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; PHILIP E. BERGER,

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

BRIEF OF *AMICI CURIAE* REPRODUCTIVE HEALTH RESEARCHERS IN SUPPORT OF PLAINTIFF-APPELLEE AND REVERSAL IN PART

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DISCLOSURE STATEMENT

Pursuant to Fed R. App. P. 26.1 and Fourth Circuit Rule 26.1(b), *Amici Curiae* Reproductive Health Researchers[1] state that they are not a corporation or other publicly held entity.

1. *Amici curiae* do not have any parent corporations.
2. No publicly held corporation or other publicly held entity owns 10% or more of the stock of *amici curiae*.
3. *Amici curiae* are unaware of any publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation.
4. This case does not arise out of a bankruptcy proceeding or criminal case.

Dated: October 17, 2024

Respectfully submitted,

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INTERESTS OF *AMICI CURIAE*

Amici curiae are over 150 distinguished researchers, clinicians, and professors who have extensive expertise in public health research regarding abortion safety, access, and effectiveness in the United States. *Amici* submit this brief to assist the Court in understanding the body of research showing the safety and effectiveness of medication abortion provided via telehealth, and showing that various requirements imposed by North Carolina's Abortion Laws do not in fact improve patient health and safety.[2] A full list of *amici* is attached as an addendum to this brief.

SUMMARY OF ARGUMENT

The State of North Carolina generally permits abortions during the first 12 weeks of pregnancy.[3] In 2023, North Carolina enacted a series of laws, entitled "Abortion Laws" that impose additional abortion restrictions.[4] As relevant here, these restrictions conflict with the U.S.

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[2] *Amici* have no personal interest in the outcome of this case. *Amici* affirm that no party or counsel for any party authored this brief in whole or in part and that no one other than *amici* or their counsel contributed any money that was intended to fund the preparation or submission of this brief.

[3] *See* N.C. Gen. Stat. § 90-21.81B(2).

[4] *See* N.C. Gen. Stat. §§ 90-21.80–21.99 (2023).

Food and Drug Administration ("FDA") requirements for the provision of medication abortion. For example, while the FDA permits medication abortions to be provided via telehealth by certified non-physician clinicians, North Carolina's Abortion Laws demand that prior to receiving a medication abortion, pregnant individuals must attend an in-person consultation that includes a transvaginal ultrasound and a blood test, and also that a physician must administer the abortion medications to the patient in person.[5]

Evaluating the extent to which the FDA's regulation of abortion medications preempt North Carolina's Abortion Laws, the District Court held that the in-person consultation, transvaginal ultrasound, and blood test requirements were not pre-empted.[6] In reaching this decision, the District Court suggested that North Carolina may have an interest in protecting pregnant individuals' health and safety and in ensuring their informed consent to an abortion—independent from the

[5] *See* N.C. Gen. Stat. §§ 90-21.83A(b), B(a)–(b).

[6] *Bryant v. Stein*, No. 1:23-CV-77, 2024 WL 1886907, at *15 (M.D.N.C. Apr. 30, 2024), judgment entered, No. 1:23-CV-77, 2024 WL 3107568 (M.D.N.C. June 3, 2024).

FDA's interest in the safe use of abortion medications.[7] Seizing on this framing, Appellants characterize North Carolina's additional abortion requirements as "regulat[ing] for health and safety" and for the "protection of women who use abortion inducing drugs."[8]

Public health research, however, does not bear this out. For example, numerous studies show that requiring an in-person consultation, transvaginal ultrasound, or Rh-blood testing prior to receiving medication abortion does *not* improve the safety and effectiveness of medication abortion, nor do they render patients "better informed." Indeed, telehealth abortion care, without these additional requirements, is now a standard practice. Moreover, research shows immense benefits of ***not*** requiring these steps, including improved access to care. This brief aims to bring to bear the public health research demonstrating that telehealth medication abortion is safe and effective—and that North Carolina's Abortion Laws do not meaningfully improve the health and safety of pregnant individuals, the quality of

[7] *Bryant v. Stein*, 2024 WL 1886907, at *9, *14–*15.

[8] Appellant Br. at 4.

care these patients receive, nor do they contribute to patients' informed consent.

As for North Carolina's requirements that only a physician may prescribe and administer abortion medications, and must do so in person, the District Court held that federal law preempts these requirements. In so doing, the District Court correctly recognized that the FDA has already determined that any certified healthcare provider may prescribe and dispense abortion medication and may do so via telehealth. This brief also seeks to highlight the public health research—much of which the FDA also relied upon—demonstrating that qualified non-physicians may safely and effectively prescribe and administer abortion medications and may do so through telehealth.

ARGUMENT

A. Telehealth medication abortions are now standard practice.

Telehealth is now a standard method of providing abortion care.[9] Medication abortion involves taking two drugs, mifepristone and

[9] American College of Obstetricians and Gynecologists ("ACOG"), *ACOG Practice Bulletin No. 225: Medication Abortion Up to 70 Days of Gestation*, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation (last accessed Oct. 10, 2024); World Health Organization, *Abortion Care*

misoprostol.[10] Mifepristone works by blocking the action of a hormone, progesterone, needed to sustain a pregnancy.[11] Misoprostol causes uterine contractions, which expels the pregnancy.[12] The FDA-approved medication abortion protocol involves taking a 200 mg pill of mifepristone, followed by a dose of misoprostol, usually 24 to 48 hours later.[13]

In 2000, the FDA first approved mifepristone for medical termination of a pregnancy through seven weeks' gestation, and in 2016

Guideline (March 8, 2022), https://www.who.int/publications/i/item/9789240039483.

[10] FDA, *Postmarket Drug Safety Information for Patients and Providers: Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation,* https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=When%20did%20the%20FDA%20approve,ten%20weeks%20gestation%20in%202016 (last accessed Oct. 10, 2024) ("FDA Postmarket Drug Safety Info.").

[11] *Id.*

[12] KFF (formerly Kaiser Family Foundation), *The Availability and Use of Medication Abortion,* https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/ (last accessed Oct. 11, 2024).

[13] *See* FDA Postmarket Drug Safety Info., *supra* note 10.

the FDA extended that time period to ten weeks.[14] Medication abortion has since emerged as the leading abortion method in the U.S.[15] In 2023, medication abortions accounted for 63% of all recorded abortions nationwide.[16]

In 2021, the FDA removed the in-person dispensing requirement for mifepristone, after years of urging by many organizations, including by the American College of Obstetricians and Gynecologists ("ACOG"), the leading professional and guideline-setting organization for obstetricians and gynecologists.[17]

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[14] Carrie N. Baker, *History and Politics of Medication Abortion in the United States and the Rise of Telemedicine and Self-Managed Abortion*, 48 J. Health Pol., Pol'y and Law, 485, 486 (2023); FDA Postmarket Drug Safety Info., *supra* note 10.

