AMERICAN CENTER
for LAW & JUSTICE

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Re: In Support of Maryland H.B. 1198: Public Health – Abortion – Drug-Induced Abortions

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For the reasons set forth herein, the American Center for Law & Justice ("ACLJ"), on behalf of itself and its members, urges that Maryland legislators vote YES on H.B. 1198.

The proposed bill, as written, protects Maryland women by regulating prescriptions and administration of lethal medications, including chemical abortions through the use of mifepristone and misoprostol.

I. Historical Background

In 1970, New York established itself as the abortion capital of America when it passed the most permissible abortion law in the United States. To this day, New York is one of the most abortion friendly states. Yet, in 1973 when the Supreme Court handed down its decision in *Roe v. Wade* – effectively legalizing abortion across the whole of the United States – the New York abortion industry was unhappy for multiple reasons, the first of which was increased market competition.

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According to a 1973 New York Times article:

> In the face of increased competition many clinics are exploring new techniques and health services, including "colonizing" other states where such abortion facilities have previously been illegal.
>
> Reports differ on how much—or even whether—nationwide legal abortion has slowed the stream of out-of-state-women, who last year had more than 60 per cent of the 118,000 abortions that were performed here.
>
> The major proportion of those pregnant three months or less patronized nonhospital clinics, ***generating what has been described as "cut throat competition" and "virtual kidnapping at airports.***"
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> "A lot of clinics are scared stiff—some talk about pooling facilities to meet their colossal overheads, especially rents," said Dr. Richard Hausknecht, who recently completed a report for the New York County Medical Society on "ideal" abortion services.
>
> "The days are doomed for doctors ***who made a million dollars or more***, doing 50 or 60 abortions per four-or-five-day week in a clinic."[2]

Second, the article noted that *Roe v. Wade* "punched holes in Article 42 of the city's Health Code," causing healthcare professionals to lament:

> "There's nothing now but professional self-discipline to keep doctors who aren't OB's or surgeons from doing first-trimester abortions in their offices . . . . And if they do them, we won't be able to keep up our standards."

In fact, the article cited an obstetrician criticizing the Supreme Court's decision as a "Catch-22":

> "In its ban on regulating first-trimester abortion, the court cited 'the now-established medical fact' of safety during this period . . . . Everybody knows this 'medical fact' was 'established' here and that the court relied on the data, experience and abortion-safety record of New York City—***which, ironically, was based on strict regulation***."

Indeed, the prediction that standards would be eroded has been fulfilled. In New York, for example, a 2014 New York Post article reported that eight of New York's twenty-five abortion clinics "were never inspected over the 2000-[20]12 span, five were inspected just once, and eight were either were inspected only twice or three times – meaning once every four or six years."[3] Moreover, a 2021 report has revealed "that more than 300 [abortion] facilities in 39 states were

[2] Laurie Johnston, *Abortion Clinics in City Face Rising Competition*, THE NEW YORK TIMES (Mar. 19, 1973), https://www.nytimes.com/1973/03/19/archives/abortion-clinics-in-city-face-rising-competition-abortion-clinics.html.

[3] Carl Campanile, *NYC's Tanning Salons Inspected More Regularly than Abortion Clinics*, NEW YORK POST (Apr. 7, 2014, 4:13 AM), https://nypost.com/2014/04/07/health-department-fails-to-regularly-inspect-abortion-clinics/.

cited for more than 2,400 health and safety deficiencies between 2008 and 2020, including hundreds of significant violations of state laws meant to ensure basic health and safety."[4]

In Maryland, specifically,

> a patient was provided with the abortion drug Misoprostol by a non-licensed staff member before the physician even arrived at the facility. That patient was subsequently determined to be likely 22 weeks pregnant, well beyond the recommend gestational age of 9 weeks for chemical abortion. The abortion business required her to go to another facility for another dose of medication, then another facility for a D&C operation to complete the abortion surgically, and potentially a second D&C at a fourth facility. For this abortion business, providing patients with Misoprostol "at 11 weeks gestation or beyond, even if the patient has not been evaluated by a physician, and even if no physician is available on site" is standard protocol.[5]

As is obvious, "professional self-discipline" and regulation is hardly sufficient to ensure safety for women, especially because there is an economic interest and incentive for the abortion industry, and deregulation – as is evidenced by the *Roe v. Wade* decision – increases those economic opportunities.

