Nos. 23-235 & 23-236

IN THE
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Respondents.

On Petitions for Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN MEDICAL ASSOCIATION, SOCIETY FOR MATERNAL-FETAL MEDICINE, AND OTHER MEDICAL AND PUBLIC HEALTH SOCIETIES AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are leading medical and public-health societies representing physicians, clinicians, and public-health professionals who serve patients in Texas and nationwide. They include: (1) The American College of Obstetricians and Gynecologists ("ACOG"). Representing more than 90% of board-certified OB/GYNs in the United States, ACOG is the nation's premier professional membership organization for obstetrician-gynecologists dedicated to access to high-quality, safe, and equitable obstetric and gynecologic care. ACOG maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. ACOG is committed to ensuring access for all people to the full spectrum of evidence-based quality reproductive health care, including abortion care, and is a leader in the effort to confront the maternal mortality crisis in the United States; (2) The American Medical Association ("AMA"), the largest professional association of physicians, residents, and medical students in the country. Through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States

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[1] Pursuant to Rule 37.6, counsel for *amici curiae* authored this brief in whole; no party's counsel authored, in whole or in part, this brief; and no person or entity other than *amici* and its counsel contributed monetarily to preparing or submitting this brief. Pursuant to Rule 37.2, counsel for *amici curiae* timely notified the counsel of record of their intent to file this brief.

are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes; (3) The Society for Maternal-Fetal Medicine ("SMFM"). Founded in 1977, SMFM is the medical professional society for maternal-fetal medicine subspecialists, who are obstetricians with additional training in high-risk pregnancies. SMFM represents more than 5,500 members who care for high-risk pregnant people and provides education, promotes research, and engages in advocacy to advance optimal and equitable perinatal outcomes for all people who desire and experience pregnancy. SMFM and its members are dedicated to ensuring that all medically appropriate treatment options are available for individuals experiencing a high-risk pregnancy; and (4) Nine other organizations whose members' work is impacted by the matter before this Court and who can offer a unique perspective not otherwise provided by the parties.

These organizations collectively represent hundreds of thousands of medical practitioners across the country, with deep expertise in both medical research and the treatment of patients in real-world settings. Courts frequently rely on *amici*'s medical and scientific expertise in cases involving pregnancy.[2] Ensuring robust access to evidence-based health care and promoting health

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[2] *See*, *e.g.*, *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2131 (2020); *Whole Woman's Health v. Hellerstedt*, 579 U.S. 582, 612–13 (2016); *Whole Woman's Health v. Paxton*, 978 F.3d 896, 910 (5th Cir. 2000); *Stenberg v. Carhart*, 530 U.S. 914, 928 (2000); *Planned Parenthood Ctr. for Choice v. Abbott*, No. A-20-CV-323-LY, 2020 WL 1815587, at *4–5 (W.D. Tex. Apr. 9, 2020).

care policy that improves patient health are central to *amici*'s missions. *Amici* believe that all patients are entitled to prompt, complete, and unbiased health care that is medically and scientifically sound. *Amici* submit this brief to explain that the current Food and Drug Administration-endorsed ("FDA") protocol for the prescription and use of mifepristone aligns with the overwhelming weight of medical evidence and allows *amici* to safely administer the drug in a manner consistent with medical ethics and medically appropriate standards of care.

Amici's ability to effectively care for patients often requires access to mifepristone, which has undergone rigorous testing and review and has been approved for use in the United States for more than 20 years. Accordingly, *amici* have a strong interest in preserving that access and ensuring that the science surrounding mifepristone's safety, efficacy, and administration is correctly understood.

Amici are the following organizations: ACOG; AMA; SMFM; American Academy of Family Physicians; American Academy of Pediatrics; American Gynecological and Obstetrical Society; American Society for Reproductive Medicine; Council of University Chairs of Obstetrics and Gynecology; North American Society for Pediatric Adolescent Gynecology; Society for Academic Specialists in General Obstetrics and Gynecology; Society of Family Planning; and Society of OB/GYN Hospitalists.

