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Re: In Opposition to Maryland SB 84: Pharmacists – Administration of Self-Administered Medications and Maintenance Injectable Medications

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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 NO on S.B. 84.

The proposed bill, as written, could be used to reduce oversight of the remote administration of lethal medications, including chemical abortions through the use of Mifepristone and Misoprostol.

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

Currently in the United States, the only Food and Drug Administration (FDA) approved medical abortion regimen is the use of Mifepristone (Mifeprex or RU486), and Misoprostol (Cytotec). The regimen to induce elective abortions is the administration of Mifepristone, which blocks hormonal support of the pregnancy and eventually leads to the death of the unborn baby, followed 24-48 hours later by the administration of Misoprostol, which induces contractions to expel the dead unborn baby.[2]

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

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[2] *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.

the supervision of a certified prescriber."[3] 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.[4]

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.[5]

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."[6]

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.[7] 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.[8] 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.[9] Additionally, one out of one hundred women who took the drug had to be hospitalized,[10] and during the clinical trials of Mifepristone, several women required surgery to stop the bleeding, with some requiring transfusions.[11] In an environment less regulated than that

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[3] *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).

[4] *Id.*

[5] *Id.*

[6] *Id*.

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

[8] 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.

[9] 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.

[10] Spitz et al., *supra* note 7, at 1243.

[11] *Id.*

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.[12]

If the FDA's current REMS protocol were to be reversed, Senate Bill 84 would effectively expand access to these dangerous chemical abortions through telemedicine and remote prescription without expanding safety measures, putting Maryland women at greater risk than they are already.

In addition to the specific danger posed to women through chemical abortions, abortion in general is unhealthy and dangerous, and no public funding should be used to promote or provide it.

Published research strongly indicates that abortion, rather than being safe – even safer than childbirth as most pro-abortion advocates falsely claim – is in fact more dangerous.

In Finland, for example, researchers drew upon national health care data to examine the pregnancy history of all women of childbearing age who died, for any reason, within one year of childbirth, abortion, or miscarriage, between the years of 1987 and 1994 (a total of nearly 10,000 women). The study found that, adjusting for age, women who had abortions were 3.5 times more likely to die within a year than women who carried to term.[13]

A subsequent study based upon Medicaid records in U.S. State, California, likewise found significantly higher mortality rates after abortion. The study linked abortion and childbirth records in 1989 with death certificates for the years 1989-97. This study found that, adjusting for age, women who had an abortion were 62% more likely to die from any cause than women who gave birth.[14]

Yet another study, this one of nearly a half million Danish women, found that the risk of death after abortion was significantly higher than the risk of death after childbirth.[15] The study specifically examined both early (before 12 weeks' gestation) and late (after 12 weeks' gestation) abortions, and found statistically significantly higher death rates for both groups as compared to mortality after childbirth.

A more recent meta-analysis of nearly 1000 studies concluded that a woman's risk of premature death increases by 50% after having an abortion, and that this lethal effect lasts at least ten years.[16]

The Finland and California studies mentioned above both showed, *inter alia*, a heightened risk of suicide after abortion.[17] (The Danish study did not examine this aspect.) A British study found the

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[12] *See* U.S. FOOD & DRUG ADMIN, *supra* note 9, at 278–80, 291–92 (statement of Cassandra Henderson).
[13] Mika Gissler, et al., Pregnancy-associated deaths in Finland 1987-1994-definition problems and benefits of record linkage, 76 Acta Obstetrica et Gynecologica Scandinavica 651 (1997).
[14] David C. Reardon, et al., Deaths Associated with Pregnancy Outcome: A Record Linkage Study of Low Income Women, 95 SO. MED. J. 834 (2002).
[15] David C. Reardon & Priscilla K. Coleman, Short and Long Term Mortality Rates Associated with First Pregnancy Outcome: Population Register Based Study for Denmark 1980-2004, 18 MED. SCI. MON. 71 (2012).
[16] David C. Reardon & John M. Thorp, Pregnancy Associated Death in Record Linkage Studies Relative to Delivery, Termination of Pregnancy, and Natural Losses: A Systematic Review with a Narrative Synthesis and Metaanalysis, 5 Sage Open Medicine 1 (2017).
[17] *See also* Mika Gissler, et al., Suicides after Pregnancy in Finland: 1987-94: Register Linkage Study, 313 BRITISH MED. J. 1431 (1996) (suicide rate after induced abortion was six times higher than suicide rate after childbirth).

