CASE NO. 23-2194

IN THE

United States Court of Appeals
FOR THE FOURTH CIRCUIT

GENBIOPRO, INC.,

Plaintiff-Appellant,

v.

KRISTINA RAYNES, in her official capacity as Prosecuting Attorney of Putnam County; PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA AT HUNTINGTON

BRIEF OF *AMICUS CURIAE* HEARTBEAT INTERNATIONAL IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

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

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

Pursuant to FRAP 26.1 and Local Rule 26.1,

Heartbeat International
(name of party/amicus)

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

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

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

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

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

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

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

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

Signature: /s/B. Tyler Brooks Date: 4/15/2024

Counsel for: Amicus Heartbeart 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 submits this brief with the consent of the parties and certifies that no counsel for a party authored this brief in whole or in part and 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 safety safeguards for mifepristone and misoprostol.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

Heartbeat respectfully urges this Court to affirm the decision of the District Court that FDA regulations do not preempt state regulations of abortion. 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 also the states have a *primary role* in the regulation of medical care, including through the licensing of medical practitioners and facilities and through setting standards of medical care.

As the District Court correctly held, West Virginia'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 by a state, such as West Virginia.

ARGUMENT

I. THE DISTRICT COURT CORRECTLY DETERMINED THAT FDA REGULATIONS RELATING TO MIFEPRISTONE DO NOT PREEMPT THE UCPA AND OTHER STATE LAW.

GenBioPro is a manufacturer of mifepristone, the first drug of a two-drug sequence administered to induce abortion. JA299. GenBioPro maintains that, through the enactment of the Food and Drug Administration Amendments Act of 2007 ("FDAAA") and FDA regulation of mifepristone, Congress and the FDA have effectively abrogated the ruling of the Supreme Court in *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 232 (2022), and thereby foreclosed state regulations like those at issue in this.

In *Dobbs*, however, 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). Indeed, the Supreme Court 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).

Following the Supreme Court's ruling in *Dobbs*, West Virginia—acting properly within its sphere of legitimate state regulation—enacted the Unborn Child Protection Act ("UCPA"). *See* W.Va. Code § 16-2R-1 *et seq.* ("UCPA"). Subject to limited exceptions (*e.g.*, nonviability, ectopic pregnancy and medical emergency), the UCPA makes it illegal to perform, induce or attempt to perform or induce an abortion. W.Va. Code

§§ 16-2R-3, 16-2R-3(a).[2] The UPCA provides penalties for violations, including the revocation of the licenses of medical professionals and criminal penalties upon "formerly licensed medical professional[s]" and "other persons" who knowingly and willfully perform or induce or attempt to perform or induce abortions. W.Va. Code §§ 16-2R-7, 16-2R-8(a), (b). The UCPA expressly includes abortions performed or induced via "medicine" or "drug." W.Va. Code § 16-2R-2.

Elsewhere in the West Virginia Code, providers are specifically prohibited from prescribing medication abortion drugs via telemedicine. W.Va. Code §§ 30-3-13a(g)(5), 30-1-26(b)(9). GenBioPro contends that those provisions, as well as certain pre-UCPA informed consent provisions imposing a waiting period and requiring counseling (W.Va. Code § 12-2I-2), which would automatically become effective if the UCPA is held unconstitutional (W.Va. Code § 16-2R-9) are all preempted.

Consistent with *Dobbs*, the District Court correctly rejected GenBioPro's conflict preemption arguments (JA266-273), concluding that the UCPA is a permissible "restriction on the incidence of abortion,

[2] The UCPA also limits it scope in the cases of sexual assault and incest. W.Va. Code §§ 16-2R-3(b) & (c).

rather than a state directive in direct conflict with the logistical REMS regulations." JA272-273.

The District Court likewise correctly rejected GenBioPro's field preemption arguments (which asserted that "Congress [has] occupied the field as to all drugs . . . subject both to a REMS and to additional elements to assure safe use"). JA 274. The District Court acknowledged, "[w]here Congress acts in a field traditionally occupied by the States, the presumption against preemption is strongest," and that matters of health, medicine and medical licensure are properly subject to State exercise of police power. Further, the District Court recognized "the [Food Drug and Cosmetic Act] does not preempt state action in the field of healthcare or medicine, absent a direct conflict." JA275. The District Court thus correctly held "Congress has not expressed an intent to occupy the field of drugs subject to a REMS in a manner which would preempt West Virginia's abortion restrictions."[3]

[3] The operative First Amended Complaint (JA298) withdrew GenBioPro's federal preemption challenge to West Virginia's telemedicine prohibitions. JA299-331.

II. 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 beginning the abortion pill regimen. By 2023, that percentage had plummeted to an alarming 62%.

An ultrasound is critical 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 critical 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 Apr. 15, 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 be referred to her physician for treatment. 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 Apr. 15, 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 Apr. 15, 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 Apr. 15, 2024).

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

Under the FDA's new 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 Apr. 15, 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%).

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 (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 Apr. 15, 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 Apr. 15, 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.[4] 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 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.[5]

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

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[4] As to the issue of "tele-heath 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).

[5] Organizations like *amicus* Heartbeat strive to help pregnant women who choose life through meeting their 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).

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 an LMP that falls within the FDA 10-week *limit.*

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

Heartbeat believes that all abortions 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-scientificview-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 Apr. 15, 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. Yet, 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). West Virginia has the authority under our Constitution to protect that human dignity for the unborn.

CONCLUSION

For the foregoing reasons, this *Amicus* respectfully urges the Court to affirm those portions of the District Court's ruling granting Defendants' motion to dismiss.

Respectfully submitted, this 15th day of April, 2024.

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CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 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 **3,410** 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.

Date: April 15, 2014

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CERTIFICATE OF SERVICE

I hereby certify that on April 15, 2024, I electronically filed the foregoing *amicus curiae* brief with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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