24-1576(L), 24-1600, 24-1617

United States Court of Appeals

for the

Fourth Circuit

AMY BRYANT, M.D.,

Plaintiff-Appellee,

– v. –

TIMOTHY K. MOORE, ET AL,

Intervenors/Defendants-Appellants,

– and –

JOSHUA H. STEIN, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL FOR THE STATE OF NORTH CAROLINA, ET AL.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA AT GREENSBORO
No. 1:23-cv-00077-CCE-LPA

BRIEF OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, SOCIETY FOR MATERNAL-FETAL MEDICINE, SOCIETY OF FAMILY PLANNING, ET AL. AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-APPELLEE'S ARGUMENT FOR REVERSAL IN PART AND AFFIRMANCE IN PART

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Local Rule 26.1(b)(1), *amici curiae* states that it has no parent corporation and that no publicly traded corporation owns 10% or more of its stock. *Amici* are not aware of any publicly held corporation that has a direct financial interest in the outcome of this appeal.

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INTERESTS OF AMICUS CURIAE[1]

Amici curiae are 15 leading medical societies representing hundreds of thousands of clinicians who serve patients nationwide. They include:

The American College of Obstetricians and Gynecologists ("ACOG"). Representing more than 90% of board-certified obstetrician-gynecologists ("OB/GYNs") in the United States, ACOG is the nation's premier professional membership organization for OB/GYNs dedicated to providing 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.

The Society for Maternal-Fetal Medicine ("SMFM"). Founded in 1977, SMFM is the medical professional society for maternal-fetal medicine

[1] Counsel for Intervenors/Defendants-Appellants consent to *amici's* filing. Counsel for Defendant-Appellees take no position as to *amici's* filing. Pursuant to Rule 29(a)(4)(E), counsel for *amici* authored this brief in whole. No party or party's counsel authored this brief in whole or in part. No person, other than *amici* and its counsel contributed money that was intended to fund preparing or submitting this brief.

subspecialists, who are obstetricians with additional training in high-risk pregnancies. SMFM represents more than 7,000 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.

The Society of Family Planning ("SFP"). 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 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.

American Academy of Family Physicians ("AAFP"). Founded in 1947, AAFP is one of the largest national medical organizations, representing 129,600 family physicians and medical students nationwide. AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the

public and by supporting its members in providing continuous comprehensive health care to all.

American Academy of Nursing ("AAN"). The American Academy of Nursing (Academy) serves the public by advancing health policy through the generation, synthesis, and dissemination of nursing knowledge. Academy Fellows are inducted into the organization for their extraordinary contributions to improve health locally and globally. With more than 3,000 Fellows, the Academy represents nursing's most accomplished leaders in policy, research, administration, practice, and academia.

American College of Medical Genetics and Genomics ("ACMG"). ACMG is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the U.S. that represents the full spectrum of medical genetics disciplines in a single organization. The ACMG is dedicated to improving health through the clinical and laboratory practice of medical genetics and to guiding the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

American College of Physicians ("ACP"). ACP is the largest medical specialty organization and the second largest physician membership society in the

United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum—from health to complex illness.

American College of Preventive Medicine ("ACPM"). ACPM is a professional medical society representing approximately 2,000 physicians, dedicated to the practice of preventive medicine and improving the health and quality of life of individuals, families, and communities through disease prevention and health promotion. ACPM supports the peer-reviewed, evidence-based practice of medical care and comprehensive reproductive health services.

American Gynecological and Obstetrical Society ("AGOS"). AGOS is composed of individuals attaining national prominence in scholarship and leadership in the discipline of Obstetrics, Gynecology and Women's Health. AGOS's mission is to promote excellence in women's health care through advocacy for research and clinical training and the development of academic leaders in obstetrics and gynecology. AGOS is committed to enhancing diversity and inclusion across the organization.

American Medical Women's Association ("AMWA"). The American Medical Women's Association is the oldest multispecialty organization dedicated

to advancing women in medicine and improving women's health. Our members are physicians, residents, medical students, pre-medical students, health care professionals, and supporters. AMWA's mission is to advance women in medicine, advocate for equity, and ensure excellence in health care.

American Society for Reproductive Medicine ("ASRM"). ASRM is dedicated to the advancement of science and the practice of reproductive medicine. Its members include approximately 8,000 medical professionals.

Council of University Chairs of Obstetrics & Gynecology ("CUCOG"). CUCOG is a diverse, inclusive, and cohesive community of OB-GYN chairs advancing women's health, whose mission is to support OB-GYN Chairs' leadership and professional development through networking and sharing of best practices to ensure our departments' clinical and academic success.

North American Society for Pediatric Adolescent Gynecology ("NASPAG"). NASPAG is a voluntary, non-profit organization devoted to conducting, encouraging, and supporting programs of medical education and professional training in the field of pediatric and adolescent gynecology ("PAG"). NASPAG members reside in all 50 states and in countries abroad. Its focus is to serve and be recognized as the lead provider in PAG education, research, and clinical care; conduct and encourage multidisciplinary and inter-professional programs of medical education and research in the field of PAG; and advocate for

the reproductive well-being of children and adolescents and the provision of unrestricted, unbiased, and evidence-based practice of PAG.

