No. 23-2194

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

GENBIOPRO, INC.,
Plaintiff-Appellant,

v.

KRISTINA RAYNES, in her official capacity as Prosecuting Attorney of Putnam County, and PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia,
Defendants-Appellees,

and

MARK A. SORSAIA, in his official capacity as Prosecuting Attorney of Putnam County,
Defendant.

On Appeal from the United States District Court for the Southern District of West Virginia,
No. 23-cv-58, Hon. Robert C. Chambers

CORRECTED BRIEF OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, THE SOCIETY FOR MATERNAL-FETAL MEDICINE, AND THE SOCIETY OF FAMILY PLANNING AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANT AND REVERSAL

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 23-2194 Caption: GenBioPro, Inc. v. Kristina Raynes

Pursuant to FRAP 26.1 and Local Rule 26.1,

American College of Obstetricians and Gynecologists
(name of party/amicus)

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who is amicus curiae, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☐NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ Nicole A. Saharsky Date: February 16, 2024

Counsel for: American College of Obstetricians and Gynecologists

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No. 23-2194 Caption: GenBioPro, Inc. v. Kristina Raynes

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Society for Maternal-Fetal Medicine
(name of party/amicus)

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Signature: /s/ Nicole A. Saharsky Date: February 16, 2024

Counsel for: Society for Maternal-Fetal Medicine

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No. 23-2194 Caption: GenBioPro, Inc. v. Kristina Raynes

Pursuant to FRAP 26.1 and Local Rule 26.1,

Society of Family Planning
(name of party/amicus)

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Signature: /s/ Nicole A. Saharsky Date: February 16, 2024

Counsel for: Society of Family Planning

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INTEREST OF THE *AMICI CURIAE*

Amici are leading medical societies whose policies represent the education, training, and experience of the vast majority of clinicians in this country.[1] The American College of Obstetricians and Gynecologists (ACOG) is the nation's leading group of physicians providing evidence-based obstetric and gynecologic care. As a private, voluntary nonprofit membership organization of more than 60,000 members, ACOG advocates for equitable, exceptional, and respectful care for all people in need of obstetric and gynecologic care; 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 patients and their families and communities. ACOG's briefs and medical practice guidelines have been cited by numerous authorities, including the U.S. Supreme Court, which recognize ACOG as a leading provider of authoritative scientific data regarding childbirth and abortion.[2]

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[1] Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), *amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici*, their members, or their counsel made a monetary contribution intended to fund its preparation or submission. All parties have consented to the filing of this brief.

[2] *See*, *e.g.*, *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2132 (2020); *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2312 (2016); *Stenberg*

The Society for Maternal-Fetal Medicine (SMFM) is the medical professional society for maternal-fetal medicine subspecialists, who are obstetricians with additional training in high-risk pregnancies. SMFM was founded in 1977, and it represents more than 7,000 members caring for high-risk pregnant people. SMFM 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 high-risk pregnancies. SMFM's *amicus* briefs also have been cited by multiple courts.[3]

The Society of Family Planning (SFP) is a leading source for abortion and contraception science. It represents more than 1,800 clinicians and scholars who believe in just and equitable abortion and contraception informed science. SFP works to build a diverse, equitable, inclusive, and multidisciplinary community of scholars and partners engaged in the science and medicine of abortion and contraception. It seeks to support the

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v. Carhart, 530 U.S. 914, 932-36 (2000); *Hodgson v. Minnesota*, 497 U.S. 417, 454 n.38 (1990); *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983).

[3] *See*, *e.g.*, *Mayor of Baltimore v. Azar*, 973 F.3d 258, 285 & n.19 (4th Cir. 2020).

production and resourcing of research primed for impact, ensure clinical care is evidence-informed and person-centered through guidance, medical education, and other activities, and develop leaders in abortion and contraception to transform the health care system.