Quite predictably, the abortion industry is pushing for even less regulation and broader access to abortion, including greater distribution of dangerous chemical abortions, despite the significant danger the administration of these drugs pose, even while regulated.

II. Legal Protections

The Supreme Court, Maryland, and the Food & Drug Administration (FDA) recognize that regulation of abortion is a valid state interest, and that is necessary to protect women.

In *Roe v. Wade*, 410 U.S. 113 (1973), the Court held that *abortion* is a fundamental right, which can only be limited in rare circumstances,[6] especially in the first trimester.[7] The Court reasoned that the Constitution protects "zones of privacy"—an idea it garnered from very different cases that dealt with searches and seizures, education, and marriage—which it inexplicably extended to include abortion, even while acknowledging that, because of the presence of the baby in the womb, the woman is not alone in her "privacy."[8] The effective result of *Roe* was not only the *creation* of a right to abortion, but the granting of that newly created "right" the highest degree of protection it could receive under the Constitution—even though the Constitution does not once mention abortion.

[4] UNSAFE: AMERICA'S ABORTION INDUSTRY ENDANGERS WOMEN, AMERICANS UNITED FOR LIFE 67 (2021), *available at* https://aul.org/publications/unsafe/.
[5] *Id.*
[6] Roe v. Wade, 410 U.S. 113, 155 (1973).
[7] *Id.* at 163.
[8] *Id.* at 152-53.

However, a central premise in *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), was the *Roe* had "undervalue[d] the State's interest in [protecting] potential life."[9] The Court therefore recognized a state's interest in protecting life throughout pregnancy. In *Casey*, the Supreme Court upheld Pennsylvania's informed consent requirement,[10] parental consent requirement,[11] and 24-hour waiting period prior to abortions.[12]

Ten years later, in *Gonzales v. Carhart*, the Supreme Court also upheld the Federal Partial-Birth Abortion Ban Act of 2003.[13] The Supreme Court reasoned that "[t]he government may use its voice and its regulatory authority to show its profound respect for the life within the woman."[14] Additionally, both *Casey* and *Gonzales* affirmed that the state has an "interest in promoting respect for human life at all stages in the pregnancy."[15]

Since *Casey*, many states have taken their regulatory role seriously, and to ensure that abortions are conducted by adequately trained personnel, 38 states have passed laws requiring that abortions be conducted by licensed physicians.[16] Although these statutes have been challenged, the Supreme Court has upheld states' rights to enact such statutes in the interest of promoting women's health.[17] These are "common sense" statutes, for it is not unreasonable for states to limit the performance of invasive medical procedures only to those who are well-trained and licensed. The burden is on abortion advocates to show why abortion should not receive the same level of protection and scrutiny that is required of other medical operations.

Maryland is one of the states that has implemented some common sense regulations on abortion, and under Maryland Code § 20-208, "[a]n abortion must be performed by a licensed physician."[18] According to § 20-207, "the word 'physician' means any person, including a doctor of osteopathy,

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[9] *Id.* at 873. Importantly, the Supreme Court in *Casey* overturned the part of *Roe* that applied different levels of judicial scrutiny to abortion regulations, depending on the trimester. *Casey*, *Id.* at 872–74. Under this set of rules,

> almost no regulation at all [was] permitted during the first trimester of pregnancy; regulations designed to protect the woman's health, but not to further the State's interest in potential life, [were] permitted during the second trimester; and during the third trimester, when the fetus is viable, prohibitions [were] permitted provided the life or health of the mother is not at stake.

Id. at 872. *Casey* replaced this "elaborate but rigid construct" with a simpler test which allows regulation of abortion so long as it does not impose an "undue burden" on the woman's right to have an abortion. *Id.* at 874–76. This test, the Court concluded, places sufficient weight on the State's interest in protecting potential human life and balances it with the woman's right to abort. *Id.* at 876.

[10] *Id.* at 887.

[11] *Id.* at 899.

[12] *Id.* at 887.