SUMMARY OF THE ARGUMENT

This Court should not allow the speculative fears of a handful of doctors to deprive patients throughout the country of an essential medication that is proven safe for use in early pregnancy. All patients are entitled to prompt, complete, and unbiased health care. No patient should be denied treatment for miscarriage or other early pregnancy loss because of Respondents' hypothetical fears or personal beliefs. Patients in states where abortion remains legal and protected should not be denied the ability to safely and privately seek to exercise that right through safe and effective medication abortion. Certainly, patients should not be forced to carry pregnancies to term or be denied appropriate medical treatment for complications that happen regularly during pregnancy or pregnancy loss simply because Respondents at the margins of medical practice fear they may encounter a patient in the vanishingly small percentage of those who suffer complications requiring treatment after a medication abortion.

Respondents claim that they will suffer legal injury if they are asked to provide medical care—as their professional ethics and positions require—to patients who may be among the very few who seek treatment after taking mifepristone to end a pregnancy. This claim of injury is unsupported for the myriad legal reasons set forth by Petitioners. But it is also untenable as a matter of maternal medicine. The issues Respondents fear are for the most part not "complications" at all as that term is used in the practice of medicine.[3] Bleeding and

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[3] "Common terms used interchangeably to refer to problems arising from medical . . . treatments include 'complication[]' [and] 'side effect'. . . . Complications refer to other diseases or

cramping are known and expected side effects of using mifepristone, as the Mifeprex label states, but they certainly are not unique to the use of mifepristone. Bleeding and cramping happen when a pregnancy ends, whether through miscarriage, medication abortion, or procedural abortion (and these effects have a real impact on patients). In describing these as "complications" of medication abortion, Respondents are disregarding the medical reality to create unwarranted fears of injury. If Respondents are concerned by treating patients presenting with bleeding and cramping that may require subsequent intervention, that risk arises with any form of pregnancy loss. These are not "complications" and they are not unique to the use of mifepristone.[4]

Respondents ask the courts to place their individual concerns about speculative and unlikely injuries of conscience above the very real and immediate life-threatening and life-altering concerns of hundreds of thousands of pregnant patients. But that is not consistent with medical ethics or practice. *Amici* represent legions of practitioners who have come to rely on the FDA's current regulatory approach to mifepristone and whose patients deserve the most current and medically appropriate standard

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symptoms that occur in relation to a given disease. Side effects refer to undesirable effects that occur concomitantly with the originally intended outcome." Young-Kyun Kim, *Malpractice and Complications*, 43 J. KOREAN ASS'N ORAL & MAXILLOFACIAL SURGEONS 1, 1 (2017).

[4] *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 230–31 (5th Cir. 2023) (citing Respondent Medical Organizations' member declarations discussing instances in which patients require procedural intervention following an incomplete abortion).

of care. Neither patients nor physicians are served by rolling the clock back by nearly a decade to the pre-2016 regulatory regime.

Restricting access to mifepristone—the safety of which is proven by decades of rigorous scientific study and millions of uses—in ways that are not medically necessary or scientifically sound would seriously increase risk for hundreds of thousands of patients, while protecting none. For already vulnerable populations (particularly those living in areas with limited access to OB/GYN care) the roll-back approved by the Fifth Circuit promises to be especially devastating and to further perpetuate racial and socioeconomic inequalities. These concerns are not speculative. The risk of harm is concrete and rooted in the reality that mifepristone is an essential component of reproductive care, including miscarriage and abortion, without which a vast number of patients will suffer.

Respondents seek to undermine decades of approved, safe, and effective use of mifepristone to the detriment of patients. *Amici* are the nation's leading medical organizations, whose policies and guidance represent the considered judgment of hundreds of thousands of physicians and clinicians in this country. *Amici* write in full support of Petitioners to alert the Court to the many ways that Respondents' view and the Fifth Circuit's endorsement of the same undermine the principles of patient care, compromise patient safety and well-being, impede the provision of quality health care services, and threaten the effective functioning of health care institutions and the practice of medicine. *Amici* urge this Court not to return doctors, patients, and the medical profession to an outdated regulatory regime that imposes restrictions the FDA has

already set aside as unnecessary and unjustified. It should grant the Petitions for Writ of Certiorari ("Petitions") and reverse the decisions below.

ARGUMENT

Amici urge this Court to grant the Petitions to preserve access to mifepristone under the conditions deemed appropriate by the FDA. The decision to re-impose the Risk Evaluation and Mitigation Strategies ("REMS") restrictions and Conditions of Use[5] the FDA previously eliminated as unnecessary in 2016 and 2021 is not supported by scientific evidence and not consistent with best medical practices. It would impede patient care and endanger individual patients who rely on the availability of mifepristone for safe, effective treatment consistent with the current standard of care.

