

IN THE
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

**BRIEF OF *AMICUS CURIAE* HEARTBEAT INTERNATIONAL
IN SUPPORT OF DEFENDANTS-APPELLANTS AND REVERSAL**

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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No. 24-1576 Caption: Bryant v. Moore and Stein, Case Nos. 24-1576(L), 24-1600, 24-1617

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

Signature: /s/B. Tyler Brooks

Date: 8/19/2024

Counsel for: Amicus Heartbeat International

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INTEREST OF *AMICUS CURIAE*¹

Amicus Heartbeat International (“Heartbeat”) is an I.R.C. § 501(c)(3) non-profit, interdenominational Christian organization whose mission is to serve women and children through an effective network of life-affirming pregnancy help centers. Heartbeat serves approximately 3,250 pregnancy help centers, maternity homes, and nonprofit adoption agencies (collectively, “pregnancy help organizations”) in over 85 countries, including approximately 2,000 in the United States—making Heartbeat the world’s largest such affiliate network.

In addition, Heartbeat owns and operates the Abortion Pill Rescue Network (the “APRN”), which provides help for women who have started, but not yet completed, the chemical abortion process and wish to continue their pregnancies. The APRN answers more than 150 calls per month from women in the midst of a chemical abortion who quickly regretted their decision to abort and are seeking to carry their pregnancies to term. Statistics show that more than 5,000 lives have been saved through the

¹ *Amicus curiae* Heartbeat International certifies that no counsel for a party authored this brief in whole or in part and that no person or entity, other than *Amicus*, its members, or its counsel, has made a monetary contribution to its preparation or submission.

Abortion Pill Rescue Network. Given its regular interactions with women who have obtained chemical abortion drugs they later regret ingesting, Heartbeat is uniquely positioned to provide relevant factual background on the impact of having safeguards for chemical abortions.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

Heartbeat respectfully urges this Court to reverse the decision of the District Court to the extent it found that federal law preempts North Carolina's statutory regulation of chemical abortion and affirm to the extent the District Court left those regulations in place. Importantly, FDA regulation does not mark the beginning and the end of protections for an individual's health in a medical setting. To the contrary, not only do other federal agencies have a regulatory role, but the states also have a *primary role* in the regulation of medical care, including through the licensing of medical practitioners and facilities, consistent with federal law.

North Carolina's laws protecting the unborn from abortion are not preempted. Moreover, the chemical abortion regimen approved by the FDA presents great risks to pregnant women. Nothing about the FDA's approval of a drug demands that a state permit the procedures in which

the drug may be used. As shown below, that relevant procedure (chemical abortion) is dangerous to women and legitimately subject to being outlawed or otherwise regulated by a state, such as North Carolina.

ARGUMENT

I. THE FDA’S REGULATIONS LEAVE SIGNIFICANT GAPS IN PROTECTIONS FOR PREGNANT WOMEN.

The FDA’s current regulations enable women to obtain mifepristone without ever talking to a physician, having a physical exam, or undergoing an ultrasound to ensure gestational age and/or an ectopic pregnancy, and they further allow women to attempt to complete a chemical abortion at home despite the serious risks to maternal health posed by chemical abortion. Heartbeat’s experience with women who have gone through abortion confirms the dangers these procedures present.

A. Chemical Abortion Without Ultrasound Results In Serious Risks To Maternal Health.

The number of women receiving ultrasounds prior to beginning a chemical abortion has dropped precipitously, representing a significant risk to women’s health and safety. When Heartbeat began operating the Abortion Pill Rescue Network in 2018, nearly 100% of contacts (women

seeking help in the midst of an abortion) reported having received an ultrasound prior to commencing the abortion pill regimen. By 2023, that percentage had plummeted to an alarming 62%.

An ultrasound is crucial prior to a chemical abortion for at least three reasons: (1) to determine the viability of the pregnancy; (2) to determine the gestational age of the unborn child; and (3) to determine the placement of the pregnancy. Each of these pieces of information is key for safeguarding the woman's health and avoiding unnecessary risks posed by the abortion pill regimen.

First, in the absence of an ultrasound to confirm the viability of the pregnancy, the woman may be exposed unnecessarily to the risks of mifepristone and misoprostol. It is estimated that ten to twenty percent of known pregnancies end in miscarriage. *See* "Miscarriage," The Mayo Clinic, <https://www.mayoclinic.org/diseases-conditions/pregnancy-loss-miscarriage/symptoms-causes/syc-20354298?p=1> (last visited Aug. 18, 2024). If the ultrasound reveals that the baby does not have a heartbeat, the woman's body may already be in the midst of a natural miscarriage, and she can consider alternative options. Often, no medications are needed to complete the miscarriage.