Society of General Internal Medicine ("SGIM"). SGIM is a member-based internal medical association of over 3,300 of the world's leading general internists, who are dedicated to improving access to care for all populations, eliminating health care disparities, and enhancing medical education. SGIM's mission is to cultivate innovative educators, researchers, and clinicians in general internal medicine, leading the way to better health for everyone. SGIM members advance the practice of medicine through their commitment to providing comprehensive, coordinated, and cost-effective care to adults; educating the next generation of outstanding physicians; and conducting cutting-edge research to improve quality of care and clinical outcomes of all patients.

Society of Gynecologic Oncology ("SGO"). SGO is the premier medical specialty society for health care professionals trained in the comprehensive management of gynecologic cancers. SGO contributes to the advancement of women's cancer care by encouraging research, providing education, raising standards of practice, advocating for patients and members, and collaborating with other domestic and international organizations.

* * *

These organizations collectively represent hundreds of thousands of medical practitioners across the country, with deep expertise in 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 and reproductive health care.[2] Ensuring robust access to evidence-based health care and promoting health 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 ("FDA") regulations for the prescription and use of mifepristone are more than sufficient to allow health care clinicians to safely administer the drug in a manner consistent with medical ethics and evidence-backed, medically appropriate standards of care.

Amici's ability to effectively care for patients can require access to mifepristone, which has undergone rigorous testing and review and has been safely used by *amici*'s members in the United States for more than 20 years. Accordingly, *amici* have a strong interest in preserving that access and ensuring that the science

[2] *See*, *e.g.*, *June Med. Servs. LLC v. Russo*, 591 U.S. 299, 340 (2020); *Whole Woman's Health v. Hellerstedt*, 579 U.S. 582, 612–13 (2016); *Stenberg v. Carhart*, 530 U.S. 914, 928 (2000); *Whole Woman's Health v. Paxton*, 978 F.3d 896, 910 (5th Cir. 2000); *Planned Parenthood S. Atl. v. State*, 882 S.E.2d 770, 787–88 (S.C. 2023); *Okla. Call for Reprod. Just. v. Drummond*, 526 P.3d 1123, 1152 n.10 (Okla. 2023).

surrounding mifepristone's safety, efficacy, and administration is correctly understood.

SUMMARY OF THE ARGUMENT

At issue in this case is an attempt by the North Carolina legislature to circumvent the FDA's reasoned judgment and, without any medical or scientific basis, limit patient access to one of the two drugs used in the standard protocol for medication abortion and miscarriage management, known in its generic form as mifepristone. Mifepristone is extremely safe. Over two decades, hundreds of medical studies and vast amounts of data have confirmed its safety and efficacy as part of a two-drug regimen for medication abortion, including for miscarriage management and other early pregnancy loss. The scientific evidence is overwhelming: major adverse events occur in ***less than 0.32%*** of patients. The risk of death is almost non-existent. Few drugs have been so extensively studied before and after their approval by the FDA and can boast such a clear and compelling record of safe use.

North Carolina legislators should not be permitted to impose restrictions that go beyond the FDA's current regulatory regime. Congress has vested the FDA with the primary responsibility to regulate prescription drugs in the United States. The FDA, acting in accordance with that mandate, has implemented protocols for the use of mifepristone that already go above and beyond what is required to ensure the

drug's safe use.[3] North Carolina now tries to take matters into its own hands and implement even more onerous restrictions on mifepristone that would severely obstruct access to a drug that is essential for comprehensive reproductive care. The State's appeals to patient health and informed consent are a red herring: the FDA has already considered—and rejected—***each and every one*** of the restrictions that North Carolina's legislature seeks to impose. The law at issue is not medically or ethically indicated, but a thinly-veiled attempt to limit access to a demonstrably safe medication because certain legislators oppose how it is used. The current FDA protocols are more than sufficient to allow practitioners to provide safe, medically-appropriate, evidence-based, and effective care.

North Carolina's law unnecessarily impedes access to a medication that is essential to reproductive care of all kinds. Mifepristone is not only widely prescribed for medication abortion, including miscarriage management and early pregnancy loss, but also prescribed for a host of other serious health conditions, including Cushing syndrome, uterine fibroids, and endometriosis. Restricting

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[3] The FDA's restrictions, while far narrower than those at issue under North Carolina's law, "still do not enhance the drug's safety profile and instead only continue to impose burdens on and create barriers for those who prescribe and those who need mifepristone." *See ACOG Relieved by Supreme Court Decision Allowing Continued Access to Mifepristone, Calls for Removal of REMS*, June 14, 2024 (https://www.acog.org/news/news-releases/2024/06/acog-relieved-by-supreme-court-decision-allowing-continued-access-to-mifepristone-calls-for-removal-of-rems).

access to it as North Carolina proposes will deprive patients of much needed care for all of these conditions and, in doing so, will worsen care and exacerbate existing inequities in maternal health for people of color, those with fewer financial resources, and those living in rural areas.

