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

On Appeal from the U.S. District Court for Southern District of West Virginia at Huntington, Honorable Robert C. Chambers, U.S. District Court Judge, Civil Action No. 3:23-cv-00058

BRIEF OF *AMICI CURIAE* ADVANCING AMERICAN FREEDOM, INC.; AMERICAN VALUES; AMERICANS UNITED FOR LIFE; ANGLICANS FOR LIFE; BOB CARLSTROM, PRESIDENT, REBECCA WEBBER, CEO, ASSOCIATION FOR MATURE AMERICAN CITIZENS; CENTER FOR POLITICAL RENEWAL; CENTER FOR URBAN RENEWAL AND EDUCATION (CURE); CHRISTIAN LAW ASSOCIATION; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; EAGLE FORUM; FAMILY COUNCIL IN ARKANSAS; CHARLIE GEROW; GLOBAL LIBERTY ALLIANCE; INTERNATIONAL CONFERENCE OF EVANGELICAL CHAPLAIN ENDORSERS; TIM JONES, FMR. SPEAKER, MISSOURI HOUSE, CHAIRMAN, MISSOURI CENTER-RIGHT COALITION; LOUISIANA FAMILY FORUM; MEN AND WOMEN FOR A REPRESENTATIVE DEMOCRACY IN AMERICA, INC.; MEN FOR LIFE; NATIONAL CENTER FOR PUBLIC POLICY RESEARCH; NATIONAL RELIGIOUS BROADCASTERS; NEW JERSEY FAMILY FOUNDATION; NEW JERSEY FAMILY POLICY CENTER; PENNSYLVANIA EAGLE FORUM; PROJECT 21 BLACK LEADERSHIP NETWORK; PRO-LIFE WISCONSIN; RIO GRANDE FOUNDATION; SETTING THINGS RIGHT; 60 PLUS ASSOCIATION; STUDENTS FOR LIFE OF AMERICA; THE CHRISTIAN LAW ASSOCIATION; THE FAMILY FOUNDATION (VIRGINIA); THE JUSTICE FOUNDATION; TRADITION, FAMILY, PROPERTY, INC.; WOMEN FOR DEMOCRACY IN AMERICA, INC.; WISCONSIN FAMILY ACTION INSTITUTE; AND YOUNG AMERICA'S FOUNDATION IN SUPPORT OF APPELLEE AND AFFIRMANCE

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

The amici curiae Advancing American Freedom, Inc.; American Values; Americans United for Life; Anglicans for Life; Bob Carlstrom, President, Rebecca Webber, CEO, Association for Mature American Citizens; Center for Political Renewal; Center for Urban Renewal and Education (CURE); Christian Law Association; Christian Medical & Dental Associations; Eagle Forum; Family Council in Arkansas; Charlie Gerow; Global Liberty Alliance; International Conference of Evangelical Chaplain Endorsers; Tim Jones, Fmr. Speaker, Missouri House, Chairman, Missouri Center-Right Coalition; Louisiana Family Forum; Men and Women for a Representative Democracy in America, Inc.; Men for Life; National Center for Public Policy Research; National Religious Broadcasters; New Jersey Family Foundation; New Jersey Family Policy Center; Pennsylvania Eagle Forum; Project 21 Black Leadership Network; Pro-Life Wisconsin; Rio Grande Foundation; Setting Things Right; 60 Plus Association; Students for Life of America; The Christian Law Association; The Family Foundation (Virginia); The Justice Foundation; Tradition, Family, Property, Inc.; Women for Democracy in America, Inc.; Wisconsin Family Action Institute; and Young America's Foundation are nonprofit corporations. They do not issue stock, and are neither owned by nor are the owners of any other corporate entity, in part or in whole. They have no parent companies, subsidiaries, affiliates, or members that have issued shares or debt

securities to the public. The corporations are operated by volunteer boards of directors.

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STATEMENT OF INTEREST OF AMICI

Advancing American Freedom (AAF) is a nonprofit organization that promotes and defends policies that elevate traditional American values, including the uniquely American idea that all people are created equal and endowed by their Creator with unalienable rights to life, liberty, and the pursuit of happiness.[1] AAF "will continue to serve as a beacon for conservative ideas, a reminder to all branches of government of their responsibilities to the nation"[2] and believes that every person, including those still in the womb, has a fundamental right to life. When governments fail to accomplish their central purpose, the protection of fundamental rights, the freedom described in the Declaration of Independence and ensured in the Constitution is undermined.