I. Mifepristone Has Been Thoroughly Studied and Is Conclusively Safe.

Amici are the nation's leading medical organizations, whose members are committed to providing ethical, evidence-based, scientifically sound care to patients throughout the country. Unlike Respondents, many of *amici*'s members

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[5] As a preliminary matter, the Fifth Circuit's decision conflates the Conditions of Use printed on the medication's label and the applicable REMS, treating both categories as though they are one in the same. They are not, and these different groups carry very different implications for providers. For this reason alone, the Court should grant review in this case to address the Fifth Circuit's failure to carefully consider the evidence proving the safety of mifepristone or appreciate the distinction between REMS and labeling protocol.

regularly prescribe mifepristone in early pregnancy and are in fact familiar with the medical needs of and risks and benefits for the many patients who rely on mifepristone.

Amici and their patients rely on the continued availability of mifepristone to provide, in combination with misoprostol, a safe and effective way to end an early pregnancy. This medication protocol combines to empty the contents of the uterus and has exceptionally low rates of major adverse events.[6] This treatment protocol may be used to induce abortion[7] and is used regularly in the effective treatment of miscarriage or early pregnancy loss[8] (including spontaneous abortions, missed abortions, incomplete abortions, and inevitable abortions). Early pregnancy loss, like pregnancy itself, is not rare but can be life-threatening. Ready access to mifepristone provides a safe treatment for the millions of patients—an estimated 10–26% of all pregnant patients—who experience it each year.[9]

The overwhelming weight of scientific evidence and two decades of medical practice show that mifepristone is safe and effective and that it is not

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[6] Combined mifepristone-misoprostol regimens are the preferred therapy for medication abortion because they are "more effective than misoprostol-only regimens." ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation* (Oct. 2020, *reaff'd* 2023).

[7] *See* ACOG Committee Opinion No. 815, *Increasing Access to Abortion* (Dec. 2020).

[8] *See* ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2021).

[9] *See id.*; Carla Dugas & Valori H. Slane, *Miscarriage*, NAT'L CTR. FOR BIOTECH. INFO. (2022) ("It is estimated that as many as 26% of all pregnancies end in miscarriage and up to 10% of clinically recognized pregnancies."); *see also Miscarriage*, MARCH OF DIMES (Feb. 2023).

medically necessary to impose additional restrictions around its use. Mifepristone has been (and continues to be) one of the most studied medications prescribed in the United States. To date, mifepristone has been discussed in more than 780 medical reviews and used in more than 630 published clinical trials—of which more than 420 were randomized controlled studies, the gold standard in research design.[10] These studies have consistently concluded that it is exceedingly rare for patients to experience even *minor* complications from medication abortion.[11] When used in medication abortion, major adverse events—significant infection, excessive blood loss, or hospitalization—occur in ***less than 0.32%*** of patients.[12] Serious infection is exceptionally rare, occurring in only 0.015% to 0.07% of patients.[13] The risk of death is almost non-existent.[14] Indeed, mifepristone has a safety profile

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

[11] *See*, *e.g.*, ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone US Post-Marketing Adverse Events Summary Through 6/30/2021*," UNIV. OF CAL., S.F. 2 (2022) [hereinafter ANSIRH, *Adverse Events 2021*].

[12] *See* Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTET. & GYNECOL. 175, 175 (2015) (a study of nearly 55,000 abortions found a major complications rate of 0.31% for medication abortion).

[13] FDA Ctr. For Drug Eval. & Rsch., *Medical Review, Application No. 020687Orig1s020*, at 53–54 (Mar. 29, 2016) [hereinafter 2016 FDA Medical Review].

[14] *See* Katherine Kortsmit et al., *Abortion Surveillance—United States, 2019*, 70 CDC MORBIDITY & MORTALITY WKLY. REP. 1, 29, tbl.15 (2021). A 2019 analysis of FDA data examining potential mifepristone-related deaths over an 18-year period by the University of San Francisco Medical Center, for example, found an approximate mortality rate of just

comparable to that of ibuprofen, which more than 30 million Americans take in any given day.[15] These strikingly low rates of adverse outcomes are observed regardless of the indication for its use.