Amici urge this Court not to let purported fears or unfounded beliefs about women's health care deprive patients in North Carolina of an essential medication that the FDA has deemed safe for use. *Amici* are the nation's leading medical organizations, representing hundreds of thousands of members, including those most familiar with the use of mifepristone in reproductive health care. Their members are the obstetricians, gynecologists, family physicians, emergency room doctors, maternal-fetal subspecialists, midwives, nurses, physician assistants, and many other providers who care for pregnant patients. Many of *amici*'s members regularly prescribe mifepristone and have extensive experience in their own practices with the risks and benefits for the many patients who rely on it. By contrast, Appellants represent a group of legislators—not medical professionals or patients—with the agenda of making mifepristone more difficult to obtain, not premised on legitimate medical or scientific concerns for the safety of North Carolinians, but with the intent to codify their personal opposition to abortion care. To justify North Carolina's unnecessary restrictions, they make inaccurate

assertions about mifepristone's safety, discounting the overwhelming evidence that mifepristone is a safe and essential component of reproductive health care.

For all of these reasons, *amici* join Appellees in asking this Court to uphold the judgment of the District Court insofar as it held that North Carolina's restrictions governing medication abortion are preempted by federal law, and reverse the judgment of the District Court to the extent it held that North Carolina's restrictions governing medication abortion are not preempted by federal law.

ARGUMENT

I. Mifepristone—An Essential Component of Reproductive Health Care—Has Been Thoroughly Studied and Is Conclusively Safe.

Mifepristone is an essential medication used in reproductive health care, with material benefits to countless patients and vanishingly small risk. Mifepristone is used in combination with misoprostol to provide a safe and effective way to end a pregnancy or manage a miscarriage or other early pregnancy loss.[4] The preferred medication management protocol for patients who experience early pregnancy loss (including miscarriage, spontaneous abortions, missed abortions, incomplete

[4] Of the roughly 5.5 million pregnancies estimated to occur in the United States each year, between 10% and 26% end in miscarriage. *See* ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2021); Ctrs. for Disease Control & Prevention, *U.S. Pregnancy Rates Drop During Last Decade* (Apr. 12, 2023).

abortions, and inevitable abortions) provides that mifepristone is administered approximately 24 hours before misoprostol to empty the contents of the uterus.[5]

In assessing the safety of mifepristone, the FDA has considered data from hundreds of studies and decades of evidence—all of which has consistently demonstrated that mifepristone is a safe and effective medication.[6] When used in medication abortion, major adverse events—including hospitalization, blood transfusion, or surgical intervention—occur in ***less than 0.32%*** of patients, according to a highly regarded study with more than 50,000 patients.[7] Serious infection is exceptionally rare, occurring in only 0.015% to 0.07% of patients.[8] The

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5 ACOG Practice Bulletin No. 200, *Early Pregnancy Loss*, *supra* n.4.

6 *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 12-15 (2018) (describing robust review of evidence in 2016 REMS changes); Letter from Patrizia A. Cavazzoni, FDA, Director, Ctr. for Drug Eval. & Res., to Donna J. Harrison, Am. Ass'n of Pro-Life Obstetricians & Gynecologists, et al., 27, 40 (Dec. 16, 2021), https://downloads.regulations.gov/FDA-2019-P-1534-0016/attachment_1.pdf [hereinafter, "Dec. 2021 Response Letter"] (denying American Association of Pro-Life OBGYNs's citizen petition seeking greater restrictions on mifepristone).

7 *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).

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

risk of death is almost non-existent.[9] A 2024 analysis of FDA data examining potential mifepristone-related deaths over a period of more than 20 years found that only 18 deaths were possibly or probably related to medication abortion, yielding an approximate mortality rate of 0.00031%.[10] These strikingly low rates of adverse outcomes were observed regardless of whether mifepristone had been administered for medication abortion or any other use.

Appellants suggest without reference to credible scientific evidence that mifepristone is a "high risk" drug and that the restrictions imposed by North Carolina are legitimately "safety-related."[11] Appellants even go as far as to imply that mifepristone is among "the most dangerous drugs approved by the FDA," likening

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9 ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone US Post-Marketing Adverse Events Summary Through 12/31/2022"* UNIV. OF CAL., S.F. 2 (2024) [hereinafter "ANSIRH, Adverse Events 2024"]; *see also* Katherine Kortsmit et al., *Abortion Surveillance—United States, 2021*, 72 CTRS. FOR DISEASE CONTROL & PREVENTION MORBIDITY & MORTALITY WKLY. REP. 8 (2023).

10 *See* ANSIRH, Adverse Events 2024, *supra* n.9, at 1–2; *see also id.* at 3 ("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."); *see also* ANSIRH, *U.S. Studies on Medication Abortion Without In-Person Clinician Dispensing of Mifepristone*, UNIV. OF CAL., S.F. 5 (2021).

11 Appellants' Opening Brief, *Bryant v. Stein*, Nos. 24-1576(L), 24-1600, 24-1617, (4th Cir.), Dkt. 21, at 1 [hereinafter "Appellants' Br."].

mifepristone to *opioids*.[12] In truth, mifepristone is not just safe—it is ***far safer*** than countless other medications and among the safest medications or devices approved by the FDA that are being used in medical practice. Studies have shown that mifepristone is *safer than* nonsteroidal anti-inflammatory drugs, a class of drugs which includes common over-the-counter medications like aspirin, naproxen sodium, and ibuprofen, which more than 30 million Americans take in any given day,[13] and other common drugs, including acetaminophen (Tylenol).[14] Using Viagra is more dangerous than using mifepristone; Viagra has a rate of 4.9 deaths for every 100,000 prescriptions.[15] Colonoscopies are a routine procedure, widely used in preventive care—yet death occurs in about 0.03% of colonoscopy cases.[16]

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12 *Id.* at 14.