Second, without an ultrasound to confirm the gestational age of the unborn child, there is an increased risk in attempting an abortion on a woman whose pregnancy is more advanced than she realizes. Practitioners with no access to ultrasound dating of a pregnancy must necessarily rely on the self-reported “Last Menstrual Period” (LMP) of the patient. But, as the American College of Obstetricians and Gynecologists (ACOG), the American Institute of Ultrasound in Medicine (AIUM), and the Society for Maternal-Fetal Medicine (SFMF) have all recognized, a reported LMP is *not the “best obstetric estimate”* of the gestational age of the unborn child. *See* Committee on Obstetric Practice, Am. Coll. of Obstetricians and Gynecologists, *Methods for Estimating the Due Date*, Committee Op. No. 700 (May 2017), *available at* <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date> (last visited Aug. 18, 2024). Studies show that about half of women inaccurately recall their LMP dates. *Id.* Even when women do accurately recall their LMP dates, though, estimating gestational age based on the first day of the LMP fails to account for irregularities in the woman’s cycle length or the changes in her ovulation patterns from month to month. *Id.* In one study, 40% of

study participants who received first trimester ultrasounds had the estimated gestational age of their unborn child adjusted by more than five days due to discrepancies between the reported LMP and the ultrasound findings.

In 2017, the American College of Obstetricians and Gynecologists (“ACOG”), released a committee opinion declaring that “ultrasound measurement of the embryo or fetus in the first trimester . . . is the most accurate method to establish or confirm gestational age” and that “[a] pregnancy without an ultrasound examination that confirms or revises the EDD before 22 0/7 weeks of gestational age should be considered suboptimally dated.” Committee on Obstetric Practice, Am. Coll. of Obstetricians and Gynecologists, *Management of Suboptimally Dated Pregnancies*, Committee Op. No. 688 (March 2017), <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/03/management-of-suboptimally-dated-pregnancies> (last visited Aug. 19, 2024).

Third, without an ultrasound to confirm the placement of the pregnancy, the practitioner will have no opportunity to diagnose a dangerous ectopic pregnancy or a previously undiagnosed adnexal mass.

Chemical abortion drugs do not resolve an ectopic pregnancy, but they produce symptoms similar to an ectopic pregnancy (pain and bleeding). Importantly, chemical abortions are contraindicated for women experiencing ectopic pregnancies. 2023 Mifeprex Label, at 1, <https://bit.ly/46Zix63>. From September 2000 to December 2022, the deaths of 32 women were reported as “adverse events” to the FDA, and until the FDA stopped requiring the reporting of non-fatal adverse events in 2016, documents show a total of 4,218 adverse events, including 1,049 hospitalizations (excluding deaths), 604 cases of blood loss requiring transfusions, 97 ectopic pregnancies, and 418 infections (75 of them “severe”). *See Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2022*, FDA, <https://www.fda.gov/media/164331/download> (last visited Aug. 18, 2024).

B. Chemical Abortion Without Follow Up Treatment Results In Serious Risks To Maternal Health.

Under the FDA’s current protocols, women are not required to have follow up treatment after receiving mifepristone and misoprostol, even though there is evidence showing a higher incident rate for chemical abortions than for other types of abortion. *See, e.g., Ushma Upadhyay et al., Incidence of emergency department visits and complications after*

abortion, OBSTETRICS & GYNECOLOGY 125, 175-83 (2015) (finding in study of 55,000 women receiving abortions that rate of complications requiring treatment after chemical abortions was 5.2%, four times higher than for first-trimester aspiration abortions); Maarit Niinimaki *et al.*, *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, OBSTETRICS & GYNECOLOGY 114, 795-804 (2009), available at https://journals.lww.com/greenjournal/Abstract/2009/10000/Immediate_Complications_After_Medical_Compared.14.aspx (last visited Aug. 18, 2014) (Finnish study finding chemical abortions have a “fourfold higher” incidence of adverse events compared to surgical abortions (nearly 20%) and a risk of hemorrhage that was nearly eight times higher, at 15.6%). State laws ensuring follow up care after a chemical abortion can help ensure timely detection and treatment of such complications.