Mifepristone is not just safe—it is far safer than countless other medications and among the safest medications or devices approved by the FDA and being used in medical practice.[16] Again, its safety profile is similar to that of ibuprofen.[17] Using Viagra is more dangerous than using mifepristone, with a rate of 4.9 deaths for every 100,000 Viagra prescriptions.[18] Colonoscopies are a routine procedure, widely used in preventive care—yet death occurs in about 0.03% of colonoscopy cases.[19] Those

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0.00035%. ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone US Post-Marketing Adverse Events Summary Through 12/31/2018*," UNIV. OF CAL., S.F. 1–2 (2019) [hereinafter ANSIRH, *Adverse Events 2018*].

15 *See* NAT'L ACADS. OF SCI., ENG'G & MED., THE SAFETY AND QUALITY OF ABORTION CARE IN THE UNITED STATES 79 (2018); *see also* R. Morgan Griffin, *Making the Decision on NSAIDs*, WEBMD (Oct. 17, 2005).

16 *See* ANSIRH, *Adverse Events 2018*, *supra* note 14, at 2 ("The safety profile [of medication abortion with mifepristone and misoprostol] is similar to that of vacuum aspiration abortion, and medication abortion is safer than continuing a pregnancy to term or using other common medications."); ANSIRH, *Adverse Events 2021*, *supra* note 11, at 3 (same); *see also* ANSIRH, *U.S. Studies on Medication Abortion Without In-Person Clinician Dispensing of Mifepristone*, UNIV. OF CAL., S.F. (2021); Elizabeth Raymond & Hillary Bracken, *Early Medical Abortion Without Prior Ultrasound*, 92 CONTRACEPT. 212 (2015); Upadhyay et al., *supra* note 12.

17 *See* sources cited *supra* note 15.

18 *See* Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 J. AM. MED. ASS'N 590, 591 (2000).

19 ASGE Standards of Practice Comm., *Complications of Colonoscopy*, 74 AM. SOC'Y FOR GASTRO. ENDOSCOPY 745, 747 (2011).

risks of death associated with childbirth are exponentially higher than the risk of death in a medication abortion involving mifepristone.[20] In light of the evidence, the FDA was and can continue to be confident in its judgment that "[n]o causal relationship between the use of MIFEPREX and misoprostol and [fatal infections and bleeding] has been established."[21] Medication abortion involving mifepristone is among the safest medical interventions in any category, pregnancy-related or not.

II. There Is No Scientific Basis for Rewinding the Clock on Evidence-Based Medical Practice to 2015.

The FDA revisited its guidance on mifepristone use in 2016 and 2021 and reached the reasoned conclusion that, based on the overwhelming evidence of mifepristone's efficacy and safety gathered before and after FDA's initial approval, certain of its prior restrictions were not necessary and could be removed. That removal has meaningfully improved access to care for patients throughout the country.

Reinstating the restrictions on access to mifepristone that Respondents request will do nothing to make patients safer or improve their

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[20] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTET. & GYNECOL. 215, 215, 217 (2012) (showing that "[t]he risk of death associated with childbirth is approximately 14 times higher than that with abortion," that the mortality rate associated with mifepristone is "0.7 per 100,00 users").

[21] Mifeprex Highlights of Prescribing Information, FDA, at 2, 5 (Mar. 2016) https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

health. They would reimpose extensive burdens on a drug that was singled out for heightened regulation because of its use in medication abortion, not because of its safety profile.[22] The FDA revisions to which Respondents object—and the Fifth Circuit would reverse—merely aligned the FDA's regulation protocols more closely with an objective, evidence-based assessment of mifepristone's safety profile. In 2016, the FDA's safety analysis relied on 11 independent clinical studies conducted between 2005 and 2015, covering well "over 30,000 patients";[23] randomized controlled trials;[24] and several prospective, retrospective, and observational studies,[25] which demonstrated the safety and effectiveness of mifepristone up to the 10-week gestational period.[26] Those studies conclusively demonstrated that "serious adverse events . . . are rarely reported . . . with rates ***generally far below***

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[22] *See* American College of Obstetricians and Gynecologists et al., FDA Citizen Petition, at 9–10 (Oct. 4, 2022).

[23] 2016 FDA Medical Review, *supra* note 13, at 47–48, 50, 61–62.

[24] *See id.* at 50.