13 *See* Nat'l Acads. of Sci., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States*, at 79 (2018); *see also* Rohab Sohail et al., *Effects of Non-steroidal Anti-inflammatory Drugs (NSAIDs) and Gastroprotective NSAIDs on the Gastrointestinal Tract: A Narrative Review*, 15 CUREUS 1.

14 ANSIRH, Adverse Events 2024, *supra* n.9 ("Other medications that are common[] or administered in outpatient settings also have risks, including a small risk of death… [a]cetaminophen (Tylenol) overdose is the most common cause of acute liver failure in the US and accounts for over 600 deaths annually.").

15 *See* Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 J. AM. MED. ASS'N at 1 (2000).

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

Medication abortion involving mifepristone is among the safest medical interventions in any category, pregnancy-related or not.

Amici are deeply concerned by Appellants' attempts to stoke fears about mifepristone that are contrary to the many years of scientific evidence. Appellants do not support their claims of mifepristone's "high risk" with any credible, peer-reviewed, evidence-based studies. Nor could they. There is no evidence to suggest, nor have *amici* observed, that heightened restrictions such as those North Carolina seeks to impose make medication abortion any safer—to the contrary, they will *harm* patients, particularly those in poverty, in marginalized communities, and those in rural and geographically isolated areas.

II. The FDA Has Already Concluded That There Is No Credible Scientific Basis for Any of North Carolina's Regulations.

Amici have been successfully providing reproductive care to patients under FDA guidelines and urge this Court to reject North Carolina's effort to impose unnecessary restrictions and curtail the prescription of mifepristone in the state. Patients, in consultation with their providers, may choose to undergo additional testing, visit their providers in person, or seek additional information before or after using mifepristone, depending on the patients' personal circumstances. But these steps should not be mandated by the state where the federal government has rightly determined that they provide no measurable safety benefit while impeding access to

care. The FDA has already considered each of the restrictions that North Carolina seeks to impose[17]—either because they were previously part of the REMS program, or because anti-abortion activists have petitioned the FDA to impose further limits on mifepristone. In each case, the FDA has either removed those restrictions based on extensive evidence from the use of mifepristone in practice, or chosen not to impose them in the first place.

A. North Carolina's Requirement for a Prescribing Physician Is Unwarranted.

North Carolina's attempt to restrict prescribing authority for mifepristone to physicians is unwarranted and will do nothing to improve patient care or health outcomes. In general, advanced medical providers, including physician assistants, nurse practitioners, and nurse midwives, are licensed to (and routinely do) prescribe medication. Although early regulations created an exception to this general practice for mifepristone and initially required it to be prescribed by physicians, the FDA eliminated that restriction in 2016 based on evidence that mifepristone use is no safer when prescribed by a certified physician than it is when prescribed by a certified non-physician clinician.[18] In 2021, the FDA considered and denied a citizen petition

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[17] *See, e.g.*, Dec. 2021 Response Letter, *supra* n.6; *see also* 2016 FDA Medical Review, *supra* n.8.

[18] 2016 FDA Medical Review, *supra* n.8.

requesting that the FDA restore this physician-prescribing limitation. Again, the FDA found no need for, and no benefit from, such a requirement, citing multiple studies showing "*no statistically significant difference*" in outcomes based on the prescriber.[19]

Amici concur. The scientific literature confirms that patients undergoing medication abortion are as safe when receiving care from certified non-physician clinicians as when they are treated by certified physicians.[20] In fact, increasing the number of providers who can prescribe mifepristone increases access to care—particularly for patients living in rural areas or areas with limited, overburdened clinics—and improves health outcomes by making treatment more broadly available.[21] It also reduces health care costs by limiting the need for patients to travel long distances for care and helping patients access care sooner.[22] Restricting

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19 Dec. 2021 Response Letter, *supra* n.6, at 10 (citing Sharmani Barnard et al., *Doctors or mid-level providers for abortion (Review)*, 7 COCHRAN DATABASE OF SYSTEMATIC REVS. at 2 (2015)).

20 ACOG Clinical Consensus No. 815, *Increasing Access to Abortion* (Dec. 2020), at n.34, 52, 53, 54, 55, 56, 57, 58. *See also* ACOG Issue Brief, *Advanced Practice Clinicians and Abortion Care Provision* (Oct. 2023); L. Porsch et al., *Advanced Practice Clinicians and Medication Abortion Safety: A 10-year Retrospective Review*, 101 CONTRACEPT. 357 (May 2020).

21 ACOG Issue Brief, *Advanced Practice Clinicians and Abortion Care Provision* (Oct. 2023).

22 Nadine El-Bawab, *New Abortion Restrictions May Push Patients to More Expensive, Complicated Care* (Aug. 7, 2022),

prescribing privileges, against the clear judgment of the FDA, will not provide any safety benefit to patients—it will only serve as a barrier to access and endanger health by needlessly limiting care.