[15] Baker, *supra* note 14 at 486; FDA Postmarket Drug Safety Info., *supra* note 10.

[16] Rachel K. Jones and Amy Friedrich-Karnick, *Medication Abortion Accounted for 63% of All US Abortions in 2023-An Increase from 53% in 2020* (Guttmacher Policy Analysis, 2024), https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020.

[17] *ACOG Applauds the FDA for its Action on Mifepristone Access During the COVID-19 Pandemic* (ACOG News Release, 2021), https://www.acog.org/news/news-releases/2021/04/acog-applauds-fda-action-on-mifepristone-access-during-covid-19-pandemic; *Improving Access to Mifepristone for Reproduction Health Indications* (ACOG Position Statement, 2021), https://www.acog.org/clinical-information/policy-and-position-statements/position-

Telehealth protocols mirror the protocols for in-person medication abortion care. To begin, providers typically require that patients complete an online screening form to assess their eligibility for a telehealth medication abortion.[18] The form focuses on five criteria: 1) confirmation of pregnancy; 2) duration of pregnancy; 3) indications of ectopic pregnancy; 4) contraindications to abortion medications, such as medical conditions and drug allergies; and 5) patient preference for an in-person, pre-treatment ultrasound or pelvic examination.[19]

Providers then initiate a telephone call, video visit, or asynchronous message exchange with the patient to discuss their

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statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications; *ACOG Statement Regarding Telemedicine Abortion* (ACOG News Release, 2015), https://www.acog.org/news/news-releases/2015/06/acog-statement-regarding-telemedicine-abortion; Ushma D. Upadhyay, et al., *Effectiveness And Safety Of Telehealth Medication Abortion In The USA,* 30 Nature Medicine 1191, 1192 (2024), https://www.nature.com/articles/s41591-024-02834-w ("Upadhyay, et al., Nature Medicine").

[18] Elizabeth G. Raymond, et al., *Commentary: No-Test Medication Abortion: A Sample Protocol Increasing Access During a Pandemic and Beyond*, 101 Contraception 361, 362 (2020), https://www.contraceptionjournal.org/article/S0010-7824(20)30108-6/pdf.

[19] *Id.*

screening form answers and their eligibility for a medication abortion.[20] This "no-test" protocol means no ultrasound or pelvic exam is required; however, depending on a patient's responses, a provider may refer that patient to first obtain an ultrasound, or to in-person abortion care.[21] It is important to emphasize that not all patients can have a no-test medication abortion. Given the strict screening criteria, many potential patients will not qualify. One study found as many as 27% of people who attempted to access a telehealth medication abortion did not qualify.[22]

Once the provider determines that a patient is eligible, they review the abortion process and medication instructions with the

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[20] Anna E. Fiastro, et al., *Remote Delivery in Reproductive Health Care: Operation of Direct-to-Patient Telehealth Medication Abortion Services in Diverse Settings*, 20 Annals of Family Medicine 336, 338 (2022) ("Fiastro, et al., *Remote Delivery*").

[21] *See, e.g.*, Planned Parenthood Pasadena & San Gabriel Valley, *Overview of the Abortion Pill (via Telehealth)*, https://www.plannedparenthood.org/planned-parenthood-pasadena-san-gabriel-valley/getcare/abortionservices/abortion-pill-via-telehealth (last accessed Oct. 10, 2024).

[22] Anna E. Fiastro, et al., *Patient Characteristics Associated With Choosing Telehealth vs. In-Clinic Medication Abortion Care* 121 Contraception 110019 (2023), supplemental online content available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2809068 at eFigure.

patient, discuss potential risks, and answer patient questions.[23] The patient is then asked to provide their consent to the abortion via an online consent form.[24] Informed consent procedures aim to document a patient's understanding of the general procedure for a telehealth medication abortion, as well as its limitations and potential complications.[25] As part of its Risk Evaluation and Mitigation Strategy ("REMS") program, the FDA further requires that all patients and their providers complete its Patient Agreement Form, which also details the medication protocol, its risks, common side effects, and signs of potential complications.[26]

Following the consultation, the provider usually mails the patient their medications or sends a prescription to a mail-order pharmacy.[27]

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[23] Raymond, et al., *supra* note 18 at 362; *see also*, Baker, *supra* note 14.

[24] Reproductive Health Access Project, *Consent For An Abortion With Pills*, https://www.reproductiveaccess.org/wp-content/uploads/2015/03/2022-04-RHAP-MAB-Consent-Form_final.pdf (last accessed Oct. 10, 2024).

[25] *Id.*

[26] FDA, *Patient Agreement Form*, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_Patient_Agreement_Form.pdf (last accessed Oct. 10, 2024) ("FDA Patient Agreement Form").

[27] Raymond, et al., *supra* note 18; Alice Mark, et al., *The Future Of Abortion Is Now: Mifepristone By Mail And In-Clinic Abortion Access In*

The provider may also make the medications available for local pickup.[28] As mandated by the FDA, the medications are delivered with a Mifepristone Medication Guide, which includes a complete set of instructions for safe use.[29] Providers instruct patients to take a pregnancy test four weeks after the abortion to ensure the procedure is complete.

In addition to any scheduled follow-up appointments, patients can also consult with their providers as needed.[30] Clinics typically incorporate an option for immediate assistance, such as text-messaging and phone calls, as well as access to patient portals with educational materials and frequently asked questions.[31]

Consistent with the FDA's determinations, clinics and patients have successfully employed telehealth medication abortion for the past

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The United States 104 Contraception 38 (2021), https://www.contraceptionjournal.org/article/S0010-7824(21)00109-8/fulltext.

[28] Raymond, et al., *supra* note 18.

[29] *Id.*; FDA, *Mifeprex Medication Guide*, https://www.fda.gov/media/72923/download (last accessed Oct. 11, 2024) ("FDA Medication Guide").

[30] Fiastro, et al., *Remote Delivery*, *supra* note 20, at 339.

[31] *Id.*; *see also* Baker, *supra* note 14 at 495.

four years. As of March 2024, telehealth medication abortions accounted for almost 20% of all abortions in the country.[32] There are nearly 20,000 telehealth medication abortions provided per month nationwide.[33]

1. Telehealth abortion care is safe and effective.

Extensive public health research confirms that medication abortion provided via telehealth is both safe and effective. Researchers define safety as the absence of serious adverse events throughout the course of the treatment, and define effectiveness as completion of an abortion without additional intervention.[34] Multiple studies show no decrease in safety or effectiveness for medication abortion via telehealth as opposed to in person.[35]

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[32] *#WeCount Report*, (Society of Family Planning, 2024), https://doi.org/10.46621/878086iuzegt, at Table 4.