Amici American Values; Americans United for Life; Anglicans for Life; Bob Carlstrom, President, Rebecca Webber, CEO, Association for Mature American Citizens; Center for Political Renewal; Center for Urban Renewal and Education (CURE); Christian Law Association; Christian Medical & Dental Associations; Eagle Forum; Family Council in Arkansas; Charlie Gerow; Global Liberty Alliance;

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[1] No counsel for a party authored this brief in whole or in part. No person other than Amicus Curiae and its counsel made any monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this amicus brief.

[2] Edwin J. Feulner, Jr, *Conservatives Stalk the House: The Story of the Republican Study Committee*, 212 (Green Hill Publishers, Inc. 1983).

International Conference of Evangelical Chaplain Endorsers; Tim Jones, Fmr. Speaker, Missouri House, Chairman, Missouri Center-Right Coalition; Louisiana Family Forum; Men and Women for a Representative Democracy in America, Inc.; Men for Life; National Center for Public Policy Research; National Religious Broadcasters; New Jersey Family Foundation; New Jersey Family Policy Center; Pennsylvania Eagle Forum; Project 21 Black Leadership Network; Pro-Life Wisconsin; Rio Grande Foundation; Setting Things Right; 60 Plus Association; Students for Life of America; The Family Foundation (Virginia); The Justice Foundation; Tradition, Family, Property, Inc.; Women for Democracy in America, Inc.; Wisconsin Family Action Institute; and Young America's Foundation believe that States have the authority to protect the right to life of the unborn where the federal government fails to ensure the protection of that right.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The fundamental purpose of government is to protect the rights of the people. As the Declaration of Independence explains, "Governments are instituted among Men" to "secure" the unalienable rights of the people "among [which] are Life, Liberty, and the pursuit of Happiness." The Declaration of Independence para. 2 (U.S. 1776). West Virginia's Unborn Child Protection Act (UCPA) seeks to protect the most fundamental rights of its most vulnerable people, a right of which the

federal government has authorized the destruction, contrary to its very reason for being.

Under Subpart H, the Food and Drug Administration (FDA) can approve drugs that "provide a meaningful therapeutic benefit to patients over existing treatments" for "serious or life-threatening illnesses." 21 C.F.R. § 314.500. The Food and Drug Administration Amendments Act of 2007 (FDAAA) required the FDA to reapprove drugs previously approved under the Subpart H approval process through the new Risk Evaluation and Mitigation Strategy (REMS) process. *See* 21 U.S.C. §§ 355-1(a), (g)(4)(B), (h). Mifepristone[3] producer GenBioPro argues that UCPA is preempted by the FDA's REMS for mifepristone which, as required under the FDAAA, consider availability as a factor in the REMS approval process.[4]

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[3] Mifepristone "terminates a pregnancy by blocking progesterone receptors in the uterus, a hormone necessary for the maintenance of a pregnancy." *The FDA and RU-486: Lowering the Standard for Women's Health*, House of Representatives Government Reform Committee; Subcommittee on Criminal Justice, Drug Policy, and Human Resources at 4 (Oct. 2006) [hereinafter *Congressional Report*], available at https://advancingamericanfreedom.com/mifepristone-resource-congressional-staff-report-the-fda-and-ru-486-lowering-the-standard-for-womens-health/.

[4] One potentially major consequence of GenBioPro's argument appears to be that States would be unable to engage in regulation of FDA-approved drugs like opioids that are nonetheless causing significant problems within their States. If FDA regulation of a drug preempts state regulation of that drug, States like West Virginia and others ravaged by opioid abuse may be limited in their ability to respond. The need for such regulation is starkly demonstrated by a West Virginia city's case against opioid manufacturers currently awaiting a West Virginia Supreme Court decision about state substantive law, Brendan Pierson, *4th Circuit Sends West Virginia City's Opioid Case to State's Top Court*, Reuters (Mar. 18, 2024, 2:39 PM) https://www.reuters.com/legal/litigation/4th-circuit-sends-west-virginia-citys-

The major questions doctrine provides a useful frame through which to understand GenBioPro's preemption argument in this case. Under the major questions doctrine, "administrative agencies must be able to point to clear congressional authorization when they claim the power to make decisions of vast economic and political significance." *West Virginia v. EPA*, 142 S. Ct. 2587, 2616 (2022) (Gorsuch, J., concurring). Here, GenBioPro claims that the FDA was granted significant regulatory authority to settle a major political debate despite a lack of any clear congressional statement to support that claim. If the FDA were granted and had exercised that power, that exercise would likely raise significant constitutional issues. Such an interpretation should be looked upon with skepticism.