B. North Carolina's 72-Hour Evaluation, Testing, and Informed Consent Regulations Are Unnecessary and Excessive.

North Carolina's new law requires that at least 72 hours in advance of mifepristone being prescribed, dispensed, and administered, the patient must: (1) undergo an ultrasound to determine the gestation of the fetus; (2) take a blood test to determine the patient's Rh-type; and (3) consult with a provider and review a consent form to understand the results of these tests and provide their "informed consent" to mifepristone use.[23] The FDA requires *none* of these steps. Clinicians are best positioned to determine the medical needs of their individual patients and to engage in joint decision-making with their patients to determine the appropriate treatment approach.

Mandating an ultrasound prior to prescription in no way increases mifepristone's safety. The FDA has acknowledged this fact by allowing the prescription of mifepristone via telehealth—which does not uniformly require a pre-

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https://abcnews.go.com/US/abortion-restrictions-push-patients-expensive-complicated-care/story?id=87803769.

[23] N.C. GEN. STAT. § 90-21.83A (2023).

prescription ultrasound. No decrease in mifepristone's safety has been observed since the approval of telehealth for prescribing mifepristone.[24] In fact, a recent study of 585 patients across six different U.S. states found that patients who obtained medication abortion after a no-test, no-ultrasound telehealth screening had a 94.4% rate of complete abortions, versus 93.3% of patients who received medication abortion after an in-person clinic visit with an ultrasound—a statistically insignificant difference—with similarly low rates of adverse events.[25]

This is because an ultrasound is not required to determine gestation. "Probable gestational age" is determinable simply by obtaining the patient's medical history, as the North Carolina law itself acknowledges.[26] The FDA has expressly considered whether to mandate ultrasounds prior to mifepristone prescription—and chose not to, because "in clinical practice, pregnancies can also be (and frequently are) dated using other clinical methods . . . it [is] inappropriate [] to mandate how providers clinically assess women for duration of pregnancy and for ectopic

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[24] Ushma D. Upadhyay et al., *Effectiveness and safety of telehealth medication abortion in the USA*, 30 NATURE MED. 1191, 1191 (2024).

[25] Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 J. AM. MED. ASS'N 898 (2024).

[26] N.C. GEN. STAT. § 90-21.83A(b)(2)b (stating that "probable gestational age" of the fetus is determined using "both patient history and by ultrasound results used to confirm").

pregnancy."[27] The FDA left this up to "the professional judgment of each provider, as no method (including [transvaginal sonogram]) provides complete accuracy."[28]

Similarly, mandating blood-type testing prior to medication abortion is not consistent with current clinical guidance. When a pregnant person with a Rh-negative blood type is carrying a Rh-positive fetus, Rh-sensitization can occur. This refers to the production of antibodies in the blood of a Rh-negative patient that may negatively impact a fetus. However, clinical findings from recent studies suggest that the risk associated with abortion or pregnancy loss at less than 12 weeks of gestation is very low.[29] As only a significant minority of the American population has negative Rh-type blood,[30] this restriction serves as a barrier to essential reproductive care for the majority of patients. Expert guidelines, including those published by ACOG, therefore no longer require routine Rh testing or the prophylactic administration of Rh D immune globulin (RhIG) for abortion or

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27 Letter from Janet Woodcock, Director, FDA, Ctr. for Drug Eval. & Res., to Donna Harrison, Exec. Director, AAPLOG et al., at 18 (Mar. 29, 2016) (hereinafter "Mar. 2016 Response Letter").

28 *Id.*

29 ACOG, Clinical Practice Update, *Rh D Immune Globulin Administration After Abortion or Pregnancy Loss at Less Than 12 Weeks of Gestation*, Obstet. & Gynecol. (Sept. 2024).

30 Laura Dean, *Blood Groups and Red Cell Antigens*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. (2005).

pregnancy loss at less than 12 weeks of gestation because of the lack of evidence to support a benefit and concerns that provision can delay or impede access to abortion care.[31] Although not routinely indicated, Rh testing and RhIg administration can be considered on an individual basis in the context of a shared decision-making discussion about the potential benefits and risks with the patient. And again, the FDA has *expressly considered and declined* to recommend in-person Rh-testing and RhIg administration.[32]

Finally, in *amici*'s experience, informed consent laws such as North Carolina's contribute little to patient safety and are often thinly veiled efforts to persuade patients not to have an abortion. Medical practitioners are ethically obligated to discuss treatment options and ensure their patients fully understand the risks and benefits of any treatment. An ultrasound has absolutely no bearing on informed consent—a provider will explain the risks of mifepristone, including the approved gestational duration limit, with or without the results of an ultrasound. So too with in-person blood type testing—a provider will explain risks inherent for pregnant patients with an Rh-negative blood type. And where a patient is concerned

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[31] ACOG, Clinical Practice Update, *Rh D Immune Globulin Administration After Abortion or Pregnancy Loss at Less Than 12 Weeks of Gestation*, Obstet. & Gynecol. (Sept. 2024).

[32] Dec. 2021 Response Letter, *supra* n.6, at 18.

or where such treatment is medically indicated, nothing prevents that patient from obtaining these additional tests—there is simply no medical reason for them to be mandatory.