C. Women Who Undergo Chemical Abortion Without Prior In-Person Counseling Are At An Increased Risk for Abortion Regret And Emotional Or Psychological Complications.

The FDA now permits chemical abortion drugs to be obtained remotely—drugs that need not even be prescribed by a licensed physician. This opens the door to more hastily made decisions and an increased chance for abortion regret and subsequent psychological and

emotional complications later. *Cf. Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 885 (1992) (“The idea that important decisions will be more informed and deliberate if they follow some period of reflection does not strike us as unreasonable.”) (permitting state requirement of 24-hour waiting period for abortion); *A Woman’s Choice-East Side Women’s Clinic v. Newman*, 671 N.E.2d 104, 111 (Ind. 1996) (“It is also possible that a woman may suffer long term emotional or psychological injury from making an ill-informed decision to abort a pregnancy.”).

Despite efforts to ignore it, abortion regret is a real phenomenon, documented in medical literature. *See, e.g.*, David C. Reardon, *The Embrace of the Proabortion Turnaway Study Wishful Thinking? Or Willful Deceptions?*, 85(3) LINACRE Q. 204, 208 (Aug. 2018) (“Widely publicized claims regarding the benefits of abortion for women have been discredited.”). One study reports that “only women who describe their abortion choice as wanted and consistent with their own values and preferences attributed any mental health benefits or a net gain in positive emotions to their abortions. All other groups attributed more negative emotions and a decline in mental health to their abortions.” David C. Reardon *et al.*, *The Effects of Abortion Decision Rightness and Decision Type on Women’s Satisfaction and Mental Health*, CUREUS J. OF

MED. SCI. 15(5): e38882 (May 2023), *available at* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10257365/> (last visited Aug. 18, 2024). The same study further found that “[s]ixty percent [of post-abortive women surveyed] reported they would have preferred to give birth if they had received more support from others or had more financial security.” *Id.*

In a recent study of post-abortive women who used chemical abortion pills, 34% “reported an adverse change in themselves, including depression, anxiety, substance abuse, and thoughts of suicide.” Eileen Smith Dallabrida, *Study Shows Long-Term Negative Effects of Medication Abortion*, Oct. 2022, at 8, *available at* <https://supportafterabortion.com/wp-content/uploads/2022/10/Study-Shows-Long-Term-Negative-Impact-of-Medication-Abortion.pdf> (last visited Aug. 18, 2024).

Another recent article concerning women’s experiences with chemical abortions confirms the importance of meaningful communication between a pregnant mother and her physician. Katherine Rafferty & Tessa Longbons, *Understanding Women’s Communication with Their Providers During Medication Abortion and Abortion Pill Reversal: An Exploratory Study*, 90(2) LINACRE Q. 172, 172 (May 2023)

(citation omitted). These researchers reported that “the majority of women in [the] study found that taking mifepristone was difficult,” which was consistent with other studies finding such a decision was filled with “tension.” *Id.* at 177.² The FDA’s protocols rush a woman through her decision, increasing the risk of postabortion regret and potentially mental or emotional health issues as a result. This danger is especially present when the woman decides to abort due to the feeling that she has no other option (such as adoption) or that she is not going to be supported in her decision to choose life by those around her, such as the child’s father or even her own parents.³

² As to the issue of “tele-health abortion,” which was also studied, the 13 authors observed that “limited communication with women’s healthcare providers can be problematic because it undermines the exchange of important health information and the provision of optimal ongoing reproductive health care, while also increasing the probability of preventable adverse events.” *Id.* (citation omitted).

³ Organizations like *amicus* Heartbeat strive to help pregnant women who choose to carry their pregnancies to term by meeting their practical, material, and spiritual needs so that they feel empowered to embrace motherhood. Often women facing an unexpected pregnancy are unaware of these resources and thus feel compelled to get an abortion, especially when facing pressure from others to abort (*e.g.*, the child’s father, a parent, or even an employer).

D. Women Who Undergo Chemical Abortion Are At An Increased Risk of Coerced Or Forced Abortions.

The Abortion Pill Rescue Network has received an increasing number of women requesting help after someone has coerced or forced them to begin a chemical abortion, as well as callers who came to learn that another person surreptitiously slipped them chemical abortion drugs. Removing the in-person dispensing requirement increases the likelihood that the drugs will fall into the hands of someone who could use them to induce an abortion in an unwilling participant. Without the safeguards of seeing the patient face-to-face, obtaining a pregnancy test and ultrasound confirmation of pregnancy, and assessing the patient's emotional state and whether her consent is free and informed, all that is necessary to obtain the chemical abortion pills is for a purported patient to self-attest that she is pregnant and claim a last menstrual period that falls within the FDA 10-week limit.