[25] *See id.*

[26] *See id.* at 47; Adriana A. Boersma et al., *Mifepristone Followed by Home Administration of Buccal Misoprostol for Medical Abortion Up to 70 Days of Amenorrhoea in a General Practice in Curacao*, 16 EUR. J. CONTRACEPT. & REPROD. HEALTH CARE 61 (2011); Beverly Winikoff et al., *Extending Outpatient Medical Abortion Services Through 70 Days of Gestational Age*, 120 OBSTET. & GYNECOL. 1070 (2012); *see also* Dina Abbas et al., *Outpatient Medical Abortion is Safe and Effective Through 70 Days Gestation*, 92 CONTRACEPT. 197 (2015). More recent studies have again confirmed these results. For example, a 2020 evidence review recognized that medication abortion can safely and effectively be used up to at least 70 days of gestation. *See* ACOG Practice Bulletin No. 225, *supra* note 6.

1.0%."[27] Based on this sound scientific evidence, the FDA correctly determined that it was appropriate to adjust the heavy restrictions on mifepristone's use and begin unwinding previously mandated requirements and other barriers to access.[28]

These adjustments better serve patients and their providers. For instance, the FDA's decision, based on the evidence and sound medical science, to eliminate the labeling condition that patients return for two in-person visits following their use of mifepristone removed a clearly unnecessary and burdensome element of the protocol on the label. The data was and remains clear: there is no medical basis for forcing patients who have taken mifepristone to make two visits to a health center afterwards. [29] Requiring two follow-up visits—regardless of the patient's circumstances—for a drug as safe as ibuprofen is burdensome and disruptive, can be costly, and is medically unnecessary. Indeed, comprehensive telehealth protocols adopted by clinics[30] ensure that patients can easily communicate with their providers and discuss any questions or

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[27] 2016 FDA Medical Review, *supra* note 13, at 56 (emphasis added).

[28] As Petitioners describe and as set forth above, the FDA adjusted both the "Conditions of Use" printed on the medication's label and eliminated certain REMS—including in-person follow-up appointments at 14 days after Mifeprex (a pre-2016 Condition of Use) and an "adverse reporting" requirement for mifepristone prescribers (a pre-2016 REMS restriction). *See* 2016 FDA Medical Review, *supra* note 13, at 7–8.

[29] *See*, *e.g.*, U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-292, FOOD AND DRUG ADMINISTRATION: INFORMATION ON MIFEPREX LABELING CHANGES AND ONGOING MONITORING EFFORTS 15 (2018) (summarizing studies).

[30] *See infra* pp. 14–17.

medical concerns that come up after use of mifepristone.

Amici also fully endorse the FDA's subsequent decision in 2021, formalized in 2023, to eliminate the in-person dispensing requirement and to permit distribution of medication abortion pills by mail. That decision was again based on the overwhelming and substantial scientific evidence showing that mifepristone is safe and that requiring patients to take a pill in the presence of a physician does nothing to improve patient health or safety.

Telehealth protocols ensure involvement of a specially trained practitioner (which the FDA still requires) and allow for the safe prescription and use of mifepristone without the need for in-person dispensing. Many health care clinics—including brick-and-mortar locations—offer comprehensive telehealth services to meet with patients before and after procedures, and reproductive health clinics that use telehealth have developed specific protocols and technologies to ensure adequate patient contact and monitoring, including health questionnaires; specialized patient platforms (e.g., a patient "portal"), messaging and chat functions; and phone or video calls.

Telehealth protocols offer all the same steps and protections—and therefore provide an equivalent level of care—as in-person dispensing. Patients are still evaluated by a qualified health care provider—just as they would be in person. They are asked about their symptoms and about facts needed to determine gestational age—just as they would be in person. They are counseled on their options and on the risks and benefits of each one—just as they would be in person. For example, although an ultrasound can help determine gestational age and

can identify an ectopic pregnancy, studies have shown that both of these goals can be accomplished just as effectively by discussing the patient's medical history—even via a telemedicine appointment.[31]

Telehealth protocols ensure involvement of a specially trained practitioner (which the FDA still requires) and allow for the safe prescription and use of mifepristone without the need for in-person dispensing. The FDA's current approach means that instead of requiring a patient to physically retrieve the medication from a doctor's office or specially certified pharmacy,[32] the medication can be conveniently delivered to the patient's home—without any additional risk, because the patient would have already been evaluated by the clinician (via telehealth or in person) and counseled with respect to the medication, as well as its administration and side effects. Likewise, rather than requiring a patient to return to the provider's office to obtain (and pay for) an ultrasound to confirm she is no longer pregnant after taking