Finally, abortion, and particularly chemical abortion, destroys the right to life of the unborn, and thus destroys that person's ability ever to exercise any of their other rights. Further, while abortion always poses a danger to the woman having the abortion, chemical abortion drugs are particularly dangerous. The UCPA protects both the rights of the unborn and the wellbeing of women by prohibiting abortions in most cases. Where the federal government, via the FDA, has authorized a drug that destroys the rights of Americans, States have an obligation to step in and protect

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opioid-case-states-top-court-2024-03-18/, and the state's settlement with CVS and Walmart for opioid distribution in the state. The Associated Press, *CVS, Walmart Reach $147.5M Opioid Settlement with West Virginia*, NBC News (Sept. 21, 2022, 7:34 AM) https://www.nbcnews.com/news/us-news/cvs-walmart-reach-1475m-opioid-settlement-west-virginia-rcna48691.

those rights. Just as northern States during the era of American slavery sought to protect the rights of escaped slaves through laws that prevented their removal, West Virginia here seeks to prevent the violation of the rights of the unborn. GenBioPro would thwart that effort and allow the continued destruction of unborn life for its commercial gain.

ARGUMENT

I. States Have the Authority and the Responsibility to Protect the Fundamental Rights of the People, Including Those of the Unborn.

A. The people delegate certain limited powers to government which is "instituted among men" to secure the rights of the governed.

American government, and all just government, depends on the fundamental idea, expressed by the Declaration of Independence, that "all humans are created in the image of God and therefore of inherent worth." *Obergefell v. Hodges*, 576 U.S. 644, 735 (2015) (Thomas, J., dissenting). Because of that inherent worth, the Founders understood that "all men are created equal, that they are endowed by their Creator with certain unalienable Rights, [and] that among these are Life, Liberty, and the pursuit of Happiness." The Declaration of Independence para. 2 (U.S. 1776). However, these rights, though always real, are not always secure.

The Founder's view of government "was rooted in a general skepticism regarding the fallibility of human nature." *See INS v. Chadha*, 462 U.S. 919, 949 (1983). In a state of anarchy, the rights of the people are real, but are subject to

violation by the strong. Under a government, the rights of the people are real but are subject to the whims of those exercising government power. According to Montesquieu, "constant experience shows us that every man invested with power is apt to abuse it, and to carry his authority as far as it will go."[5] In thousands of years of recorded human history, that nature has not changed.[6]

Thus, government is constituted to protect the rights of the people, rights which pre-exist government. As the Declaration explains, "Governments are instituted among Men" to secure the unalienable rights of the people, and "deriv[e] their just powers from the consent of the governed." The Declaration of Independence para. 2 (U.S. 1776). The Tenth Amendment expressly reserves the powers not granted to the federal government to the States and to the people. U.S. Const. amend X. The Constitution grants only limited powers to the federal government because the Founders knew that government, just as much as anarchy, can bring about the destruction of the rights of the people. One of those rights, a right the continuation of which is a necessary precondition for the exercise of all others, is the right to life.

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[5] Montesquieu, *Spirit of the Laws*, § 11.4 (Thomas Nugent trans. 1752) (1748).

[6] *See* Jefferson, *supra* note 3 at 130 ("Human nature is the same on every side of the Atlantic, and will be alike influenced by the same causes. The time to guard against corruption and tyranny is before they shall have gotten hold on us. It is better to keep the wolf out of the fold, than to trust to drawing his teeth and talons after he shall have entered.").

B. The right to life of the unborn is both fundamental to the freedom of the unborn person and is well established in Anglo-American law.