same thing.[18] All these studies are consistent with the many studies documenting adverse emotional consequences after abortion.[19]

Of course, abortion can also cause physical harm, beyond the harm (i.e., death) to the unborn child. This can result directly from the procedure itself (e.g., perforation of the uterus, laceration of the cervix), from the deprivation of the health benefits of continuing pregnancy (e.g., eliminating the protective effect of a full-term pregnancy against breast cancer),[20] or by masking other dangerous symptoms (e.g., a woman with an infection or an ectopic pregnancy may believe her symptoms are merely normal after-effects of abortion, leading her to delay seeking medical help).[21]

Furthermore, another U.S. study revealed that

> 58.3% of the women reported aborting to make others happy, 73.8% disagreed that their decision to abort was entirely free from even subtle pressure from others to abort, 28.4% aborted out of fear of losing their partner if they did not abort, 49.2% reported believing the fetus was a human being at the time of the abortion, 66% said they knew in their hearts that they were making a mistake when they underwent the abortion, 67.5% revealed that the abortion decision was one of the hardest decisions of their lives, and 33.2% felt emotionally connected to the fetus before the abortion.[22]

In that same study, the women were asked what positives stemmed from their decision to abort. Twenty-two percent of the women chose not to answer this question, while 31.6% responded by choosing the survey answer as "none".[23]

When asked about the most significant negatives that had impacted them from the decision to abort, women listed the following:

- Took a life/loss of a life of lives
- Depression
- Guilt/Remorse

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[18] Christopher L. Morgan, et al., Mental Health May Deteriorate as a Direct Effect of Induced Abortion, 314 BRITISH MED. J. 902 (Mar. 22, 1997) (letters section) (found suicide attempts more than four times as frequent after abortion than after childbirth).

[19] *See* David C. Reardon, Abortion Decisions and the Duty to Screen: Clinical, Ethical and Legal Implications of Predictive Risk Factors of Post-Abortion Maladjustment, 20 J. CONTEMP. HEALTH L. & POL'Y 33, 39 n.14 (2003) (citing nearly three dozen sources).

[20] *See* Justin D. Heminger, Big Abortion: What the Antiabortion Movement Can Learn from Big Tobacco, 54 CATH. U.L. REV. 1273, 1288-89 & nn.119 & 121 (2005).

[21] *See generally Physical Effects of Abortion: Fact Sheets, News, Articles, Links to Published Studies and More*, THE UNCHOICE, www.theunchoice.com/physical.htm (listing sequelae and referencing sources) (last visited 29 Aug. 2020).

[22] Priscilla K. Coleman, Ph.D., et al., *Women Who Suffered Emotionally from Abortion: A Qualitative Synthesis of Their Experiences*, JOURNAL OF AMERICAN PHYSICIANS & SURGEONS, Vol. 22 No. 4, p. 115 (2017), *available at* https://www.jpands.org/vol22no4/coleman.pdf.

[23] *Id.*

- Self-hatred/anger at self/self-loathing/feelings of worthlessness/unworthy of love
- Shame
- Addiction, alcohol or drug abuse
- Regret
- Self-destructive behaviors including promiscuity, self-punishment, and poor choices
- Low self-esteem
- Anxiety/fear
- Suicidal/suicidal thoughts/wanting to die/self-harm/dangerous risks/suicidal attempts[24]

All of these factors contribute to the repugnant nature of abortion and to the reasons why it should continue to be carefully regulated and why U.S. taxpayers should not be forced to fund it.

2. A Majority of Americans Do Not Support the Public Funding of Abortion

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 should be opposed.

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[24] *Id.* at 116-17.