[33] *Id.* at Figure 6.

[34] Upadhyay, et al., Nature Medicine*, supra* note 17 at 1192.

[35] *Id.* at 1194; Holly A. Anger, et al., *Clinical and Service Delivery Implications Of Omitting Ultrasound Before Medication Abortion Provided Via Direct-To-Patient Telemedicine And Mail In The U.S.* 104 Contraception 659 (2021), https://pubmed.ncbi.nlm.nih.gov/34329607/ ("Anger, et al., 2021"); Holly A. Anger, et al., *Clinical And Service Delivery Outcomes Following Medication Abortion Provided With Or Without Pretreatment Ultrasound Or Pelvic Examination: An Updated Comparative Analysis* Contraception (2024), online ahead of print at:

Recently, researchers from the University of California, San Francisco published the results of the California Home Abortion by Telehealth ("CHAT") Study, which evaluated the safety and effectiveness of over 6,000 telehealth medication abortions. The reference to California notwithstanding—the study followed patients at three virtual clinics operating in 20 states and Washington D.C. between April 2021 and January 2022.[36] Individuals were screened based on the "no-test" protocol described above, and ultimately 6,034 telehealth abortions were provided. The study found that there was no difference in safety and effectiveness between telehealth abortion care and in-person medication abortion care.[37] Specifically, the CHAT Study

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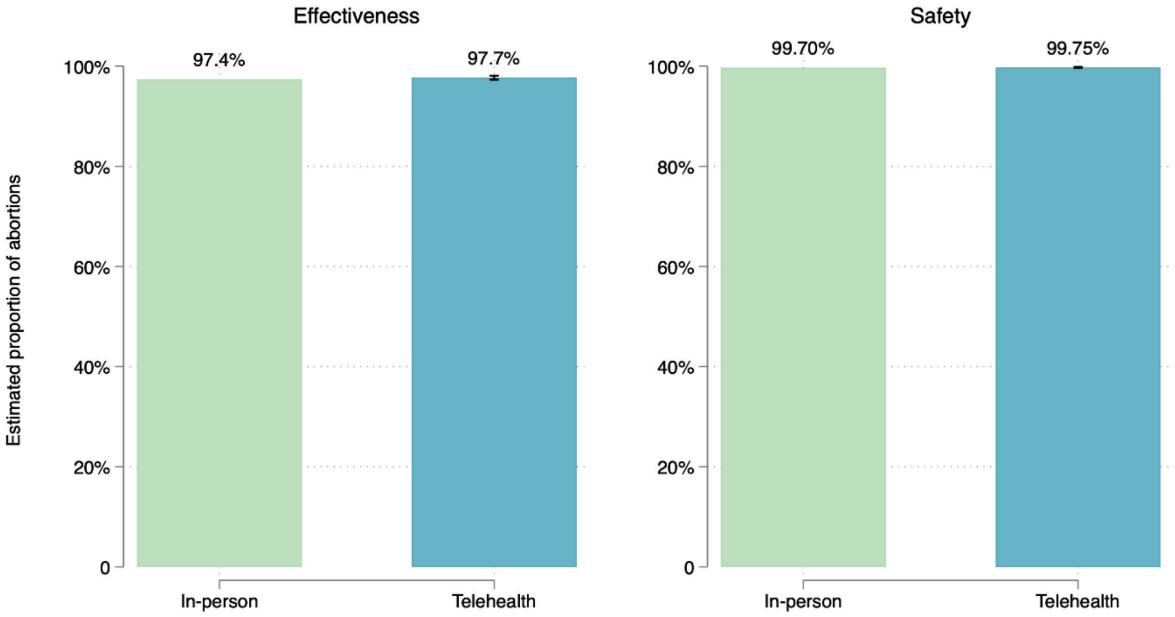
doi: 10.1016/j.contraception.2024.110552 ("Anger, et al., 2024"); Courtney Kerestes, et al., *Provision Of Medication Abortion In Hawai'i During COVID-19: Practical Experience With Multiple Care Delivery Models* 104 Contraception 49 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8005318/; Lauren J. Ralph, et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion,* 332 JAMA 898 (2024), https://jamanetwork.com/journals/jama/article-abstract/2820321; Silpa Srinivasulu, et al., *Telehealth Medication Abortion in Primary Care: A Comparison to Usual in-Clinic Care*, 37 J. of the Am. Board of Family Medicine, 295 (2024);

[36] Upadhyay, et al., Nature Medicine, *supra* note 17 at 1191–98.

[37] *Id.*

showed that 97.7% of telehealth abortions were effective, and 99.7% were safe, meaning no adverse event followed.[38] As reflected in Figure 1 below, these results are similar to the safety and effectiveness of in-person medication abortion care in the U.S., as shown by previous studies and summarized on the FDA medication label for mifepristone.

Figure 1. Abortion effectiveness and safety estimates: telehealth and published estimates of in-person care.



Sources
In-person dispensing: US Food and Drug Administration Label for Mifepristone, 2016.
Telehealth dispensing: Upadhyay UD *et al.* Effectiveness and safety of telehealth medication abortion in the USA. Nature Medicine, 2024.

[38] Notably, effectiveness remained the same across many variables, including age, pregnancy duration, race, ethnicity, previous birth, previous abortion, or whether the patient had received a pre-abortion ultrasound. *Id.*

The CHAT Study reaches similar results as earlier research.[39] In a 2021 study, researchers evaluated asynchronous, fully-remote medication abortion care provided to 141 patients in the U.S. In that more limited sample, researchers found that 95% of patients had a complete abortion and zero patients reported any serious adverse events.[40] This comports with research from the United Kingdom spanning 52,142 patients demonstrating that no-test telehealth abortion is safe and effective.[41] In short, a significant body of research confirms that telehealth abortion care is as safe and effective as in-person care.[42]

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[39] *See* Anger, et al., 2024, *supra* note 35; Ralph, et al., *supra* note 35.

[40] Ushma D. Upadhyay, et al., *Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic*, JAMA Network Open (2021) ("Upadhyay, et al., JAMA").

[41] Aiken A, Lohr, et al., *Effectiveness, Safety And Acceptability Of No-Test Medical Abortion (Termination Of Pregnancy) Provided Via Telemedicine: A National Cohort Study,* 128 BJOG 1464 (2021); The World Health Organization has also determined that medication abortion need not be dispensed in person for it to be safe and effective. *See, e.g.,* World Health Organization, *Abortion Care Guideline*, *supra* note 9.