The right to life, and the recognition that the unborn possess that right, are deeply rooted in American and English law. As noted above, the Declaration of Independence lists the right to life as one of the fundamental inalienable rights governments exist to secure. For centuries, American and English law recognized that the right to life of the unborn deserved legal protection. For example, English treatises said that abortion was a crime, and "English cases dating all the way back to the 13th century corroborate the treatises' statements that abortion was a crime." *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228, 2249 (2022) (citing J. Dellapenna, *Dispelling the Myths of Abortion History* 126 and n. 16, 134-52, 188-94, and nn. 84-86 (2006); J. Keown, *Abortion, Doctors and the Law*, 3-12 (1988)). In America, according to the Supreme Court, "the historical record is similar." *Id*. at 2251.

Evidence from the colonies shows that abortion was a crime. *Id*. In one 1652 case, the court said that a man "Murtherously endeavoured to destroy or Murther the Child by him begotten in the womb." *Id*. at 2251 (internal quotation marks omitted) (quoting *Proprietary v. Mitchell*, 10 Md. Archives 80, 183 (1652) (W. Browne ed. 1891)). Further, "by the 19th century, courts frequently explained that the common law made abortion of a quick child a crime." *Id*. (citing *Smith v. Gaffard*, 31 Ala. 45, 51 (1857); *Smith v. State*, 33 Me. 48, 55 (1851); *State v. Cooper*, 22 N.J.L. 52, 52-

55 (1894); *Commonwealth v. Parker*, 50 Mass. 263, 264-68 (1845)). That description was consistent with the law of the States at the time, "the vast majority of [which] enacted statutes criminalizing abortion at all stages of pregnancy." *Id*. at 2252. "By 1868, the year when the Fourteenth Amendment was ratified, three-quarters of the States, 28 out of 37, had enacted statutes making abortion a crime even if it was performed before quickening." *Id*. at 2253 (footnote omitted). Of the other nine States, eight had criminalized abortion at all stages by 1910. *Id*. The territories were similarly restrictive. *Id*. "By the end of the 1950s . . . statutes in all but four States and the District of Columbia prohibited abortion 'however and whenever performed, unless done to save or preserve the life of the mother.'" *Id*. (quoting *Roe v. Wade*, 410 U.S. 113, 139 (1973)).

Throughout most of American history in most American jurisdictions, the law has recognized the inherent value of the unborn child. That is understandable. An abortion prevents all the joy and beauty of life for the aborted child, and not for him or her only, but for all the countless children and grandchildren of whom he or she may have been the father or mother, grandfather or grandmother. Any attempt to draw the line of life later than conception requires making arbitrary distinctions.[7] In

[7] While some abortion laws before the 19th century limited their application to after quickening, as the Court explains, this may well have been a practical limitation rather than a philosophical distinction. *Dobbs*, 142 S. Ct. at 2251-52. Today, medical technology allows doctors to find life very early on in the pregnancy.

passing the UCPA, West Virginia sought to fulfill the foundational responsibility of government, the protection of rights, in an area where the federal government has failed to do so. Federal statutes should not be interpreted to interfere with this fundamental exercise of state authority without a clear statement of intent to do so from Congress.

II. GenBioPro's Claim that the FDA Has Authority to Preempt, and has Preempted, State Law on the Issue of Chemical Abortion, Must be Rejected Because it Would Constitute the Delegation of a Power to Address an Issue of Profound Political Controversy Without a Clear Congressional Statement Delegating that Authority.

The Tenth Amendment embraces the principle of subsidiarity and reserves to the States and the people, "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the states." U.S. Const. amend. X. This system, federalism, protects the authority of the States from federal imposition except in areas in which the Constitution grants the federal government powers. Per Article VI, federal law is binding on the States, contrary state law notwithstanding. U.S. Const. art. VI, cl. 2. Caution is warranted when state laws are attacked as inconsistent with, and thus preempted by, federal law in areas that are traditionally left to the states.