C. In-Person Prescribing, Dispensing, and Administering Requirements Are All Unnecessary and Burdensome.

The FDA has already concluded that healthcare providers can safely prescribe, dispense, and administer mifepristone to patients without an in-person appointment. The FDA initially imposed this requirement out of an abundance of caution because of a lack of available data assessing whether mifepristone could be administered safely at home.[33] Then, during the COVID-19 pandemic, the FDA announced that it would not enforce in-person dispensing requirements. Evidence from the period between July 13, 2020 and January 12, 2021 showed no increase in rates of adverse event reporting. Based on this new information—and an extensive review of the latest scientific literature—the FDA decided in December 2021 to temporarily suspend the in-person dispensing requirement.[34] When evidence continued to show no increased risks, the FDA made this decision permanent in 2023.

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[33] 2000 FDA Approval Memorandum, 2:22-CV-00223-Z, Nov. 18, 2022, Compl. Ex. 24, ECF No. 1-25, at 2–3.

[34] *See* Dec. 2021 Response Letter at 25–27.

The FDA continues to require involvement of a practitioner for telehealth visits but allows that provider to prescribe mifepristone, and the patient to use it, without in-person dispensing. Under the FDA's current requirements, for example, instead of being required to physically retrieve the medication from a doctor's office or certified pharmacy, the patient can have it delivered to their home after being evaluated by a clinician (via telehealth or in person) and counseled regarding the medication, including its administration and side effects. Then, instead of being expected to return to the provider's office to confirm they are no longer pregnant, the patient can answer a series of questions asked by the provider, take an at-home pregnancy or blood test, and communicate the results to their provider via telehealth.

Reproductive health clinics and providers 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, all of which enable the provision of care with fewer in-person visits. For prescription of mifepristone for use in medication abortion or early pregnancy loss, telehealth protocols offer the same protections as in-person dispensing and provide an equivalent level of care. 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 medical eligibility—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.[35] And they engage in shared-decision making with their trusted clinician to determine the appropriate course of treatment for them—just as they would in person.

The latest data, collected from more than 6,000 patients in 20 states, shows that "[t]elehealth medication abortion is effective, safe, and comparable to published rates of in-person medication abortion care."[36] *Amici* also have not observed any increase in adverse outcomes since the removal of the in-person dispensing and administration requirement. The percentage of patients that ever visit an emergency room for abortion-related complications remains exceedingly small,[37] and the underlying manner in which the medication is prescribed does not alter its safety profile.

Removing the in-person dispensing and administration requirement has improved patient access and, in any case, has not prevented patients from being seen in-person by a clinician where an individual chooses to do so, or where the provider

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35 *See* Elizabeth Raymond & Hillary Bracken, *Early Medical Abortion Without Prior Ultrasound*, 92 CONTRACEPT. 212 (2015); 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); 2000 FDA Approval Memorandum, *supra* n.33, at 5.

36 Upadhyay et al., *supra* n.24.

37 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).

has any concerns regarding a particular patient. Although some patients will continue to prefer in-person care, telehealth provides an important alternative and offers substantial benefits for patients who choose it. In a study of 1,600 patients who received abortion care through telemedicine, "nearly all participants were very satisfied with telehealth abortion"—96% of those surveyed felt it was the right decision—and patients reported that choosing telehealth not only made care more accessible but allowed them to receive care quickly, privately, at lower cost, and in the comfort of their own home.[38]

The North Carolina legislature's effort to eliminate the telehealth option for patients in need of reproductive care will most substantially affect patients living in areas without access to in-person providers—healthcare deserts[39]—as well as low income, uninsured, and minority patients. For example, one recent study found that for patients who are low-income, rural, or persons of color, and were able to obtain timely abortion care, approximately half were able to do so specifically because of

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[38] *See* Leah R. Koenig et al., *Patient Acceptability of Telehealth Medication Abortion Care in the United States, 2021–2022: A Cohort Study*, 114 AM. J. PUB. HEALTH 241 (2024).

[39] *Nowhere to Go: Maternity Care Deserts Across the US*, MARCH OF DIMES (2024).

telehealth.[40] The fact that a patient lacks a local provider or health insurance is not a basis to deny them ibuprofen; it should not be a basis to deny them another medication that is just as safe because it is used for reproductive care. Mifepristone is exceptionally safe, and that remains true regardless of whether it is handed to a patient in person or shipped by mail.

D. In-Person Follow-Up Requirements Are Unnecessary and Burdensome.

As the data shows, and as the District Court accepted, there is no medical reason to expect a patient who has taken mifepristone to make in-person follow-up visits afterwards.[41] It provides no benefit to the patient and can be burdensome, disruptive, and costly, rendering access to an essential medical protocol inaccessible to many patients. Effective methods of follow-up that do not require in-person visits to a clinic include "[f]ollow-up [] performed by telephone at 1 week, with subsequent at-home urine pregnancy testing at 4 weeks after treatment, which avoids the need for the patient to go to a facility."[42] To the extent after-care is needed or requested

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40 *See* Leah R. Koenig et al., *The Role of Telehealth in Promoting Equitable Abortion Access in the United States: Spatial Analysis*, JMIR PUB. HEALTH & SURVEILLANCE (2023).

41 *See*, *e.g.*, U.S. GOV'T ACCOUNTABILITY OFF., *supra* n.6 (summarizing studies).