This case involves West Virginia's Unborn Child Protection Act (UCPA), W. Va. Code § 16-2R-1 *et seq*., which prohibits using any drug or medicine to perform or induce an abortion, including by prescribing mifepristone. Mifepristone is a medication commonly used to induce medication abortion. It has undergone rigorous testing and review and has been approved for use in the United States for over 20 years. *Amici*'s members need access to FDA-approved mifepristone to effectively care for patients. Many of *amici's* members regularly prescribe mifepristone in pregnancy and are experts in the medical needs of, and risks and benefits for, the patients who rely on mifepristone. Accordingly, *amici* have a strong interest in ensuring that the science surrounding mifepristone's safety and efficacy is correctly understood. *Amici* all agree that mifepristone is exceedingly safe and effective, and that access to mifepristone is an essential component of health care.

INTRODUCTION AND SUMMARY OF ARGUMENT

The UCPA bans performing, inducing, or attempting to perform or induce an abortion in West Virginia, subject to very limited exceptions. In particular, the Act expressly prohibits using any drug or medicine to perform or induce an abortion, which includes mifepristone. *Amici* oppose West Virginia's effort to ban an FDA-approved drug that decades of scientific research has shown to be a safe and effective treatment and that is needed by West Virginia residents.

Pursuant to its statutory authority, the FDA has approved mifepristone, and it has repeatedly reduced its restrictions on access to mifepristone based on years of safe use and a vast amount of data. The FDA's determinations are amply supported by the medical evidence. Hundreds of medical studies, performed over two decades, conclusively show that mifepristone is safe and effective. The FDA's initial approval of mifepristone in 2000 relied on a robust body of evidence that showed the drug is extremely safe. The studies performed since then only confirm this point. The data demonstrate that serious side effects occur in fewer than 1% of patients; that major adverse events (such as significant infection, blood loss, or hospitalization) occur in fewer than 0.3% of patients; and that the risk of death is almost non-existent.

The FDA's determination that mifepristone should be broadly available is particularly appropriate because for many patients, pregnancy can be a serious or life-threatening condition. Under the Food & Drug Administration Amendment Act (FDAAA), one factor the FDA must consider in determining what restrictions to place on access to mifepristone is the burden on patients with serious or life-threatening conditions. The risk of maternal mortality in the U.S. is alarmingly high, and that risk increases dramatically for patients who are Black or Indigenous, who have fewer financial resources, or who have limited access to reproductive care. Pregnancy can cause hemorrhaging, infection, dangerously high blood pressure, and many other critical physiological conditions that require prompt and effective intervention to preserve the life of the pregnant person. These dangers directly impair the health and well-being of pregnant patients, often in lasting and material ways. Mifepristone, when used as part of a two-drug medication abortion regimen, is one safe and common course of treatment that is used with pregnancy loss or obstetrical complications leading to fetal demise. Medication abortion, including the use of mifepristone, thus is an important part of reproductive care.

Amici urge the Court to reverse the district court's decision.

ARGUMENT

Since it first approved mifepristone in 2000, the FDA has revisited its guidance on mifepristone on multiple occasions based on decades of use and dozens of studies demonstrating that the drug is extremely safe, and each time it has removed restrictions on access to mifepristone that it determined were not medically necessary.[4] The FDA's decisions are well-supported by the medical evidence, and are appropriate in light of the fact that pregnancy can be a serious or life-threatening condition for many patients.

A. Mifepristone Is Safe And Effective

Amici and their patients rely on the continued availability of mifepristone to provide, in combination with misoprostol, a safe and effective way to end a pregnancy.[5] This treatment protocol may be used to induce abortion[6] and is used regularly in the effective treatment of miscarriage or pregnancy

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[4] *See* JA256-258.

[5] 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,* 136 Obstetrics & Gynecology 4, 9 (Oct. 2020, reaff'd 2023).

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

loss[7] (including spontaneous abortions, missed abortions, incomplete abortions, and inevitable abortions). As of 2020, medication abortions account for most abortions in the United States.[8]

The overwhelming weight of scientific evidence and two decades of medical practice show that mifepristone is safe and effective. Mifepristone has been (and continues to be) one of the most studied medications prescribed in the United States. There have been over 780 medical reviews discussing mifepristone, and more than 630 published clinical trials involving the drug – of which more than 420 were randomized controlled studies, the most rigorous research study design.[9] These studies have consistently concluded that it is rare for patients to experience even minor complications from medication abortion.[10] When used in medication abortion, major adverse events – significant infection, excessive blood loss, or hospitalization

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[7] *Id.*

[8] Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions,* Guttmacher Inst. (Dec. 21, 2022), https://bit.ly/3HR55Gk.