The power to regulate medical practice is a traditional State power. *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc*., 471 U.S. 707, 715 (1985) (finding a "presumption that state and local regulation of matters related to health

and safety is not invalidated under the Supremacy Clause"). Where, "the field that Congress is said to have pre-empted has been traditionally occupied by the States," the Court starts with the assumption that traditional state powers "were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id*. (internal quotation marks omitted) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

Further, States have a legitimate interest in the safety of women and their preborn children. This interest is recognized by the Court today and has been for at least three decades. *See Dobbs*, 142 S. Ct. at 2284 ("[States'] legitimate interests include respect for and preservation of prenatal life at all stages of development [and] the protection of maternal health and safety.") (citation omitted); *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 846 (1992). There is no enumerated power to regulate healthcare in the Constitution. Congress does have the power "[t]o regulate commerce . . . among the several states." U.S. Const. art. I, § 8. Whatever the legitimacy of interpreting this grant of legislative power to include regulating drugs like mifepristone, it is clear that there is tension between the States' traditional authority to regulate medical intervention and Congress's power to regulate interstate commerce, a power which it has in part, rightly or wrongly, delegated to the FDA and other executive agencies.

The major questions doctrine provides a useful lens through which to consider whether a claimed interpretation of a federal statute is consistent with government authority. In *West Virginia v. EPA*, Justice Gorsuch in his concurrence found three situations in which an agency interpretation triggers the major questions doctrine, two of which are relevant here. 142 S. Ct. at 2620-21 (Gorsuch, J., concurring). First, there must be a clear statement "when an agency claims the power to resolve a matter of great 'political significance,' or end an 'earnest and profound debate across the country,'" *Id*. at 2620 (quoting *NFIB v. OSHA*, 142 S. Ct. at 665; *Gonzales v. Oregon*, 546 U.S. 243, 267 (2006)). Second, agencies may also need a clear statement from Congress "when an agency seeks to 'intrude into an area that is the particular domain of state law.'" *Id*. (quoting *Alabama Association of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021)). GenBioPro's interpretation of EMTALA in this case is clearly both related to an issue of great political significance and is intended to intrude into a particular domain of state law.

First, GenBioPro's interpretation is intended to preempt state law in an area of great political significance in the United States. The "Court has indicated that the [major questions] doctrine applies when an agency claims the power to resolve a matter of great 'political significance' or end an 'earnest and profound debate across the country.'" *Id*. at 2620 (internal quotation marks omitted) (quoting *NFIB v. OSHA*, 142 S. Ct. at 665). This is precisely what GenBioPro is asking the courts to do for it;

interpret FDAAA as settling the profound chemical abortion debate. Abortion is a matter of significant political controversy in the United States. As the majority noted in *Dobbs*, "Abortion presents a profound moral issue on which Americans hold sharply conflicting views." 142 S. Ct. at 2240.

Second, the guidance intrudes into an area that is the particular domain of state law. States have a legitimate interest in the safety of women and their preborn children. This interest is recognized by the Court today and has been for at least three decades. *See Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228, 2284 (2022) ("[States'] legitimate interests include respect for and preservation of prenatal life at all stages of development [and] the protection of maternal health and safety.") (citation omitted); *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 846 (1992). In *Dobbs* the Court held that rational basis scrutiny applies to state laws restricting abortion. *Dobbs*, 142 S. Ct. at 2283. It recognized that, "A law regulating abortion, like other health and welfare laws, is entitled to a 'strong presumption of validity.'" *Dobbs*, 142 S. Ct. at 2284 (quoting *Heller v. Doe*, 509 U.S. 312, 319 (1993)).

More broadly, regulation of the medical field is a traditional area over which States have authority. Because abortion law falls within the category of health and welfare regulation, it is within the domain of state regulation. Whatever the scope of the interstate commerce clause, it cannot swallow up areas of state authority. If it

did, there would have been no reason to enumerate the powers of the federal government (it could have been given a general grant of authority) and the Constitution would not have been ratified. As a practical matter, too, it is essential that States retain this power even where the FDA has engaged in regulation. States need the ability to protect their citizens not only from dangerous abortion drugs but also from drugs like opioids that are ravaging the populations of many States. If the FDA's regulation of a particular drug preempts States' regulation of that drug, they will be handicapped in their ability to protect those within their jurisdiction.

Because the FDAAA does not contain a provision explicitly granting authority to the FDA to preempt state law, courts should be skeptical of any claim that it does preempt state law in this area. That is particularly true given the fact that regulating the medical practice is within the realm of traditional state power and because the federal government's authority to regulate that area is only indirect. If Congress had granted authority to the FDA to preempt state abortion law, that delegation would be subject to constitutional challenge on several grounds. This Court should avoid raising those issues by requiring a clear statement before finding that Congress has granted such significant power over such a controversial issue to an agency staffed by unelected and unaccountable bureaucrats.