[42] *See* Leonardo Cely-Andrade, et al., *Telemedicine For The Provision Of Medication Abortion To Pregnant People At Up To Twelve Weeks Of Pregnancy: A Systematic Literature Review And Meta-Analysis* 21 Reprod. Health 136 (2024) https://doi.org/10.1186/s12978-024-01864-4 (meta-analysis of 21 articles published between 2011 and 2022,

Moreover, contrary to the arguments of *amici* in support of Defendants-Appellants, Heartbeat International and Advancing American Freedom, et al., an overwhelming body of research demonstrates that medication abortion itself is safe and effective.[43] Those *amici* misrepresent the studies upon which they purport to rely. For example, they offer a study by Niinimaki, et al., which they argue demonstrates that medication abortion causes adverse events. Heartbeat Int'l Br. at 8; Advancing American Freedom Br. at 20. However, that study classified any patient consultation regarding excess bleeding as a "hemorrhage" or an "adverse event," even when it did not justify treatment, leading to overestimates of "adverse events."[44] They also cite a study by Ushma Upadhyay, et al., which found that in

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concluding there are no significant differences in safety, effectiveness, or patient satisfaction when comparing telehealth to in-person abortion care).

[43] *See, e.g.* Amy S. Walker, et al., *Are Abortion Pills Safe? Here's the Evidence*. N.Y. Times, April 1, 2023 (updated February 2024), https://www.nytimes.com/interactive/2023/04/01/health/abortion-pill-safety.html. (referencing more than 100 scientific studies concluding that medication is a safe method for terminating a pregnancy).

[44] Maarit Niinimaki, et al., *Immediate Complications After Medical Compared With Surgical Termination Of Pregnancy*, 114 Obstetrics & Gynecology 795 (2009). This is particularly problematic because the medication is itself intended to cause significant bleeding.

some instances additional treatments were needed to complete a medication abortion.[45] *See* Heartbeat Intl. Br. at 7–8. But that further treatments are sometimes required is not a reflection of the medication's ***safety*** as *amici* suggest.[46]

Advancing American Freedom, et al., also rely on clinical trials from the 1980s—long before the current dosing protocols were established—to suggest mifepristone is unsafe. Adv. American Freedom Br. at 16–19. For example, in one of the cited studies, 11 women in Geneva were given 200 mg of mifepristone each day for three consecutive days and no misoprostol; unsurprisingly, only 9 of the 11 pregnancies were successfully terminated. *Id.* The current FDA-approved protocol is a single dose of 200 mg of mifepristone followed by a dose of misoprostol 24 to 48 hours later. These cited clinical trials are thus inapposite, at best.

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[45] Ushma D. Upadhyay, et al., *Incidence Of Emergency Department Visits And Complications After Abortion,* 125 Obstetrics & Gynecology 175 (2015).

[46] *See also* Ushma D. Upadhyay and Chris E. Adkins, *Deception By Obfuscation: Studnicki et al.'s Retracted Longitudinal Cohort Study Of Emergency Room Utilization Following Abortion,* 134 Contraception 110417 (2004).

2. Telehealth abortion care adequately facilitates patients' informed consent.

The District Court identified improved informed consent as another potential benefit of the Abortion Laws' in-person consultation requirements. However, research shows that not only is telehealth abortion care safe and effective, it also provides sufficient guardrails to ensure a patient's informed consent.

Informed consent refers to the process of explaining a medical procedure and associated risks to the patient and having the patient agree to undergo a procedure.[47] The American Medical Association Model Code of Ethics outlines the following steps providers should take to ensure a patient's informed consent:

1) Assess the patient's understanding of the relevant medical information and the implications of treatment alternatives and their ability to make an independent, voluntary decision;

2) Provide relevant information with care, in keeping with the patient's preferences for receiving medical information, including where

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[47] American Medical Association, *Code of Medical Ethics, Opinion 2.1.1: Informed Consent,* https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent (last accessed Oct. 11, 2024).

that information concerns the burdens, risks, and expected benefits of all options; and

3) Document the informed consent conversation and the patient's decision in the patient's medical record.[48]

Telehealth informed consent procedures meet all three of these standards.[49] As described above, the telehealth process screens eligible patients according to a "no-test" protocol. Providers then contact patients to discuss their screening form answers and ensure the patient understands the risks associated with medication abortions. Patients then provide their consent online. The FDA's REMS program further requires that all patients sign the FDA's Patient Agreement Form and receive a Mifepristone Patient Medication Guide, both of which describe how to take the medications, side effects, and the risks and warning signs of a potential adverse event.[50]

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[48] *Id.*

[49] Shelly Kaller, et al., *Pre-Abortion Informed Consent Through Telemedicine vs. in Person: Differences in Patient Demographics and Visit Satisfaction,* 31 Women's Health Issues 227, 228 (2021), https://www.sciencedirect.com/science/article/abs/pii/S1049386721000116.

[50] FDA Patient Agreement Form, *supra* note 26; FDA Medication Guide, *supra* note 29.

Telehealth offers many opportunities for patients and providers to build trust and rapport, despite the lack of in-person communication. Telehealth patients can select between providers who offer care synchronously or asynchronously, and can also select to receive care over the phone, via secure messaging, or face-to-face if needed or preferred.[51] The availability of multiple methods for communicating is likely helpful to individuals in digesting and understanding information.[52]

To the extent patient satisfaction reflects patient comfort and informed consent to the procedure, research shows that patients experience a high level of trust with telehealth abortion care. In one study, researchers surveyed the experiences of 1,600 patients who had a telehealth abortion between 2021 to 2022. The study found that most

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[51] Amy Tressan, et al., *Telemedicine Abortion in Primary Care: An Exploration of Patient Experiences,* 22 Annals of Family Medicine 19 (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11233084/.

[52] Emily M. Godfrey, et al., *Patient Perspectives Regarding Clinician Communication During Telemedicine Compared With In-Clinic Abortion*, 141 Obstetrics & Gynecology 1139 (2023), https://doi.org/10.1097/AOG.0000000000005192.

patients trusted the provider (98%), felt telehealth was the right decision (96%), and felt cared for (92%).[53]

Another study, published in 2023, reported similar results. The study involved qualitative interviews of 30 abortion patients—20 of whom received telehealth care and 10 who received in-person care from a facility in Washington State.[54] The telemedicine patients reported "high-quality patient-clinician communication."[55]

Finally, while *amicus curiae* Heartbeat International suggest that telehealth care renders it more difficult to ascertain whether a patient's consent is truly voluntary and not the product of coercion or outside influence, they offer no studies to support that argument.[56] Indeed, one study focused on this question concluded that a patient is no more likely to disclose coercion during an in-person consultation than they would

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[53] Leah R. Koenig, et al., *Patient Acceptability of Telehealth Medication Abortion Care in the United States, 2021–2022: A Cohort Study*, 114 American Journal of Public Health 241, Table 2 (2024) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10862199; Tressan, et al., *supra* note 51.