42 ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation* (Oct. 2020, *reaff'd* 2023).

by a patient, comprehensive telehealth protocols adopted by clinics[43] make it easy for patients to communicate with their providers and discuss questions or medical concerns that arise after use of mifepristone. And, of course, alleviating the requirement for follow-up visits in no way prevents patients who prefer in-person consultation from doing that instead.

E. Non-Fatal Adverse Event Reporting Is Unnecessary and Potentially Harmful.

As Appellants also acknowledge, the FDA has not required supplemental, non-fatal adverse event reporting since 2016.[44] The FDA's 2016 changes to the reporting requirements stated that only deaths needed to be reported by prescribers directly to the FDA, while serious, unexpected adverse event reporting and non-expedited individual case safety reports could continue to be submitted periodically.[45] The FDA made this decision based on the fact that the safety profile of mifepristone had not changed in the 15 years prior.[46]

Despite this, the North Carolina law would require that providers report to the state Department of Health and Human Services not only any adverse event—

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43 *See supra* p. 23–28.

44 Appellants' Br. at 11.

45 2016 FDA Medical Review, *supra* n.8, at 48–49.

46 *Id.*

whether or not it is serious—but also identifying information of the provider, demographic information of the patient, probable gestation of the fetus, details of the physician's attempts to schedule and encourage a follow-up appointment, and more. Such requirements do not serve to increase patient health and safety but rather only to bog providers down with administrative tasks and intimidate clinicians from providing, and patients from accessing, essential reproductive care due to the risk of being identified and targeted.[47] Abortion providers have historically faced violence and harassment unlike any other field of medicine.[48] Requiring providers to identify themselves to state agencies each time they provide abortion care increases their risk of facing violence and harassment if their names were ever leaked or used for improper purposes. In a recent qualitative study from Massachusetts, researchers found this very valid concern about signing the required prescriber agreement was a barrier even among physicians who only prescribed mifepristone for miscarriage care.[49]

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47 *See generally* Danielle Calloway et al., *Mifepristone Restrictions and Primary Care: Breaking the Cycle of Stigma Through a Learning Collaborative Model in the United States*, 104 CONTRACEPT. 24 (2021).

48 David S. Cohen & Krysten Connon, *Living in the Crosshairs: The Untold Stories of Anti-Abortion Terrorism*, OXFORD UNIVERSITY PRESS (2015).

49 *See* Sara Neill et al., *Medication Management of Early Pregnancy Loss: The Impact of the U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategy [A289]*, 139 OBSTET. & GYNECOL. 83 (2022).

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

Amici are concerned that if the Court permits North Carolina to impose on mifepristone targeted restrictions that provide no measurable benefit and are deemed unnecessary by the FDA, it will embolden states to further impair access to mifepristone nationwide—even for miscarriage management and other non-abortion uses, and even in states where abortion remains legal—endangering pregnant patients and upending the broader health care system.

Without mifepristone, pregnancy will be even more dangerous than it already is. To date, the empirical evidence shows that pregnant people are at least 14 times more likely to die during childbirth than during any abortion procedure[50] and are at an increased risk of experiencing hemorrhage, infection, and injury to other organs during pregnancy and childbirth.[51] Even under the best of circumstances, pregnancy and childbirth impose significant physiological changes that can exacerbate

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[50] *See* Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childhood in the United States*, 119 OBSTET. & GYNECOL. 215, 216 tbl.1 (2012); Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, CTRS FOR DISEASE CONTROL & PREVENTION (last reviewed Mar. 16, 2023); Kortsmit et al., *supra* n.9, at 1; Nat'l Acads. of Sci., Eng'g & Med., *supra* n.13, at 74.

[51] *See* Raymond & Grimes, *supra* n.50, at 216–17 fig.1.

underlying conditions and severely compromise health, sometimes permanently.[52] Pregnancy, particularly when coupled with preexisting conditions, can quickly evolve into a life-threatening situation necessitating critical care.

The dangers of pregnancy in the U.S. are far greater for people of color, those with less financial resources, and those living in rural areas.[53] These populations are most likely to experience severe maternal morbidity, more likely to die from pregnancy-related complications, and are disproportionately harmed by restrictions on abortion care.[54] The majority of abortion care patients identify as people of color, and "75% of those seeking abortion [care] are living at or below 200% of the federal

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[52] *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. 183, *Postpartum Hemorrhage* (Oct. 2017).

[53] *See* Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them*, KFF (Nov. 2022); Office of Minority Health, *Advancing Rural Maternal Health Equity*, CTRS. FOR MEDICARE & MEDICAID SERVS., at 1 (2022).

[54] *See* Rachel K. Jones et al., *COVID-19 Abortion Bans and Their Implications for Public Health*, 52 PERSPS. ON 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 POOR & UNDERSERVED 415, 416-17 (2011); ACOG Clinical Consensus No. 815, *Increasing Access to Abortion* (Dec. 2020).

poverty level."[55] Pregnant people of color are also more likely to experience early pregnancy loss or miscarriage, the treatment for which can include mifepristone.[56]

This Court ought to consider the substantial evidence demonstrating that *denial* of abortion care causes harm. Patients who are denied requested abortion care are more likely to experience intimate partner violence compared with patients who were able to access this care.[57] Forced pregnancy undermines maternal and fetal health and exacerbates the risks inherent in pregnancy itself.[58] Studies have repeatedly shown that being denied abortion care not only leads to worse health outcomes, but exacerbates patients' economic hardships, revealing "large and statistically significant differences in the socioeconomic trajectories of women who were denied requested abortions compared with women who received abortions—

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55 ACOG Clinical Consensus No. 815, *supra* n.52.