III. Mifepristone is a Dangerous Drug that is Deadly for the Unborn and Potentially Deadly or Very Harmful for the Woman Who Takes it, Thus Leading to the Destruction of the Rights of the Former, and the Effective Undermining of the Rights of the Latter.

Government exists to protect the fundamental rights of the people. Where the federal government fails to do so, it is the responsibility of the States to protect them. GenBioPro's interpretation of FDAAA would turn that statute into one reminiscent of the Fugitive Slave Act, forcing States to ignore the fundamental rights of those within their jurisdictions. West Virginia, after all, was born of the conviction that all people share fundamental human dignity. Abortion is always destructive to the rights of the unborn. As discussed above, States have an interest in protecting the rights of the unborn, as recognized by the Supreme Court. However, abortion, including chemical abortion, is a danger to the wellbeing of mothers who take the drugs as well.

The FDA approved mifepristone for use as an abortifacient under Subpart H. To be approved under Subpart H, a drug must provide a "meaningful therapeutic benefit over existing treatments." 21 CFR § 314.500. There was ample evidence prior to the FDA's approval of mifepristone in 2000 that chemical abortions provided no such benefit over the existing procedure, surgical abortions.

In 1981, human trials of mifepristone took place in Geneva, Switzerland after seventeen months of animal research. Congressional Report at 10. Even those initial human trials indicated the dangers of mifepristone when used as an abortifacient.

Those trials resulted in two unsuccessful abortions out of eleven attempts. Two additional women required further medical intervention including, in one case, emergency surgery and a blood transfusion. Congressional Report at 10. The next round of trials, conducted in several different countries, produced widely varied success rates from as low as fifty-four percent (54%) to as high as ninety percent (90%). Congressional Report at 10-11. That success rate increased to ninety-four percent (94%) in one trial when doctors in Sweden began to administer prostaglandin alongside mifepristone, though it remained significantly lower than the ninety-nine percent (99%) success rate of surgical abortion at the time.[8] *Id*.

After mifepristone was approved in France,[9] a committee of experts reviewed data on 30,000 women who had used mifepristone as an abortifacient and found numerous significant risks associated with use of the drug. Congressional Report at

[8] Success was defined as fetal death without the need for further medical intervention.

[9] A French manufacturer handed over the technologies and patent rights to Population Council. The plan for this donation was first recommended to president-elect Clinton by Ron Weddington (co-counsel with his wife Sarah in *Roe v Wade*) in a 1992 letter where he proposed expanding access to cheap chemical abortions "to eliminate the barely educated, unhealthy and poor segment of our country" since "26 million food stamp recipients is more than the economy can stand." Weddington JR. Letter to President-To-Be Clinton, Jan 6 1992. In: Rasco C, editor. OA/Box OA7455, File Folder: RU-486 [Internet]. Clinton Library; 1992. p. 54–8. Available from: https://clinton.presidentiallibraries.us/files/original/f8977047aefa0c1f90a24665cabf95bc.pdf

11-12. Further, the World Health Organization released a study in 1991 in which just under three percent (3%) of women with completed abortions and almost thirty percent (30%) of those with incomplete abortions "had to be given 'antibiotic therapy to prevent or cure suspected genitourinary infection' during the six-week follow-up period." Congressional Report at 12, n. 63.

Writing before mifepristone's approval, the FDA's medical reviewer found that chemical abortions were of limited value given the short time period during which they were available, the need for three visits to a medical facility during the process, the need for a follow-up visit to ensure that surgical intervention is not required, and because of specific problems with chemical abortion in comparison to surgical abortion. Congressional Report at 29-30. In particular, the reviewer noted the higher failure rates, greater frequency of symptoms including cramping, nausea, and vomiting, and increased blood loss associated with chemical as opposed to surgical abortions. Congressional Report at 29-30.

Further, the FDA Medical Officer's review found that for women with pregnancies up to seven weeks, the original gestational limit approved by the FDA, the failure rate was almost eight percent (8%), with the percentage increasing at longer gestational periods, up to twenty-three percent (23%) for pregnancies between eight and nine weeks. Congressional Report at 31.