[54] Godfrey, et al., *supra* note 52.

[55] *Id.*

[56] Heartbeat Int'l Br. at 12.

remotely.[57] The study explained that the privacy and numerous methods of communication available via telehealth may actually better facilitate patients' disclosure of coercion.[58]

The research thus indicates that the benefits of telehealth care do not come at the expense of a patient's ability to provide informed consent for medication abortion.[59]

3. Telehealth offers patients high quality of care and several benefits over in-person abortion care.

Research shows that telehealth abortions offer patients significant advantages over in-person care.[60] In one survey, patients most commonly cited privacy (76%), timeliness (74%), and the ability to avoid

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[57] Elizabeth C. Romanis, et al., *Safeguarding and Teleconsultation For Abortion*, 298 The Lancet 555, 556 (2021), https://www.thelancet.com/journals/lancet/article/PIIS01406736(21)01062X/fulltext#:~:text=Most%20objections%20to%20telemedical%20abortion%20by%20politicians%20and,home%20administration%20of%20the%20drugs%20themselves%20are%20unfounded.

[58] *Id.*

[59] Heartbeat International claims that without in-person counseling, patients are at increased risk for regret and psychological sequalae. Heartbeat Int'l Br. at 8. But there is zero evidence to suggest that mental health outcomes would be different between people who have a telehealth versus in-person abortion, and Heartbeat International does not offer any.

[60] Koenig, et al., *supra* note 53; Tressan et al., *supra* note 51.

traveling out of the home (71%) among the top benefits of telehealth abortion.[61]

Cost is a significant concern for many patients. In most states, including North Carolina, public insurance, *e.g.* Medicaid and similar state-run programs, do not cover abortion care.[62] Accordingly, many patients must pay out of pocket for the procedure. Online abortion providers can charge less than in-clinic providers by avoiding rent and other costs associated with maintaining a brick-and-mortar location.[63] As a result, purely virtual clinics offer telehealth abortion care for an average of $150, versus the $600 average cost for in-person medication abortion care in North Carolina.[64]

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[61] Koenig, et al., *supra* note 53.

[62] Alina Salganicoff, et al., *Coverage for Abortion Services in Medicaid, Marketplace Plans and Private Plans* (KFF, 2019), https://www.kff.org/womens-health-policy/issue-brief/coverage-for-abortion-services-in-medicaid-marketplace-plans-and-private-plans/.

[63] Baker, *supra* note 14 at 495; *see also Appointments and Cost* (Carafem, 2024), https://carafem.org/cost/; Mark, et al., *supra* note 27 ; Ushma D. Upadhyay, et al., *Pricing Of Medication Abortion In The United States, 2021-2023*, Perspectives on Sexual and Reproductive Health (2024), https://onlinelibrary.wiley.com/doi/full/10.1111/psrh.12280 ("Upadhyay et al., *Pricing*").

[64] Upadhyay et al., *Pricing*, *supra* note 63 at Table 2.

Studies show that privacy may be better addressed through telehealth care. For example, in the earlier described survey of 1,600 telehealth abortion patients, one study respondent explained:[65]

> I felt more comfortable and less anxious about the whole process from being able to be home. I really appreciate having the opportunity to be in the comfort of my own home for the abortion and with my spouse for the entire duration and not in a cold room with strangers to have an uncomfortable procedure.

In another study, researchers interviewed 14 patients who obtained telehealth medication abortions. One respondent explained: [66]

> I was actually really sick during that pregnancy. I was vomiting the whole time up until the end of the abortion. So that was definitely a plus of not having to leave the house and be able to be in the comfort of my home and have the visits there.

Another important aspect of telehealth is the ability to close the distance and shorten the time to care, making abortion more accessible. Time, travel, the need to potentially arrange for time off from work or for childcare, and the costs related to these factors, are frequently cited

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[65] Koenig, et al., *supra* note 53 at 243.

[66] Tressan, et al., *supra* note 51 at Table 1.

as obstacles to obtaining in-person abortion care. In the same study, one patient explained: [67]

> I have kids, so honestly, everywhere I will be going, I will be going with them, because I have no one to stay with them… And also the transport fare. I don't drive, so I have to transport myself to the hospital. Then the stress of looking after the kids, while I, at the same time, see the doctor, and all the examination processes. So [telemedicine] was quite convenient for me.

In North Carolina, the average distance to the closest in-person abortion care facility is 29 miles but the range is 6 to 127 miles.[68] Traveling up to 127 miles each way for an in-person consultation and then again for the procedure can pose a significant barrier to many.[69] Moreover, clinics are often booked weeks out for in-person visits and

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[67] *Id.* Fifty-five percent of people seeking abortion already have children. Rachel K. Jones, *Medicaid's Role In Alleviating Some Of The Financial Burden Of Abortion: Findings From The 2021-2022 Abortion Patient Study*, Perspectives on Sexual and Reproductive Health (2024), https://onlinelibrary.wiley.com/doi/10.1111/psrh.12250.

[68] Caitlin Myers, *Myers Abortion Facility Database* (October 9, 2024), https://doi.org/10.17605/OSF.IO/8DG7R.

[69] Jill Barr-Walker, et al., *Experiences of Women Who Travel For Abortion: A Mixed Methods Systematic Review*. 14 PloS one, e0209991 (2019); Katrina Kimport, et al., *Exploring The Emotional Costs Of Abortion Travel In The United States Due To Legal Restriction*, 120 Contraception 109956 (2023); Ortal Wasser, et al.*, Experiences Of Delay-Causing Obstacles And Mental Health At The Time Of Abortion Seeking,* 6 Contraception: X 100105 (2024).

timing is often a crucial consideration because abortions are not available in North Carolina after 12 weeks.

In the CHAT Study, patients avoided an average of 1 hour and 25 minutes of round-trip public transit time by opting for telehealth.[70] Among a subsample of 1,586 CHAT Study patients surveyed, 43% reported that telehealth made it possible for them to obtain timely care. Telehealth was most likely to make it possible to have a timely abortion for people who are most disadvantaged: patients under age 25, rural patients, those experiencing food insecurity, and those who would otherwise need to travel over 100 miles to their closest abortion facility.[71]

B. Extensive research demonstrates that mandatory transvaginal ultrasounds, and Rh-blood testing do not improve patient health and safety outcomes for abortion care.

Research shows that North Carolina's requiring of universal transvaginal ultrasounds and Rh-blood testing do not improve the safety or effectiveness of medication abortions. These requirements—

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[70] Leah R. Koenig, et al., *The Role of Telehealth in Promoting Equitable Abortion Access in the United States: Spatial Analysis*, 9 JMIR Public Health Surveillance (2023), https://publichealth.jmir.org/2023/1/e45671.