E. States Have Many Reasons To Protect The Dignity Of The Unborn.

Heartbeat believes that abortions generally have two victims: the child aborted as well as the mother. Biology itself defines the beginning of human life with the fertilization of an egg by a sperm. *See generally* Emile M. Scarpelli, *Personhood: A Biological Phenomenon*, 29 J. PERINAT. MED. 417 (2001). “[T]he fundamental approaches of biomedical and social (secular) practice must begin with the understanding that the subject before birth is a person . . . by successful fertilization of the egg.” *Id.* at 425; *see* Asim Kurjak & Ana Tripalo, *The Facts and Doubts about Beginning of the Human Life and Embryo*, 4(1) J. OF THE ASSOC. OF BASIC MED. SCI. 5 (Feb. 2004) (“The biological line of existence of each individual, without exception begins precisely when fertilization of the egg is successful.”); *see also* Maureen Condic, *A Scientific View of When Life Begins*, Charlotte Lozier Inst., June 11, 2014, *available at* <https://lozierinstitute.org/a-scientific-view-of-when-life-begins/> (“The conclusion that human life begins at sperm-egg fusion is uncontested, objective, based on the universally accepted scientific method of distinguishing different cell types from each other and on ample scientific evidence (thousands of independent, peer-reviewed publications).”) (last

visited Aug. 19, 2024). “To hide from this in silence or ignorance should be unacceptable to all.” Scarpelli, *supra*, at 425.

These scientific realities of when human life begins inform the consciences of religious and nonreligious Americans alike, and they underscore for millions of religious Americans the dignity of each individual person. Nor is the idea that all human life is deserving of respect and dignity necessarily based in religious faith. Reasoning from this proposition leads many to defend the rights of the unborn, as the unborn child is in fact a person with rights and not a disease to be treated. *See, e.g.*, Secular Pro-Life, Mission, *available at* <https://secularprolife.org/mission/> (“We envision a world in which . . . people of all faith traditions, political philosophies, socioeconomic statuses, sexualities, races, and age groups oppose abortion[.]”); *see also* Daniel Brudney, *Pregnancy is not a Disease: Conscientious Refusal and the Argument from Concepts*, 5 HASTINGS CTR. REPORT 43, 44 (2014) (describing argument that “medicine is about curing or preventing disease; pregnancy is not a disease; therefore, it is not a medical professional’s job, qua medical professional, to ‘cure’ . . . pregnancy”).

Our Nation’s Founders and subsequent generations also understood the dignity of each individual. It is, after all, a foundational principle of the United States that “all men are created equal[] [and] that they are endowed by their Creator with certain unalienable Rights[.]” Preamble, Decl. of Independence (1776). To be sure, this was an aspirational statement about principles and not intended as a description of the legal status of all persons at the time. But, despite national struggles over slavery and equal rights for all, “the assumption that ‘first come rights and then comes government’ pervades [the U.S. Constitution, . . . and it is] expressly recognized in the Ninth Amendment[.]” RANDY BARNETT, OUR REPUBLICAN CONSTITUTION 64 (2016). Undoubtedly, then, our law recognizes “the essence of human dignity inherent in all persons[.]” *Brown v. Plata*, 563 U.S. 493, 510 (2011). North Carolina has the authority under our Constitution and other federal laws to protect the human dignity of a mother and the unborn alike.

II. NORTH CAROLINA’S REGULATIONS ON CHEMICAL ABORTION PROTECT WOMEN’S HEALTH.

With the above medical and scientific realities in mind, it becomes clear why the District Court’s judgment granting a permanent injunction on key elements of North Carolina’s abortion regulations undermines the state’s efforts to protect maternal health.

Here, the District Court appropriately concluded that certain provisions of North Carolina law were *not* preempted. *Bryant v. Stein*, ___ F. Supp. 3d. ___, Case No. 1:23-CV-77, 2024 WL 1886907, *21 (M.D.N.C. Apr. 30, 2024). The Court was thus correct in upholding those provisions of state law that require an in-person 72-hour advance consultation prior to a chemical abortion in addition to an ultrasound and blood type testing. *See* N.C. Gen. Stat. §§ 90-21.83A & -21.83B. In so doing, the District Court observed that “[t]he state’s in-person advance consultation, ultrasound, in-person exam, and blood type determination requirements implicate general patient health and safety, informed consent to the termination of a pregnancy, and regulation of the medical profession” *Bryant*, 2024 WL 1886907, at *13.