By 2006, the dangers of chemical abortion had become even more evident than they were when the FDA approved the drugs for that use in 2000. Before the House Subcommittee on Criminal Justice, Durg Policy and Human Resources, Committee on Government Reform in May of 2006, Dr. Donna Harrison testified:

> In my experience as an ob-gyn, the volume of blood loss seen in the life-threatening cases is comparable to that observed in major surgical trauma cases like motor-vehicle accidents. This volume of blood loss is rarely seen in early surgical abortion without perforation of the uterus, and it is rarely seen in spontaneous abortion.[10]

Dr. Harrison added that no risk factors predicted such hemorrhage and that it was life threatening for women without access to immediate medical care. *Id*. Such dangers have been ignored by the FDA in its effort to push mifepristone over the past 23 years.

Information that has become available since the Congressional Report was published in 2006 is no more positive. Several studies have shown the medical risk associated with the use of chemical abortion. One study found that ten percent (10%) of women, after use of chemical abortion, require follow-up medical treatment for failed or incomplete abortion,[11] and twenty percent (20%) of women who use

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[10] *RU-486: Demonstrating a Low Standard for Women's Health?* Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform, 109th Cong. at 142 (May 17, 2006), available at https://advancingamericanfreedom.com/mifepristone-resource-congressional-hearing-ru-486-demonstrating-a-low-standard-for-womens-health/.

[11] Maarit Niinimaki et al., *Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study*, BMJ,

mifepristone to induce abortions will have an adverse event, including hemorrhaging and infections.[12] This rate of adverse events is four times greater than the adverse event rate of surgical abortion. *Id*.

In 2024, adverse events are widely underreported because the FDA only requires prescribers to report deaths, not other less-than-lethal adverse events associated with mifepristone. In 2000, the FDA approved mifepristone with certain safeguards and requirements to decrease the dangers mifepristone could pose to women, consistent with Subpart H. *See* 21 C.F.R. § 314.520. Although compliance with those requirements was insufficient to prevent adverse events, they were much more stringent than the requirements imposed today. Among those requirements in 2000, prescribers were obligated to report non-fatal but serious adverse events to the drug manufacturer.[13] However, beginning in 2016, prescribers need only report deaths associated with the drug, not other serious adverse events.[14]

April 20, 2011, at 4.

[12] Maarit Niinimaki et al., *Immediate complications after medical compared with surgical termination of pregnancy*, 114 Obstetrics & Gynecology 795 (2009).

[13] Food and Drug Administration, Approved Labeling Text for Mifeprex (Sept. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.

[14] Food and Drug Administration, Risk Evaluation and Mitigation Strategy (March 2016), https://www.fda.gov/media/164649/download. Food and Drug Administration, Risk Evaluation and Management Strategy (May 2021), https://www.fda.gov/media/164651/download.

The FDA's inexplicable slackening of adverse event reporting requirements forces researchers to look overseas for data on mifepristone's harm to women. Even recent experience with mifepristone bears out the fact that it continues to be more dangerous than surgical abortion, contrary to the requirements of Subpart H. As British researcher and medical doctor Calum Miller explains:

> During the COVID-19 pandemic, a small minority of countries permitted abortion providers to send abortion pills—usually mifepristone and misoprostol—by post to women after a remote consultation by video or telephone (hereafter, "telemedicine" refers to either)—that is, without any in-person contact throughout the process. This was an unprecedented move since full telemedicine had not been studied in legal, experimental conditions prior to this… In the United Kingdom… ambulance calls and responses relating to medical abortion also increased dramatically between 2018 and 2021, following the introduction of [chemical abortion] at home and then full telemedicine.[15]

Further, British researchers:

> [U]sing [their] rights under the Freedom of Information Act . . . asked each of the ten [National Health Service] Ambulance Trusts in England to provide data related to the number of emergency ambulance responses made when the caller indicated complications arising from the use of abortion pills, a combination treatment of mifepristone and misoprostol. Data was requested for three time periods: A – during 2018, when all medical abortions were provided in a clinic; B – during

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[15] Calum Miller, "Telemedicine Abortion: Why It Is Not Safe for Women," in Nicholas Colgrove, ed., *Agency, Pregnancy and Persons : Essays in Defense of Human Life* at 288, 296 (forthcoming, 2023). ProQuest Ebook Central, http://ebookcentral.proquest.com/lib/wfu/detail.action?docID=6998328.