[71] *Id.*

contrary to the District Court's suggestion—also do not contribute to a patient's ability to provide informed consent.

1. Telehealth practitioners can verify pregnancy and its duration and identify risks of ectopic pregnancy without requiring that all patients be subject to a transvaginal ultrasound.

Typically, a clinician has three key goals when evaluating a patient prior to a medication abortion: (1) confirm the pregnancy is within the gestational limit for effective and safe treatment; (2) establish that the patient has no other contraindications to medication abortion; and (3) identify any potential ectopic pregnancy.[72] North Carolina's requirement that every person receive a transvaginal ultrasound prior to obtaining a medication abortion is unnecessary for meeting these clinical goals.[73] A transvaginal ultrasound involves the insertion of a wand-like instrument called a transducer into a person's vagina where it releases sound waves that bounce off the various structures inside the pelvis to produce an image of the pelvic region.[74]

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[72] Raymond, et al., *supra* note 18, at 363.

[73] *See* N.C. Gen. Stat. § 90-21.83A(b)(2)(b).

[74] Mayo Clinic, *Transvaginal Ultrasound* (2024), https://www.mayoclinic.org/diseasesconditions/pcos/multimedia/transvaginal-ultrasound/img-20007770.

Experts suggest that a transvaginal ultrasound can be triggering, especially for trauma survivors.[75] Research shows that all three of the clinical evaluation goals for medication abortion can be achieved without requiring universal transvaginal ultrasounds.

First, to confirm pregnancy, a patient can take a high-sensitivity urine pregnancy test as part of a telehealth consultation.[76] These tests are highly accurate and if results are unclear, a patient can take a second test. Providers can then assess pregnancy duration based on

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[75] Jessica N. Coleman, et al., *Psychological Distress And Pain Related To Gynecologic Exams Among Female Survivors Of Sexual And Physical Violence: A Systematic Review*, 37 J. of Traumatic Stress 217 (2024), https://onlinelibrary.wiley.com/doi/abs/10.1002/jts.23006; Monika Krolak, et al., *Prevalence Of Medically Induced Psychological Trauma And Its Influence On Women's Health*, 161 Int'l J. of Gynecology & Obstetrics 568 (2023), https://obgyn.onlinelibrary.wiley.com/doi/full/10.1002/ijgo.14691; Nina M. Carroll and Amy Banks, *Health Care For Female Trauma Survivors (With Posttraumatic Stress Disorder Or Similarly Severe Symptoms* (UpToDate, 2024), (last accessed Oct. 11, 2024), https://www.uptodate.com/contents/health-care-for-female-trauma-survivors-with-posttraumatic-stress-disorder-or-similarly-severe-symptoms/print.

[76] Raymond, et al., *supra* note 18 at 363; Carrie N. Baker, *How Telemedicine Startups are Revolutionizing Abortion Health Care in the U.S.*, Ms. Magazine (Nov. 16, 2020), https://msmagazine.com/2020/11/16/just-the-pill-choix-carafem-honeybee-health-how-telemedicine-startups-are-revolutionizing-abortion-health-care-in-the-u-s/.

patients' answers to a few basic questions including the date of their last menstrual period.[77] Assuming the accuracy of ultrasound-based duration determinations, one study published in 2022 demonstrated that patients' self-reported last menstrual period date as well as their answers to associated questions—for example, when they think they got pregnant, or when their first positive pregnancy test was—accurately

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[77] Hillary Bracken, et al., *Alternatives to Routine Ultrasound For Eligibility Assessment Prior To Early Termination Of Pregnancy With Mifepristone–Misoprostol*. 118 BJOG 17 (2011), https://obgyn.onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2010.02753.x; Lauren J. Ralph, et al., *Accuracy Of Self-Assessment Of Gestational Duration Among People Seeking Abortion*, 226 Am. J. of Obstetrics & Gynecology 710 (2022), https://www.ajog.org/article/S0002-9378(21)02683-1/fulltext; Charlotte Ellertson, et al., *Accuracy Of Assessment Of Pregnancy Duration By Women Seeking Early Abortions*, 355 The Lancet 9207 (2000), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(99)10170-3/abstract. *Amicus curiae* Heartbeat International point to a study that reports that half of all women could not accurately recall the date. Heartbeat Int'l Br. at 5. While the study they refer to found that only 56% of women accurately recalled the date of their last menstrual period, 74% of women were within 1 day and 84% were within 3 days. Ganesa Wegienka & Donna D. Baird, *A Comparison Of Recalled Date Of Last Menstrual Period With Prospectively Recorded Dates*, 14 J. of Women's Health 248 (2005). In the most commonly used telehealth abortion protocol, if a potential patient cannot recall the date of their last menstrual period within a week, they would not qualify for a telehealth abortion and would be referred out for an ultrasound or in-person abortion care.

screened 96% of participants as eligible based on pregnancy duration.[78] Moreover, an exact pregnancy duration is not necessary, so long as the provider can assess that the pregnancy is ten or fewer weeks along. Should these non-invasive efforts prove inconclusive, individual patients who need additional diagnostic testing can be referred for an ultrasound or in-person abortion care.

Because the research shows that an assessment based on the patient-reported date of last menstrual period and other related questions can very accurately identify pregnancy duration of over ten weeks, there is no reason to universally require transvaginal ultrasounds for the purpose of determining pregnancy duration. Because these other methods are highly accurate, contrary to the District Court's suggestion, a patient also need not undergo an ultrasound in order to have "required gestational age information obtained through a reliable method before she makes a decision" as to consent.[79]

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[78] Ralph, et al., *supra* note 77 at Table 4.

[79] *Bryant v. Stein*, 2024 WL 1886907, at *13.

Requiring universal transvaginal ultrasounds is also not necessary for identifying ectopic pregnancies. Instead, during telehealth consultations, providers ask a series of questions to determine whether the patient may be at high risk for an ectopic pregnancy.[80] Those designated as high risk can then be referred for in-person care and ultrasounds and other diagnostic tests as needed.[81] Perhaps most importantly, if a pregnancy is ectopic, a patient will not experience bleeding from the medication, but the medication itself does not increase any health risks.[82] In fact, to the extent telehealth allows more timely abortion care, it may accelerate the detection and treatment of ectopic pregnancies when a patient does not have bleeding after taking abortion medications.[83]

In sum, universally requiring transvaginal ultrasounds is an unnecessarily invasive and needlessly costly method for clinical evaluation prior to medication abortion. There are sufficient

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[80] Raymond, et al., *supra* note 18 at 2.

[81] *Id*.

[82] Raymond, et al., *supra* note 18 at 361.