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

[10] *See, e.g.,* Advancing New Standards in Reproductive Health (ANSIRH), *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone US Post-Marketing Adverse Events Summary Through 6/30/2021"* at 1 (Nov. 2022) (ANSIRH, *Adverse Events 2021*).

– occur in fewer than 0.32% of patients.[11] The risk of serious infection is even lower, occurring in only 0.015% to 0.07% of patients.[12]

The risk of death from medication abortion is almost nonexistent.[13] A 2019 analysis of FDA data examining potentially mifepristone-related deaths over an 18-year period by the University of San Francisco Medical Center found that only 13 deaths were possibly or probably related to medication abortion, yielding an approximate mortality rate of 0.00035%.[14] Even when considering deaths that followed a medication abortion but did not appear to be related to mifepristone, that number rises to only 0.00065%.[15] Indeed, mifepristone has a safety profile comparable to that of

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

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

[13] *See* Katherine Kortsmit et al., *Abortion Surveillance – United States, 2019,* 70 CDC Morbidity & Mortality Wkly. Rep. 1, 29, tbl.15 (2021).

[14] ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone US Post-Marketing Adverse Events Summary Through 12/31/2018"* at 1 (2019) (ANSIRH, *Adverse Events 2018*).

[15] *Id.*

ibuprofen, which more than 30 million Americans take on any given day.[16] 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.[17] Again, mifepristone is as safe as ibuprofen. Using mifepristone is safer than using Viagra or having a colonoscopy. Viagra has a rate of 4.9 deaths for every 100,000 Viagra prescriptions.[18] And colonoscopies, despite being a routine and medically recommended procedure that is widely used in preventive care, has a death rate

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[16] *See* Nat'l Acads. of Sci., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States* 79 (2018) (Nat'l Acads.); R. Morgan Griffin, *Making the Decision on NSAIDs,* WebMD (Oct. 17, 2005).

[17] *See* ANSIRH, *Adverse Events 2018, supra* note 15, 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* 1 (2021); Elizabeth Raymond & Hillary Bracken, *Early Medical Abortion Without Prior Ultrasound,* 92 Contracept. 212 (2015); Upadhyay, *supra* note 12, at 175.

[18] *See* Mike Mitka, *Some Men Who Take Viagra Die – Why?,* 283 J. Am. Med. Ass'n 590, 593 (2000).

of about 0.03%.[19] The risks of death associated with childbirth are exponentially higher than the risk of death in a medication abortion involving mifepristone.[20]

In short, medication abortion involving mifepristone is among the safest medical interventions in any category, pregnancy-related or not. The scientific evidence thus amply supports the FDA's decisions to approve mifepristone and then to repeatedly ease its restrictions on access to mifepristone.[21]

B. Pregnancy Can Be A Serious Or Life-Threatening Condition

Under the FDAAA, in determining what restrictions to place on access to mifepristone, the FDA is required to consider the burden on "patients with serious or life-threatening diseases or conditions." 21 U.S.C. § 355-1(f)(2)(C)(i). The medical evidence demonstrates that for many patients,

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[19] ASGE Standards of Practice Comm., *Complications of Colonoscopy,* 74 Am. Soc'y for Gastro. Endoscopy 745, 747 (2011).

[20] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States,* 119 Obstetrics & Gynecology 215, 215, 217 (2012) (Raymond & Grimes) (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"); *see* Nat'l Acads., *supra* note 17, at 74.

[21] *See* JA257-258.

pregnancy can be a serious or life-threatening condition. Medication abortion is one potential and important tool for responding to medical emergencies that arise in connection with pregnancy that lead to pregnancy loss, as well as for obstetrical complications that lead to fetal demise.