Even the most zealous advocates for mifepristone did not countenance that: "Prescribing RU 486 will maintain the same doctor-patient relationship that accompanies the use of an antibiotic or any drug." Lader 1995 at 17.

> 2019, when women were able to self-administer misoprostol (the second part of the combined treatment) at home, after having received the mifepristone (the first part of the combined treatment) at an abortion clinic; C – from April 2020, when women were able to self-administer both mifepristone and misoprostol at home… Data obtained from five NHS Ambulance Trusts in England, show that emergency ambulance responses for complications arising after a medical abortion are three times higher for women using pills-by-post at home, compared to those who have their medical abortion in a clinic . . . In a related freedom of information investigation, we found that complications arising from the failure of medical abortion treatment result in 590 women presenting at the emergency department of their local NHS hospital in England every month. The treatment failure rate is 5.9%, 1-in-17.[16]

At the time of the FDA's initial approval, a woman seeking a chemical abortion was required to visit the doctor three times to receive a chemical abortion prescription. In 2016, that number of visits dropped to one.[17] In 2021, the FDA removed the in-person visit requirement altogether, meaning that a woman can obtain mifepristone through the mail without in-person examination, sonogram, or laboratory analysis.[18]

Prescribing chemical abortion drugs via telemedicine exposes women to several risks. One of the most significant of these is a ruptured ectopic pregnancy.

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[16] *Id*.

[17] Information on Mifeprex Changes and Ongoing Monitoring Efforts, Government Accountability Office at 7 (Mar. 2018) https://www.gao.gov/assets/gao-18-292.pdf.

[18] Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, U.S. Food and Drug Administration (Mar. 2023) https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

Ultrasounds, which require an in-person assessment, are critical in identifying gestational age and in ruling out ectopic pregnancies. Chemical abortion is ineffective in cases of ectopic pregnancy. The current REMS require only that the prescriber have the "[a]bility to diagnose ectopic pregnancies," not that a doctor actually assess whether the patient has one.[19]

Finally, telemedicine may not allow for a thorough discussion of the patient's medical history or assessment of her needs, potentially missing important details that could impact the procedure's safety. Telemedicine also leads to uncertainty and the inability to confirm that a woman is not being coerced into performing an abortion against her will. Further, "We can expect that 1-in-17 women using the abortion pills at home, will subsequently need hospital treatment for complications arising from the medical abortion treatment failure, presenting with retained products of conception and/or hemorrhage."[20]

Abortion, including chemical abortion, also risks harm to the woman's mental health. A comprehensive review of the literature on abortion and mental health found that at least some women experienced negative mental health outcomes as a result

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[19] Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200MG, Food and Drug Administration at 1 https://www.fda.gov/media/164651/download?attachment.

[20] FOI Investigation into Medical Abortion Treatment Failure, Percuity at 4 (Oct. 2021) https://percuity.files.wordpress.com/2021/10/foi-ma-treatment-failure-211027.pdf.

of their abortions and that "[t]he ability to identify women who are at greater risk of negative reactions has resulted in numerous recommendations for abortion providers to screen for these risk factors in order to provide additional counseling both before an abortion, including decision-making counseling, and after an abortion." [21]

Given the dangerous nature of mifepristone when used as an abortifacient and the FDA's repeated lessening of the limitations on the drug's prescription, it is entirely reasonable for States like West Virginia to take legislative action to ensure that women, as well as their unborn children, are protected.

CONCLUSION

For the forgoing reasons, this Court should rule for Appellees.

[21] David C. Reardon, *The abortion and mental health controversy: A comprehensive literature review of common ground agreements*, *disagreements, actionable recommendations, and research opportunities*, 6 Sage Open Medicine 1, http://journals.sagepub.com/doi/10.1177/2050312118807624.

Respectfully submitted,

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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(d) because this brief contains **5,397** words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), as calculated by the word-counting function of Microsoft Office 365.

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 Times New Roman.

Dated: April 15, 2024

/s/ J. Marc Wheat
J. MARC WHEAT

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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