[83] Antonia Biggs, et al., *Experiences of Ectopic Pregnancy Among People Seeking Telehealth Abortion Care*, 134 Contraception 110405 (2024), https://www.sciencedirect.com/science/article/pii/S0010782424000581.

alternatives that can achieve similar results in terms of confirming a pregnancy and its duration and location. As shown by the CHAT Study, and other similar studies regarding telehealth discussed above, forgoing transvaginal ultrasounds for patients who qualify for a no-test telehealth abortion has no overall impact on the safety and effectiveness of the medication abortion procedure.[84]

2. Research demonstrates that Rh-blood testing is not necessary for first-trimester abortions.

North Carolina's Abortion Laws require an Rh-blood type test[85] and the provision of "[i]nformation about Rh incompatibility" as part of the informed consent process prior to a medication abortion.[86] However, research shows that neither requirement is medically necessary for first-trimester abortions.

Rh (or Rhesus) factor is a protein that can be found on the surface of red blood cells.[87] People often refer to this in conjunction with their

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[84] Upadhyay et al., Nature Medicine, *supra* note 17 at 1195, Table 2.

[85] N.C. Gen. Stat. § 90-21.83B(a)(2).

[86] N.C. Gen. Stat. § 90-21.83A(b)(2)(g).

[87] ACOG, *The Rh Factor: How It Can Affect Your Pregnancy,* https://www.acog.org/womens-health/faqs/the-rh-factor-how-it-can-affect-your-pregnancy (last accessed Oct. 10, 2024).

blood type, for example "A positive" or "O negative" with positive or negative referring to the presence or absence of Rh factor. Approximately only 15% of the U.S. population has Rh-negative blood.[88] When an individual with Rh-negative blood carries a fetus with Rh-positive blood to term, and if the two blood types mix, Rh incompatibility or "sensitization" may occur, meaning the Rh-negative pregnant individual may produce Rh antibodies in response to the Rh-positive fetal blood cells.[89] While there may not be impacts on the instant pregnancy, this "sensitization" can cause significant complications in future pregnancies carried to term whereby the maternal antibodies may attack the fetal blood cells of a future Rh-positive fetus.[90] Administering Rh immunoglobulin can stop the pregnant individual's body from producing Rh antibodies and prevent these potential subsequent complications.[91]

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[88] Sarah Horvath, et al., *Society of Family Planning Committee Consensus On Rh Testing In Early Pregnancy*, 114 Contraception 1, 2 (2022) ("Horvath, et al., *Society of Family Planning*").

[89] ACOG, *The Rh Factor, supra* note 87; Horvath, et al., *Society of Family Planning, supra* note 88.

[90] ACOG, *The Rh Factor, supra* note 87.

[91] *Id.*

The obstetrician gynecologist community agrees that Rh immunoglobulin yields significant medical benefits if administered to those at risk in the ***third trimester*** or shortly after delivery—when there is sufficient fetal blood and sufficient opportunity for it to mix with maternal blood.[92] However, research no longer supports its use earlier in pregnancy.

Accordingly, many national and international guidelines, including the World Health Organization, the Society of Family Planning, and the Royal College of Obstetricians and Gynecologists no longer recommend Rh testing or immunoglobin administration prior to 12 weeks' gestation.[93] The National Abortion Federation's Clinical Policies Committee, and ACOG, similarly recommend forgoing Rh testing and immunoglobulin for induced abortions before 12 weeks.[94]

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[92] Horvath, et al., *Society of Family Planning, supra* note 88.

[93] Sarah Horvath, et al*., Economic Analysis Of Foregoing Rh Immunoglobulin For Bleeding In Pregnancy <12 Weeks Gestation*, 139 Contraception 110530, 2 (2024) ("Horvath, et al., *Economic Analysis*").

[94] Horvath, et al., *Society of Family Planning, supra* note 88; ACOG, *Clinical Practice Update Rh D Immune Globulin Administration After Abortion or Pregnancy Loss at Less Than 12 Weeks of Gestation* (Sep. 10, 2024), https://journals.lww.com/greenjournal/fulltext/9900/rh_d_immune_globulin_administration_after_abortion.1145.aspx; *see also* Michelle Chan, et

Historically, Rh testing and Rh immunoglobulin administration was also recommended during the early stages of pregnancy, but the research supporting that recommendation has since been found unreliable.[95] Those older studies, experts explain, only evaluated the occurrence of fetal-maternal hemorrhage during early pregnancy, as opposed to whether sensitization in fact followed, or whether there was any impact on future pregnancy outcomes.[96] These older studies were additionally problematic because they were based on "outdated methods

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al., *Rhesus Isoimmunisation In Unsensitised Rhd-Negative Individuals Seeking Abortion At Less Than 12 Weeks' Gestation: A Systematic Review*, 48 BMJ Sexual & Reprod. Health 163 (2022), http://dx.doi.org/10.1136/bmjsrh-2021-201225; Sarah Horvath, et al., *Induced Abortion and the Risk of Rh Sensitization,* 330 JAMA 1167, 1167 (2023) ("Horvath, et al., *Induced Abortion*"); Stefanie J. Hollenbach, et al., *"Provoked" Feto-Maternal Hemorrhage May Represent Insensible Cell Exchange In Pregnancies From 6 To 22 Weeks Gestational Age,* 100 Contraception 142 (2019), http://dx.doi.org/10.1016/j.contraception.2019.03.051; Ellen R. Wiebe, *Can We Safely Stop Testing For Rh Status And Immunizing Rh-Negative Women Having Early Abortions? A Comparison Of Rh Alloimmunization In Canada And The Netherland*s, 1 Contraception: X 100001 (2019) http://dx.doi.org/doi.org/10.1016.j.conx.100001; Alice Mark, et al., *Foregoing Rh testing and anti-D immunoglobulin for women presenting for early abortion: a recommendation from the National Abortion Federation's Clinical Policies* Committee, 99 Contraception 265 (2019) ("Mark, et al., *Foregoing Rh Testing*").

[95] Horvath, et al., *Economic Analysis, supra* note 93.

[96] Mark, et al., *Foregoing Rh Testing*, *supra* note 94.

of abortion including sharp curettage" and relied on "unclear gestational age dating" and on blood tests with methodological limitations.[97]

In contrast, more recent research based on improved methods and data shows that Rh testing and administering Rh immunoglobulin during the first trimester offers ***no*** statistically significant health or safety benefits.[98] This is because during the first trimester there is limited fetal blood circulating, and little chance for sensitization to occur. A 2022 study of 506 participants undergoing medication or procedural abortion care during the first 12 weeks of pregnancy without receiving any Rh immunoglobin found that all but one participant had no indication of Rh sensitization.[99] In other words, the study found that

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[97] *Id.*

[98] Horvath, et al., *Induced Abortion*, *supra* note 94; Sarah Horvath, et al., *The Concentration Of Fetal Red Blood Cells In First-Trimester Pregnant Women Undergoing Uterine Aspiration Is Below The Calculated Threshold For Rh Sensitization,* 102 Contraception 1 (2020).