56 *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).

57 *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).

58 *See* Nadine El-Bawab et al., *In post-Roe America, Women Detail Agony of Being Forced to Carry Nonviable Pregnancies to Term*, ABC NEWS, (Dec. 14, 2023) https://abcnews.go.com/US/post-roe-america-women-detail-agony-forced-carry/story?id=105563349.

with women denied abortions facing more economic hardships."[59] These effects are not isolated; many patients seeking abortion care have children already, and the dangers to them—physically, emotionally, and economically—ripple outwards within each family and community. As medical providers throughout the country, *amici* are seriously concerned that making it more difficult to obtain mifepristone will make it more difficult to provide medication abortion care to those who need it, consistent with the current standard of care. This alone endangers patients.

Restricting access to mifepristone also endangers *anyone* who is pregnant, because its use in the practice of medicine goes far beyond abortion care. Mifepristone has critical off-label uses in maternal care beyond abortion care,[60] and, as mentioned, is widely prescribed for management and treatment of miscarriages, including spontaneous, missed, inevitable, and incomplete abortions.[61] Nearly one

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[59] Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 112 AM. J. PUB. HEALTH 1290, 1295 (2018).

[60] *See* Blake M. Autry & Roopma Wadhwa, *Mifepristone*, NAT'L LIBR. MED. (Feb. 28, 2024).

[61] *See* ACOG Practice Bulletin No. 200, *supra* n.4; *see also* 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), https://www.npr.org/sections/health-shots/2019/01/10/666957368/a-drug-that-eases-miscarriages-is-difficult-for-women-to-get.

out of every five people who becomes pregnant will experience a miscarriage at some point in her life—more than a million patients each year.[62] Untreated, miscarriage can occur over two to eight weeks, exacerbating the emotional strain of pregnancy loss.[63] *Amici*'s members frequently prescribe mifepristone when a patient is experiencing early pregnancy loss because it can ease the process and lead to better health outcomes.[64] Patients already enduring miscarriage should not be forced to suffer through limited access to a safe and effective medication.[65]

Studies have also examined mifepristone for a range of other maternal-health purposes, including treatment of Cushing syndrome, uterine fibroids (tumorous

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62 *See* Carla Dugas & Valori H. Slane, *Miscarriage*, NAT'L LIBR. MED. (June 27, 2022) ("as many as 26% of all pregnancies end in miscarriage and up to 10% of clinically recognized pregnancies").

63 *id.* (stating that "[a]pproximately 80% of women achieve complete passage of intrauterine contents within 8 weeks").

64 *See*, *e.g.*, ACOG Practice Bulletin No. 200, *supra* n.4; Jessica Beaman et al., *Medication to Manage Abortion and Miscarriage*, 35 J. GEN. INTERNAL MED. 2398, 2400 (2020).

65 *See* Silpa Srinivasulu et al., *US clinicians' perspectives on how mifepristone regulations affect access to medication abortion and early pregnancy loss care in primary care*, 104 CONTRACEPTION 92 (2021); Caitlin Dewey, *Many women can't access miscarriage drug because it's also used for abortions*, ALA. REFLECTOR (Oct. 21, 2023), https://alabamareflector.com/2023/10/21/many-women-cant-access-miscarriage-drug-because-its-also-used-for-abortions/; Lorena O'Neil, *Doctors grapple with how to save women's lives amid 'confusion and angst' over new Louisiana law*, (Sep. 3, 2024), https://lailluminator.com/2024/09/03/louisiana-women/.

growths of uterine muscle), and treatment of endometriosis (abnormal tissue growth outside the uterus, which can cause severe pain and infertility).[66] Mifepristone has also been studied for use in reducing the duration of bleeding or hemorrhaging during certain serious pregnancy complications.[67] Restricting access to mifepristone will prevent patients from receiving much-needed treatment for these conditions as well.

In short, Appellants should not be permitted to undermine the nation's longstanding drug approval system—much less target a single drug—and deny patients and providers access to a safe and effective medication used to promote maternal health based on their opposition to abortion.

CONCLUSION

For the reasons set forth above, *amici* urge this Court to uphold the judgment of the District Court insofar as it held that North Carolina's laws governing

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66 *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).

67 *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).

medication abortion are preempted by federal law, and to reverse the judgment of the District Court insofar as it held that North Carolina's laws governing medication abortion are not preempted by federal law.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 29(a)(4) and 32(g)(1), I hereby certify that the foregoing complies with the type-volume limitations of Federal Rules of Appellate Procedure 29(a)(5). According to the word count feature of Microsoft Word, the word-processing system used to prepare the brief, the brief contains 7,627 words.

I further certify that the foregoing brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman font, a proportionally spaced typeface.

Dated: October 17, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on October 17, 2024, I electronically filed the foregoing document with the United States Court of Appeals for the Fourth Circuit by using the CM/ECF system.

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