Pregnancy often entails significant health risks. The U.S. mortality rate associated with live births was 32.9 deaths per 100,000 live births in 2021[22] – up from 8.8 between 1998 and 2005.[23] Empirical evidence shows that women are at least 14 times more likely to die during childbirth than during any abortion procedure and are at an increased risk of experiencing hemorrhage, infection, and injury to other organs during pregnancy and childbirth as well.[24]

Complications in pregnancy are common and potentially life-threatening. While not all pregnancy complications require emergency

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[22] Donna Hoyert, CDC Nat'l Ctr. for Health Stat., *Maternal Mortality Rates in the United States, 2021* at 1 (Mar. 2023), https://bit.ly/42u7PCW.

[23] Raymond & Grimes, *supra* note 21, at 216; *see* Marian F. MacDorman et al., *Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends from Measurement Issues*, 128 Obstetrics & Gynecology 447 (2016) (finding a 26.6% increase in maternal mortality rates between 2000 and 2014); David Boulware, *Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends from Measurement Issues,* 129 Obstetrics & Gynecology 385, 385-86 (2017).

[24] *See* Raymond & Grimes, *supra* note 21, at 215, 216-17 fig.1.

intervention, emergencies involving pregnant patients can be dangerous.

Some of the issues pregnant patients may present with include:

- **Pre-labor rupture of membranes,** where the amniotic sac ruptures before fetal viability, potentially leading to serious maternal infection and sepsis.[25]
- **Excessive bleeding,** which can be caused by placenta accreta spectrum and other conditions.[26]
- **Gestational hypertension and preeclampsia (high blood pressure)**, which complicate 2-8% of pregnancies globally and are among the leading causes of maternal mortality around the world. It is estimated that instances of these complications occurring within the first year of delivery cost $2.18 billion in the United States annually.[27]
- **Placental abruption,** which is when the placenta separates from the inner wall of the uterus, causing serious and potentially uncontrollable bleeding. It is the cause of stillbirth in up to 10% of cases and can result in serious complications like cardiac arrest or kidney failure.[28]
- **Gestational diabetes mellitus**, which complicates approximately 6 to 7% of pregnancies, frequently leading to

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[25] ACOG Practice Bulletin No. 217, *Prelabor Rupture of Membranes* 135 Obstetrics & Gynecology e80 (Mar. 2020).

[26] *See FAQs: Bleeding During Pregnancy,* ACOG (Aug. 2022), https://bit.ly/3UA1Jz0; ACOG Obstetric Care Consensus No. 7, *Placenta Accreta Spectrum,* 132 Obstetrics & Gynecology e259 (Dec. 2018, reaff'd 2021) (ACOG, *Placenta Accreta Spectrum*).

[27] ACOG Practice Bulletin No. 222, *Gestational Hypertension and Preeclampsia,* 135 Obstetrics & Gynecology e237 (June 2020) (ACOG, *Gestational Hypertension*).

[28] ACOG Obstetric Care Consensus No. 10, *Management of Stillbirth,* 135 Obstetrics & Gynecology e116 (Mar. 2020, reaff'd 2021).

> maternal and fetal complications, including developing diabetes later in life.[29]

These are just a few examples. The American Board of Emergency Medicine's Model of Clinical Practice of Emergency Medicine, the definitive source and guide to the core content found on emergency physicians' board examinations, contains an entire section devoted to "Complications of Pregnancy."[30] Nearly all listed conditions are graded as "critical" or "emergent," meaning that they "may progress in severity or result in complications with a high probability for morbidity if treatment is not begun quickly."[31]

Even under the best of circumstances, pregnancy and childbirth impose significant physiological changes that can exacerbate underlying conditions and severely compromise health, sometimes permanently.[32]

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[29] ACOG, *Gestational Diabetes*, *supra* note 38,at e49.

[30] Michael S. Beeson et al., Am. Bd. of Emergency Med., *2019 Model of the Clinical Practice of Emergency Medicine* 36 (2019), https://bit.ly/3w5CqdT.

[31] *Id.* at 9 tbl.2, 36-37.