While the provisions found not to be preempted are vitally important, the North Carolina General Assembly had ample justification to likewise provide further protections, and the injunction is therefore injurious to the same legitimate state interests as the provisions found to not be preempted. The state statutory requirements that mifepristone be provided in person, that there be a follow up appointment after provision of the drug, and that it only be prescribed by a licensed

physician, *see* N.C. Gen. Stat. § 14-44.1; *id.* §§ 90-21.93A, -21.93B & -90-21.93, serve critical objectives related to the practice of medicine and protection of women’s health within the state. As discussed above (*see supra* at I.B), there is a higher incident rate of adverse events for chemical abortions than for other types of abortion. *See, e.g.*, Upadhyay *et al., supra*, at 175-83. This includes a nearly ***eight-times higher risk of hemorrhage***, at 15.6%, for chemical abortions compared to other methods. Niinimaki *et al., supra*, at 795-804. In-person appointments and follow ups can help protect against these complications by providing timely ascertainment of complications and provision of appropriate medical care. *See* Rafferty & Longbons, *supra*, at 172. These provisions also help prevent mifepristone’s dissemination to a bad actor. (*See supra* at I.D).

The District Court further upheld the requirement that non-fatal adverse events be reported to state health authorities, stating “[t]here is nothing to indicate that Congress intended . . . to preempt states from collecting health and safety data acquired by medical professionals.” *Bryant*, 2024 WL 1886907, at 14; *see* N.C. Gen. Stat. § 90-21.93(d). Yet, it held that N.C. Gen. Stat. § 90-21.93(c), the state requirement to report

certain adverse events to the FDA, was preempted because the FDA has removed *its* requirement to receive reports of non-fatal adverse events. *Bryant*, 2024 WL 1886907, at *18. Requiring reporting of adverse events, fatal or not, to the FDA, though, does not “override” the FDA’s authority, as the District Court found. *Id.* Indeed, providers may voluntarily report adverse events on any number of drugs. There is a rational basis for North Carolina to mandate the reporting of adverse events which harm its citizens to the very federal agency that is tasked with preventing those exact types of harms. This aspect of state law simply creates a supplementary regulation of the practice of medicine in North Carolina that neither conflicts with, nor undermines, federal law, which should have been upheld.

In *Dobbs v. Jackson Women’s Health Org.*, 597 U.S. 215 (2022), the U.S. Supreme Court stated clearly: “The States may regulate abortion for legitimate reasons, and when such regulations are challenged under the Constitution, courts cannot ‘substitute their social and economic beliefs for the judgment of legislative bodies.’” *Id.* at 300 (citations omitted.) The Court further explained: “A law regulating abortion, like other health and welfare laws, is entitled to a ‘strong presumption of validity’ which

‘must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests.’” *Id.* at 301 (citations omitted). The Supreme Court even explicitly recognized that “legitimate state interests” include, among others, “respect for and preservation of prenatal life at all stages of development,” “the protection of maternal health and safety,” “the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession” and “the mitigation of fetal pain.” *Id.* (citations omitted).

Accordingly, while the District Court properly preserved from preemption certain elements of state law on chemical abortions, it nevertheless erred when it found preempted those laws “requiring physician-only prescribing, in-person prescribing, dispensing, and administering, scheduling of an in-person follow-up appointment, and non-fatal adverse event reporting to the FDA[.]” *Bryant*, 2024 WL 1886907, at *21.

CONCLUSION

For the foregoing reasons, this *Amicus* respectfully urges the Court to reverse the judgment of the District Court insofar as it holds that

federal law preempts North Carolina's General Statutes related to chemical abortion.

Respectfully submitted, this 19th day of August, 2024.

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**CERTIFICATE OF COMPLIANCE
WITH FED. R. APP. P. 29(a)(5) & 32(a)**

1. This brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B) and Fed. R. App. P. 29(a)(5) because this brief contains 3,592 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), as calculated by the word-counting function of Microsoft Office 2022.
2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally-spaced typeface using Microsoft Office Word in 14-point Century Schoolbook.

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