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[31] *See* Raymond & Bracken, *supra* note 16; Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 J. AM. MED. ASS'N INTERNAL MED. 482, 489 (2022) (finding that "mifepristone can be dispensed safely either in person or by mail" and "pregnancy duration can be reasonably estimated by history and if no symptoms or risk factors for ectopic pregnancy are present"); *cf.* Compl. Ex. 24, 2000 FDA Approval Memorandum, 2:22-CV-00223-Z (Nov. 18, 2022), ECF No. 1-25, at 6 ("In practice, dating pregnancies occurs through using other clinical methods, as well as through using ultrasound.").

[32] At least as of July 2023, no major national retail pharmacy had received certification, though some had applied. *See* Press Release, Walgreens, Walgreens and Mifepristone: The Facts, (July 11, 2023).

mifepristone, the patient can simply take an at-home pregnancy or blood test and communicate the results to her provider via telehealth. The importance of this option is essential, since requiring in-person visits has a clear disparate impact on individuals that come from historically marginalized populations or that live in the increasing number of places in our country where appropriate medical providers are not easily available.[33] Should the provider have any concerns based on a patient's reported symptoms or test results, an in-person appointment would be scheduled if appropriate—but would not be unnecessarily required without any regard to the patient's individual circumstances. Notably, if a patient preferred to receive follow-up in-person care even if it were *not* medically required, she could do so. The choice is up to her and her provider, whereas Respondents would mandate in-person medical appointments regardless of the circumstances—an approach that intrudes on the physician-patient relationship, renders care unavailable to many patients, and undermines the trained, independent medical judgment of physicians as to what follow-up care is and is not needed in a particular situation.

With these protections in place, the FDA's current approach of allowing patients to take mifepristone outside the physical presence of a physician has not had any detrimental effect on patient care, nor has it resulted in any increased burden on emergency rooms. The percentage of

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[33] Indeed, 6.9 million women of childbearing age live in areas of the United States where maternity care is limited or nonexistent. *See Maternity Care Desert*, MARCH OF DIMES (Oct. 2022); *see also* Office of Minority Health, *Advancing Rural Maternal Health Equity*, CTRS. FOR MEDICARE & MEDICAID SERVS. at 1 (2022).

patients that ever visit an emergency room for abortion-related complications remains exceedingly small.[34] Respondents point to no data suggesting that significantly more patients have experienced serious harm or life-threatening injury as the result of telehealth protocols, which is consistent with the experience of our clinicians. Given these facts and the dearth of accessible in-person health care in large portions of this country, there is no medical or scientific reason to implement barriers to medical care and place burdens on patients with no medical benefit.

III. Restricting the Use of Mifepristone Will Harm Pregnant Patients and Have Severe Negative Impacts on the Broader Health Care System.

The Fifth Circuit's decision will unnecessarily restrict mifepristone nationwide—even in states where abortion remains legal—and impose a severe cost on pregnant patients without any discernible benefit. Because mifepristone is an essential component of medication abortion care and of treatment for miscarriage or early pregnancy loss, even temporary lack of access to mifepristone caused by reimposing the previously removed REMS will

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[34] That patients sometimes seek emergency care for reasons other than the severity of their symptoms is consistent with prior studies. A 2018 study concluded that only 0.01% of emergency department visits among women aged 15–49 were abortion-related and that many could have been "managed at a less costly level of care." Ushma D. Upadhyay et al., *Abortion-Related Emergency Department Visits in the United States: An Analysis of a National Emergency Department Sample*, 16 BMC MED. 1, 10 (2018).

cause patients to suffer physical and psychological harm. Restricting access to mifepristone endangers patients and jeopardizes their lives and health by forcing those who seek abortion to use more medically onerous means with greater side effects and by depriving patients suffering miscarriage of an essential and safe form of care. *Amici* are concerned that the Fifth Circuit's failure to meaningfully address the overwhelming body of evidence reflecting the safety of medication abortion, or the primacy in medical practice of ethical commitments and evidence-based care, has allowed Respondents' fear of remote and implausible psychological injury to trump the very real, very serious consequences for patients.