[32] *See, e.g.,* ACOG Clinical Consensus No. 1, *Pharmacologic Stepwise Multimodal Approach for Postpartum Pain Management,* 138 Obstetrics & Gynecology 507 (Sept. 2021) (ACOG, *Multimodal Approach*); ACOG, *Gestational Hypertension*, *supra* note 32; ACOG Practice Bulletin No. 198, *Prevention and Management of Obstetric Lacerations at Vaginal Delivery,* 132 Obstetrics & Gynecology e87 (Sept. 2018) (ACOG, *Obstetric Lacerations*); ACOG Practice Bulletin No. 190, *Gestational Diabetes Mellitus,* 131 Obstetrics & Gynecology e49 (Feb. 2018) (ACOG, *Gestational Diabetes*);

Pregnancy, particularly when coupled with preexisting conditions, can quickly evolve into a life-threatening situation necessitating critical care, including abortion. Examples of threats posed by worsening pre-existing conditions include:

- **Sickle-cell disease**, which may worsen during pregnancy, leading to severe anemia and vaso-occlusive crisis, a condition resulting in significant pain.[33]
- **Inherited thrombophilia**, which can be undetected until a triggering event such as pregnancy, entails a high risk of patients developing life-threatening blood clots.[34]
- **Asthma**, which may become life-threatening for pregnant persons.[35]
- **Type 1 diabetes**, which is associated with a number of serious health conditions that can worsen during pregnancy, including high blood pressure that can, in turn, increase the risk of preeclampsia.[36]

Labor and delivery likewise carry significant risks. These include hemorrhage, placenta accreta spectrum (a potentially life-threatening

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ACOG Practice Bulletin No. 183, *Postpartum Hemorrhage* (Oct. 2017) (ACOG, *Postpartum Hemorrhage*).

[33] ACOG, Practice Bulletin No. 78, *Hemoglobinopathies in Pregnancy,* 109 Obstetrics & Gynecology 229-230 (Jan. 2007, reaff'd 2022).

[34] ACOG, Practice Bulletin No. 197, *Inherited Thrombophilias in Pregnancy,* 132 Obstetrics & Gynecology e18 (July 2018, reaff'd 2022).

[35] ACOG, Practice Bulletin No. 90, *Asthma in Pregnancy* 2 (Feb. 2008, reaff'd 2020).

[36] ACOG, Practice Bulletin No. 201, *Pregestational Diabetes Mellitus*, 132 Obstetrics & Gynecology e228, e231-32 (Dec. 2018).

complication that occurs when the placenta is unable to detach at childbirth), hysterectomy, cervical laceration, and debilitating postpartum pain.[37] Approximately one in three people who give birth in the United States do so by cesarean delivery, a major surgical procedure that carries increased risk of complications.[38] The complications of pregnancy and childbirth are numerous and well documented. These risks are even higher in states with laws that limit emergency intervention in a pregnancy until a mother's life is in danger.

In Texas, a woman named Amanda Eid suffered previable premature rupture of the membranes, which resulted in her water breaking at just 18 weeks.[39] Her doctors determined that the fetus could not survive and that Ms. Eid would inevitably develop a dangerous infection, however, a Texas law prohibited them from terminating the doomed pregnancy until she was "sick enough that [her] life was at risk."[40] Three days later, "she went

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[37] ACOG, *Postpartum Hemorrhage*, *supra* note 38; ACOG, *Placenta Accreta Spectrum*, *supra* note 31; ACOG, *Obstetric Lacerations*, *supra* note 38; ACOG, *Multimodal Approach*, *supra* note 38.

[38] CDC, *National Vital Statistics Reports Vol. 70, No. 2, Births: Final Data for 2019* 6-7 (2021); ACOG, *Multimodal Approach*, *supra* note 38,at 511-12.

[39] Elizabeth Cohen & John Bonifield, *Texas Woman Almost Dies Because She Couldn't Get an Abortion,* CNN (Nov. 16, 2022), https://bit.ly/3HOY20H.

