRLDEF

Lawyering Project

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

Lift Louisiana

Louisiana Coalition for Reproductive Freedom

Mabel Wadsworth Center

Maine Family Planning

Maitri Wellness

Mayday Health

Medical Students for Choice

Men of Reform Judaism

Metro Area Modern Reproductive Care LLC

Michigan Voices

Miscarriage and Abortion Hotline

MYA Network

NARAL Pro-Choice America

National Association of Nurse Practitioners in Women's Health (NPWH)

National Center for Law and Economic Justice

National Center for Lesbian Rights

National Council of Jewish Women

National Crittenton

National Education Association

National Employment Law Project

National Family Planning & Reproductive Health Association

National Health Law Program

National Hispanic Medical Association

National Institute for Reproductive Health

National Latina Institute for Reproductive Justice

National Organization for Women Foundation

National Partnership for Women & Families

National Perinatal Association

National Network of Abortion Funds

National Women's Health Network

National Women's Law Center

National Women's Liberation

National Women's Political Caucus

Nebraska Abortion Resources

New Era Colorado

New Georgia Project

New Suffragettes

New York Abortion Access Fund (NYAAF)

NOISE FOR NOW

North Dakota WIN Abortion Access Fund

North Seattle Progressives, Health & Wellness Committee

Northland Family Planning Centers

Northwest Health Law Advocates

Nurses for Sexual and Reproductive Health

Oklahoma Call for Reproductive Justice

Oregon Affiliate of the American College of Nurse-Midwives

Pacific Islander Health Board of Washington

PAI

Palmetto State Abortion Fund

Partners in Abortion Care

Patient Forward

Pensacola Abortion Rights Task Force

People For the American Way

People Power United

Plan C

Positive Women's Network-USA

Possible Health Inc.

Power to Decide

Pregnancy Justice

Pro-Choice Arizona

Pro-Choice Missouri

Pro-Choice Montana

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

Reclaim, Inc. (Abortion Fund)

Red River Women's Clinic

REPRO Rising Virginia

Reproaction

Reproductive Equity Now

Reproductive Freedom Fund of New Hampshire

Reproductive Health Access Project

RHITES (Reproductive Health Initiative for Telehealth Equity & Solutions)

Reproductive Justice Action Collective

Reproductive Rights Coalition

Rhia Ventures

Ryan Residency Training Program

Seattle Chapter, National Organization for Women

SHERo Mississippi

Shout Your Abortion

SIECUS

South Asian SOAR

Southern Birth Justice Network

Southwestern Women's Options

SPARK Reproductive Justice NOW

State Innovation Exchange (SiX)

Tennessee Freedom Circle

Texas Equal Access Fund

The Collective

The National Abortion Federation

The Periods Pill Project

The Rapid Benefits Group Fund

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

URGE: Unite for Reproductive & Gender Equity

URMC Family Planning Service

VoteProChoice

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 of Reform Judaism

Women's Law Project

Women's Reproductive Rights Assistance Project (WRRAP)

Women's Rights and Empowerment Network

2+ Abortions Worldwide

10,000 Women Louisiana