Empirical evidence shows that women are at least 14 times more likely to die during childbirth than during any abortion procedure[35] and are at an increased risk of experiencing hemorrhage, infection, and injury to other organs during pregnancy and

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[35] *See* Raymond & Grimes, *supra* note 20, at 216–17, fig.1. The U.S. mortality rate associated with live births from 1998 to 2005 was 8.8 deaths per 100,000 live births. *Id.* at 216 tbl.1. Rates have sharply increased since then. David Boulware, *Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends from Measurement Issues*, 129 OBSTET. & GYNECOL. 385, 385–86 (2017). By contrast, the mortality rate associated with abortions performed from 1998 to 2005 was 0.6 deaths per 100,000 procedures. *See* Raymond & Grimes, *supra* note 20, at 216 tbl.1. A committee of the National Academies in a 2018 peer-reviewed, evidence-based report similarly concluded that abortion is safer than pregnancy; specifically, "the risk of death subsequent to a legal abortion (0.7 [deaths] per 100,000 [patients]) is a small fraction of that for childbirth (8.8 [deaths] per 100,000 [patients])." NAT'L ACADS. OF SCI., ENG'G & MED., *supra* note 14, at 74.

childbirth as well.[36] Even under the best of circumstances, pregnancy and childbirth impose significant physiological changes that can exacerbate underlying conditions and severely compromise health, sometimes permanently.[37] Pregnancy, particularly when coupled with preexisting conditions, can quickly evolve into a life-threatening situation necessitating critical care, including abortion.

These dangers are far greater for women of color, low-income women, and those living in rural areas. Low-income patients and patients of color[38] are most likely to experience severe maternal morbidity and more likely to die from pregnancy-related

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[36] *See* Raymond & Grimes, *supra* note 20 at 215, 216–17 fig.1.

[37] *See*, *e.g.*, ACOG Clinical Consensus No. 1, *Pharmacologic Stepwise Multimodal Approach for Postpartum Pain Management* (Sept. 2021); ACOG Practice Bulletin No. 222, *Gestational Hypertension and Preeclampsia* (June 2020); ACOG Obstetric Care Consensus No. 7, *Placenta Accreta Spectrum* (Dec. 2018); ACOG Practice Bulletin No. 198, *Prevention and Management of Obstetric Lacerations at Vaginal Delivery* (Sept. 2018); ACOG Practice Bulletin No. 190, *Gestational Diabetes Mellitus* (Feb. 2018); ACOG Practice Bulletin No. 183, *Postpartum Hemorrhage* (Oct. 2017).

[38] *See* Rachel K. Jones et al., *COVID-19 Abortion Bans and Their Implications for Public Health*, 52 PERSPS. SEXUAL & REPROD. HEALTH 65, 66 (2020); *see also* Christine Dehlendorf & Tracy Weitz, *Access to Abortion Services: A Neglected Health Disparity*, 22 J. HEALTH CARE FOR THE POOR & UNDERSERVED 415, 416-17 (2011); Jenna Jerman et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, GUTTMACHER INST. (2016), at 11–12; *see also* Rural Health Council, *CMS Rural Health Strategy*, CTRS. FOR MEDICARE & MEDICAID SERVS. at 2 (2018).

complications,[39] and those in rural areas are disproportionately harmed by restrictions on abortion care.[40] The majority of abortion patients identify as people of color, and "75% of those seeking abortion [care] are living at or below 200% of the federal poverty level."[41] Pregnant people of color are also more likely to experience early pregnancy loss or miscarriage, the treatment for which can include procedural or medication abortion.[42] Restricting the use of mifepristone without medical justification will harm these patients by making it more difficult to obtain a relatively accessible and entirely safe treatment—which in some cases may result in the complete denial of medical care.

Reimposing unnecessary restrictions on mifepristone will exacerbate these inequities and have the most severe consequences for those who are already most poorly served by our maternal health system. Substantial evidence demonstrates that the *denial* of abortion care causes harm. Patients who are denied requested abortions are more likely to experience intimate partner violence compared with patients who were able to have an abortion.[43] Studies have repeatedly shown that being denied an abortion also exacerbated patients' economic hardships, revealing "large and statistically

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39 *See* Office of Minority Health, *supra* note 33, at 1; *see also* Juanita Chinn et al., *Health Equity Among Black Women in the United States*, 30 J. WOMEN'S HEALTH 212, 215 (2021).