[99] Horvath, et al., *Induced Abortion*, *supra* note 94. The one participant who had fetal red blood cell counts above the published threshold for Rh sensitization after the abortion had above-threshold fetal red blood cell counts before the abortion. *Id.*

administering Rh immunoglobulin after a first-trimester abortion is not necessary because forgoing the treatment had no meaningful impact.[100]

In another study, 57 Rh-negative women who had Rh-positive partners were evaluated after having a spontaneous abortion, also known as a miscarriage. Follow-up examinations of all 57 participants reflected no sensitization, and none of the women experienced any Rh sensitization impacts during the 11 Rh-positive pregnancies that occurred after.[101] Based on these studies, the consensus among medical researchers is that "Rh testing or immunoglobulin following induced first-trimester abortion is unnecessary."[102] In light of the more recent research regarding Rh sensitization during the first trimester, there is also no medical reason for conditioning informed consent to access a first-trimester medication abortion upon the provision of "[i]nformation about Rh incompatibility."[103]

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[100] *Id.* at 1, 3.

[101] R.D. Visscher and H.C. Visscher, *Do Rh-Negative Women With An Early Spontaneous Abortion Need Rh Immune Prophylaxis?*, 113 Am. J. Obstetrics and Gynecology 158 (1972).

[102] Horvath, et al., *Society of Family Planning, supra* note 88.

[103] N.C. Gen. Stat. § 90-21.83A(b)(2)(g).

Not only are North Carolina's Rh-related requirements out of step with research, but they also impose significant costs. One economic study estimates the annual savings in the U.S. of forgoing universal Rh testing and Rh immunoglobulin administration before 12 weeks' gestation could be as much as $5.5 million for every 100,000 total pregnancies.[104]

In sum, the research does not support any improved health or safety benefit from requiring universal Rh-testing during the first trimester of pregnancy. Likewise, North Carolina's required provision of information about Rh sensitization to persons receiving first-trimester abortions is out of step with the evidence and thus does not enhance informed consent.

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[104] Horvath, et al., *Economic Analysis, supra* note 93. There is also a national shortage of Rh immunoglobulin and the unnecessary use of Rh immunoglobulin during the first trimester of pregnancy exacerbates this shortage. *See* FDA, *CBER-Regulated Products: Current Shortages*, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages (last visited Oct. 10, 2024); ACOG, *Rho(D) Immune Globulin Shortages*, https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2024/03/rhod-immune-globulin-shortages (last visited Oct. 10. 2024).

C. Certified healthcare providers may prescribe and dispense medication abortion safely and effectively.

North Carolina's Abortion Laws mandate that only physicians can prescribe abortion medications and that the physician be "in the same room" as the patient when the medication "is administered."[105] We discuss in Section A above, the research relating to in-person care versus telehealth. In this section we explain how the research shows there is also no reason for limiting the provision of medication abortion to physicians only.

In fact, research shows that a variety of qualified healthcare providers may prescribe and dispense abortion medications safely and effectively. These include nurse practitioners, physician assistants, and certified nurse midwives.[106] Indeed, the World Health Organization

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[105] N.C. Gen. Stat. § 90-21.83B(b).

[106] ACOG, *Advanced Practice Clinicians and Abortion Care Provision*, https://www.acog.org/advocacy/abortion-is-essential/trending-issues/issue-brief-advanced-practice-clinicians-and-abortion-care-provision (last accessed Oct. 10, 2024); American Public Health Association, *Policy No. 20112: Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants,* https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/28/16/00/provision-of-abortion-care-by-advanced-practice-nurses-and-physician-assistants (last accessed Oct. 10, 2024); Upadhyay, et al., JAMA, *supra* note 40 (study consisting of 141 patients who all received treatment by nurse practitioners, 95%

guidelines state that nurses, nurse midwives, and midwives can be qualified to administer medication abortion during the first trimester of pregnancy.[107]

Public health studies are consistent with the World Health Organization's recommendations. For example, three randomized controlled trials with a combined 3,200 participants and one cohort study with 596 participants found no statistical differences in effectiveness and safety of medication abortion when administered by a physician versus some other qualified healthcare provider.[108]

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of whom had complete abortions without intervention and 100% of whom experienced no serious adverse events); Kayla N. Rasmussen, et al., *Expanding Access To Medication Abortion Through Pharmacy Dispensing Of Mifepristone: Primary Care Perspectives From Illinois*, 104 Contraception 98, 98-103 (July 2021).

[107] World Health Organization, *Expanding Health Worker Roles for Safe Abortion In the First Trimester of Pregnancy*, https://iris.who.int/bitstream/10665/206191/1/WHO_RHR_16.02_eng.pdf (last accessed Oct. 10, 2024).

[108] Claudia Diaz Olavarrieta, et al., *Nurse Versus Physician-Provision of Early Medical Abortion in Mexico: A Randomized Controlled Non-Inferiority Trial.* 93 Bull. World Health Organ. 249, 249–258 (2015); Helena Kopp Kallner, et al., *The Efficacy, Safety and Acceptability of Medical Termination of Pregnancy Provided by Standard Care by Doctors or By Nurse-Midwives: A Randomized Controlled Equivalence Trial*, 122 BJOG 510, 510–517 (2015). (efficacy of 99% with certified nurse midwives versus 97.4% with physicians); IK Warriner, et al., *Can Midlevel Health-Care Providers Administer Early Medical Abortion As*

Consistent with these findings, and in reliance on much of this research, the FDA already determined in 2016 that any certified healthcare provider may prescribe and dispense abortion medications safely and effectively.[109] Accordingly, there is no demonstrated improvement to safety or effectiveness to justify North Carolina's requirement that only physicians may administer abortion medications.

CONCLUSION

For the foregoing reasons, the Court should affirm in part and reverse in part the district court's order and hold that all of North Carolina's Abortion Laws as applied to medication abortion are preempted.

Safely And Effectively As Doctors? A Randomised Controlled Equivalence Trial In Nepal. 377 The Lancet 1155, 1155–61 (2011); Mahesh Puri, et al., *The Role Of Auxiliary Nurse-Midwives And Community Health Volunteers In Expanding Access To Medical Abortion In Rural Nepal.* 22 Reprod. Health Matters 94, 94–103 (2015).

[109] Food and Drug Administration, *2016 Mifeprex Risk Evaluation and Mitigation Strategy (REMS),* https://www.fda.gov/media/164649/download?attachment (last visited October 10, 2024).

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Respectfully submitted,

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