[13] Gonzales v. Carhart, 550 U.S. 124, 158 (2007). The Court had previously struck down a ban on partial birth abortions in Stenberg v. Carhart, 530 U.S. 914 (2000). In upholding the Partial-Birth Abortion Ban Act in *Gonzales*, the Court also lowered the standard of abortion regulation even further by adding a "rational basis" test (the lowest level of protection under the Constitution) to the undue burden standard outlined in *Casey*. *Id.*

[14] *Id.* at 157.

[15] *Id.* at 157.

[16] GUTTMACHER INST., STATE LAWS & POLICIES: AN OVERVIEW OF ABORTION LAWS (2021), *available at* https://www.guttmacher.org/print/state-policy/explore/overview-abortion-laws.

[17] Connecticut v. Menillo, 423 U.S. 9 (1975) (per curiam); Mazurek v. Armstrong, 520 U.S. 968 (1977 (per curiam).

[18] M.D. Health-Gen Code § 20-208, *available at* https://law.justia.com/codes/maryland/2013/article-ghg/section-20-208/.

licensed to practice medicine in the State of Maryland in compliance with the provisions of Title 14 of the Health Occupations Article."[19]

The language of H.B. 1198 is in line with § 20-208, requiring, *inter alia*, "an abortion-inducing drug [to] be prescribed only by a qualified physician."

III. Mifepristone/Misoprostol and Elective Abortion Are Dangerous for Women

The FDA also regulates the administration of chemical abortions. Currently in the United States, the only FDA approved chemical abortion regimen is the use of mifepristone (Mifeprex or RU486), and misoprostol (Cytotec). The regimen to induce elective abortions – recommended only for up to ten weeks gestation – is the administration of mifepristone, which blocks hormonal support of the pregnancy and eventually leads to the death of the preborn baby, followed 24-48 hours later by the administration of misoprostol, which induces contractions to expel the dead preborn baby.[20]

In 2006, the FDA instituted a Risk Evaluation and Mitigation Strategy (REMS). The FDA's REMS policy is intended to "mitigate the risk of serious complications associated with mifepristone" chiefly by "[e]nsuring that mifepristone is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber."[21] This program is implemented only for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh the risks of its use.[22]

The purpose of REMS for mifepristone is to mitigate the risk of serious complications associated with mifepristone by:

> Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS Program. Ensuring that mifepristone is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber. Informing patients about the risk of serious complications associated with mifepristone.[23]

This is how REMS operates in all cases where drugs fit into this safety program. The REMS protocol focuses "on preventing, monitoring and/or managing a specific serious risk by informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event."[24]

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[19] *Id.* § 20-207, *available at* https://law.justia.com/codes/maryland/2013/article-ghg/section-20-207/.
[20] *Medical Management of Elective Induced Abortions*, AAPLOG (Feb. 25, 2020), https://aaplog.org/wp-content/uploads/2020/03/FINAL-PB-8-Medical-Management-of-Elective-Induced-Abortion.pdf.
[21] *Approved Risk Evaluation and Mitigation Strategies (REMS): Mifepristone*, FDA, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390 (last updated Apr. 11, 2019).
[22] *Id.*
[23] *Id.*
[24] *Id*.

Although the FDA declared that mifepristone is safe and effective, it puts perfectly healthy women in the hospital, and it may not work in a safe or effective way nearly 25% of the time it is used.[25] Complications from the administration of Mifepristone include, but are not limited to, ruptured ectopic pregnancies, hemorrhage, infection and retained pregnancy tissue, which require surgery in as many as one in twenty women.[26] Sadly, despite carefully screening to eliminate all but the most physically ideal candidates, 2% of those participating in U.S. clinical trials of Mifepristone hemorrhaged.[27] Additionally, one out of one hundred women who took the drug had to be hospitalized,[28] and during the clinical trials of Mifepristone, several women required surgery to stop the bleeding, with some requiring transfusions.[29] In an environment less regulated than that of a clinical trial, complications are more serious and more common, especially for those women who do not have immediate access to emergency medical care.[30]

In fact, according to the FDA, as of 2018 the chemical abortion pill has taken more than 3.7 million preborn lives, caused 24 maternal deaths, and resulted in at least 4,195 reported adverse maternal reactions.[31]

Despite the dangers, if the abortion industry had its way, the FDA's current REMS protocol would be reversed. In fact, last year abortion advocates attacked the REMS protocol, strategically trying to exploit the COVID-19 crisis to deregulate chemical abortions.[32] A U.S. District Court judge granted a preliminary injunction suspending the FDA's REMS "in-person dispensing and signature requirements applicable to the prescribing of mifepristone to medical abortion patients."[33] However, in January 2021, the Supreme Court reversed that decision and upheld and the FDA regulations on chemical abortions discussed in detail *supra*.[34]

Thus, H.B. 1198 is consistent with Maryland law, Supreme Court precedent, and FDA regulations, and would serve to protect Maryland women by upholding common sense medical standards by

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[25] Irving M. Spitz, et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 NEW ENGLAND J. MED. 1243–44 (1998).