40 *See* ACOG Committee Opinion No. 815, *supra* note 7.

41 *Id.*

42 *See* Lyndsey S. Benson et al., *Early Pregnancy Loss in the Emergency Department, 2006–2016*, 2 J. AM. COLL. EMERGENCY PHYSICIANS OPEN e12549 at 6–7 (2021).

43 *See* 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, 6 (2014).

significant differences in the socioeconomic trajectories of women who were denied requested abortions compared with women who received abortions—with women denied abortions facing more economic hardships."[44] Making it more difficult to obtain mifepristone will make it more difficult to obtain medication abortion care consistent with the current standard of care. This alone endangers patients.

But *anyone* who is pregnant will be at greater risk if they and their providers have more limited access to mifepristone. That is because, as with many medications, mifepristone has critical off-label uses in maternal care beyond abortion.[45] Mifepristone is already widely prescribed for management and treatment of miscarriages, including spontaneous, missed, inevitable, and incomplete abortions.[46] Miscarriage is sadly common in this country, occurring with unfortunate frequency and affecting around one out of every five women.[47] When a patient is miscarrying or experiencing early pregnancy loss, mifepristone can ease the process, reduce the risk of infection and pain experienced,

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[44] Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 AM. J. PUB. HEALTH 407, 412 (2018).

[45] *See* Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87 MAYO CLINIC PROC. 982, 982–85 (2012).

[46] *See* Honor MacNaughton et al., *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 AM. FAM. PHYSICIAN 473, 475 (2021); Mara Gordon & Sarah McCammon, *A Drug that Eases Miscarriages is Difficult for Women to Get*, NPR (Jan. 10, 2019).

[47] *See* sources cited *supra* note 9.

and lead to better health outcomes.[48] Patients already enduring miscarriage should not be forced to suffer through limited access to critical medication.

Studies have also examined mifepristone for a range of other maternal-health purposes, including treatment of uterine fibroids (tumorous growths of uterine muscle) and treatment of endometriosis (abnormal tissue growth outside the uterus, which can cause severe pain and infertility).[49] Mifepristone is also used off-label to reduce the duration of bleeding or hemorrhaging during certain serious pregnancy complications, and it may have beneficial effects on the cervix in full-term pregnancies, which in turn may affect the likelihood of successful labor.[50] Patients who may benefit from these and other treatments for reasons unrelated to abortion will also face additional hurdles to receiving this medication—again, with no medical justification.[51]

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[48] *See*, *e.g.*, ACOG Practice Bulletin No. 200, *supra* note 8; Jessica Beaman, *Medication to Manage Abortion and Miscarriage*, 35 J. GEN. INTERNAL MED. 2398, 2400 (2020).

[49] *See* Y. X. Zhang, *Effect of Mifepristone in the Different Treatments of Endometriosis*, 43 CLINICAL & EXPERIMENTAL OBSTET. & GYNECOL. 350 (2016); Mario Tristan et al., *Mifepristone for Uterine Fibroids*, COCHRANE DATABASE SYSTEMATIC REVS. (2012).

[50] *See* Yanxia Cao et al., *Efficacy of Misoprostol Combined with Mifepristone on Postpartum Hemorrhage and Its Effects on Coagulation Function*, 13 INT'L. J. CLINICAL & EXPERIMENTAL MED. 2234 (2020); Kanan Yelikar et al., *Safety and Efficacy of Oral Mifepristone in Pre-Induction Cervical Ripening and Induction of Labour in Prolonged Pregnancy*, 65 J. OBSTET. & GYNAECOL. INDIA 221 (2015).

[51] *See*, *e.g.*, Press Release, Endocrine Soc'y, Endocrine Society Alarmed by Texas Court Ruling Banning Mifepristone (Apr. 10, 2023) (recognizing that "mifepristone is [also] used to treat people with Cushing's syndrome and diabetes or high blood sugar who are not surgical candidates or have failed surgery"

Again, these harms are concrete, certain, and will affect hundreds of thousands of patients and their providers. *Amici* fear for the patients they treat if the decision below is allowed to stand.

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and that the District Court's decision could restrict access to such treatment).

CONCLUSION

For the reasons set forth above, the Petitions for Writ of Certiorari should be granted.

Respectfully submitted,

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