[40] *Id.*

downhill very, very fast[,]" her fever spiking "in a matter of maybe five minutes."[41] By this time, her bacterial infection was severe enough that antibiotics and a blood transfusion were unable to stop it – she went into septic shock, requiring invasive treatment and leaving it unclear whether she would survive.[42] Emergency physicians were ultimately able to save her life, but the infection caused uterine scarring that may leave Ms. Eid unable to have another child.[43]

A nearly identical experience happened to Amanda Zurawski.[44] Ms. Zurawski suffered from previable premature rupture of the membranes – but because the threat to her life was not sufficiently acute, she, like Ms. Eid, was sent home for expectant management.[45] As a result of this delay, she became septic and nearly died from the infection, and her uterus and fallopian tubes were heavily scarred as a result of the infection, permanently impacting her fertility and making it challenging (if not

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[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] Ms. Zurawski and 12 other women with similar stories have filed a lawsuit in Texas seeking to prevent this same pattern from occurring again and again. *See* Pls.' First Am. V. Pet. for Declaratory J. and Appl. for Temporary and Permanent Inj. ¶¶ 7-236, *Zurawski v. Texas,* No. D-1-GN-23-000968 (Dist. Ct. Travis Cty., Tex. May 22, 2023).

[45] *Id.* ¶¶ 11-29.

impossible) for her to become pregnant in the future.[46] In both cases, these two women suffered physical trauma and life-long impairments, showcasing the dangers and long lasting effects of complications in pregnancy that can be exacerbated by restrictions on abortion.

The potential risks posed by pregnancy are far greater for persons of color, low-income persons, and those living in rural areas.[47] Low-income patients and patients of color[48] are most likely to experience severe maternal morbidity and more likely to die from pregnancy-related complications,[49] and those in rural areas are disproportionately harmed by

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[46] *Id.* ¶¶ 25-29.

[47] This also is relevant to another factor the FDA is required to consider in determining the appropriate restrictions on mifepristone. *See* 21 U.S.C. § 355-1(f)(2)(C)(ii) (FDA must consider burden on patients "who have difficulty accessing health care (such as patients in rural or medically underserved areas)").

[48] *See* Rachel K. Jones et al., *COVID-19 Abortion Bans and Their Implications for Public Health,* 52 Perspectives on Sexual & Reprod. Health 65, 66 (2020) (Jones, *Abortion Bans*); 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., Guttmacher Inst., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008* 11-12 (2016); *see also* Rural Health Council, Ctrs. for Medicare & Medicaid Servs., *CMS Rural Health Strategy* 2 (2018).

[49] *See* Office of Minority Health, Ctrs. for Medicare & Medicaid Servs., *Advancing Rural Maternal Health Equity* 1 (2022) (Office of Minority Health); Juanita Chinn et al., *Health Equity Among Black Women in the United States,* 30 J. Women's Health 212, 215 (2021) (Chinn).

restrictions on abortion care.[50] For Black and Indigenous pregnant people, the rates of maternal mortality are three to four times the national average.[51] Restrictions on the use of mifepristone that are not medically justified serve only to put these patients at additional risk by making it more difficult for them to obtain a relatively accessible and entirely safe treatment.

In sum, the medical evidence amply demonstrates that pregnancy can be a serious or life-threatening condition. For clinicians who treat pregnant persons, mifepristone is an important tool in their toolbox for responding to medical emergencies that can arise during pregnancy. The medical evidence thus amply justifies the FDA's decisions to approve mifepristone and to reduce restrictions on access to mifepristone.

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[50] *See* ACOG Committee Opinion No. 815, *Increasing Access to Abortion,* 136 Obstetrics & Gynecology at e109 (Dec. 2020) (ACOG, *Increasing Access*).

[51] Elizabeth Howell, *Reducing Disparities in Severe Maternal Morbidity and Mortality*, 61 Clinical Obstetrics & Gynecology 387, 387 (2018).

CONCLUSION

The Court should reverse the district court's decision.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), undersigned counsel certifies that this brief:

(i) complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because it contains 3,851 words, including footnotes and excluding the parts of the brief exempted by Rule 32(f); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Office Word 2016 and is set in Century Schoolbook font in a size equivalent to 14 points or larger.

Dated: February 16, 2024

s/ *Nicole A. Saharsky*
Nicole A. Saharsky

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system on February 16, 2024. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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