[26] American College of Obstetricians and Gynecologists Practice Bulletin 143: "Medical management of first trimester abortion." Obstet Gynecol 2104;123:676-692. DOI: 10.1097/01.AOG.0000444454.67279.7d. Available at: https://journals.lww.com/greenjournal/Abstract/2014/03000/Practice_Bulletin_No__143___Medical_Management_of.40.aspx; Chen M, Creinin M. "Mifepristone with buccal misoprostol for medical abortion: a systemic review." Obstet Gynecol 2015;126:12-21. DOI: 10.1097/AOG.0000000000000897 Free full text: https://escholarship.org/uc/item/0v4749ss.

[27] U.S. FOOD & DRUG ADMIN., NEW DRUG APPLICATION FOR THE USE OF MIFEPRISTONE FOR INTERRUPTION OF EARLY PREGNANCY 56 (July 19, 1996), https://wayback.archive-it.org/7993/20170403223214/https://www.fda.gov/ohrms/dockets/ac/96/transcpt/3198t1a.pdf.

[28] Spitz et al., *supra* note 25, at 1243.

[29] *Id.*

[30] *See* U.S. FOOD & DRUG ADMIN, *supra* note 27, at 278–80, 291–92 (statement of Cassandra Henderson).

[31] Mifepristone U.S. Post- Marketing Adverse Events Summary Through 12/31/2018, *available at* https://www.fda.gov/media/112118/download.

[32] Olivia Summers, *21 Pro-Abortion Attorneys General Exploit Pandemic to Demand FDA Expand Access to Abortion Pills*, ACLJ.ORG (Apr. 14, 2020), https://aclj.org/pro-life/21-pro-abortion-attorneys-general-exploit-pandemic-to-demand-fda-expand-access-to-abortion-pills.

[33] Amer. College of Obstetricians & Gynecologists v. Food & Drug Amin., Civil Action No. TDC-20-1320, at 80 (July 13, 2020), *available at* https://www.acog.org/-/media/project/acog/acogorg/files/advocacy/pi-order-medication-abortion-71320.pdf?la=en&hash=D20597427CA8EBEA568D45EB9672AA80.

[34] Food & Drug Admin. v. Amer. College of Obstetricians & Gynecologists, 592 U.S. ___ (2021).

wisely limiting access to these dangerous chemical abortions through telemedicine and remote prescription.

IV. A Majority of Americans Do Not Support Deregulation of Abortion

Moreover, as Americans, we have always valued the right to life, and we should continue to do so. While there is certainly robust debate surrounding the issue of abortion in the United States, a recent poll revealed that a large majority of American's support restrictions on abortion, and "the finding that 70% of Americans either oppose abortion or favor limits on it rather than having it legal under any circumstances is echoed in the large majorities of Americans who have consistently said it should not be legal in the second (65%) and third (81%) trimesters."

Indeed, abortion is one of the gravest of all offenses against human life and against justice because it entails the deliberate killing of an innocent human being. A procedure that deliberately takes the life of a live human being, heart pounding away in his or her mother's womb, is plainly a procedure that fosters insensitivity to, and disdain of, the life in the womb. Certainly, such a killing is the embodiment of disdain for human life.

It is an indisputable scientific fact that the human child in the womb is a distinct biological organism, is alive, and belongs to the species homo sapiens. Thus, any justification of abortion (aside from the extremely rare life vs. life situations where a mother is at serious risk of dying from continuing the pregnancy) fundamentally rests on the proposition that some members of the human race do not have even the most basic of human rights, the right to live. That proposition is incompatible with our Declaration of Independence.

CONCLUSION

For the reasons stated above, the proposed bill is supported.