December 15, 2020

Submitted Electronically

Re: Ohio General Assembly House Health Committee Hearing on Senate Bill 260, Regarding abortion-inducing drugs

On behalf of Americans United for Life, I write in strong support of SB 260, which would ensure that Ohioans receive the medical care they need when taking abortion-inducing drugs, and penalize doctors who do not provide appropriate oversight for the dispensing and use of this dangerous drug regimen.

My name is Katie Glenn, and I serve as Government Affairs Counsel for Americans United for Life. Founded in 1971, Americans United for Life (AUL) is the first and most active pro-life nonprofit legal advocacy organization in the country. AUL has dedicated nearly 50 years to advocating for comprehensive legal protections for human life from conception to natural death and for health and safety regulations ensuring that women receive comprehensive medical care when seeking abortion. To this end, AUL has created model bills protecting women's health and safety,[1] based on leading hospital systems' best practices[2] and longstanding federal policies.[3]

Ohio SB 260, which requires that the physician prescribing and administering abortion-inducing drugs be physically present when the patient consumes the initial dose aligns with current federal Food and Drug Administration (FDA) policy. It ensures that she is the person taking the drug—it is not being obtained for someone else—and that she has been evaluated for contraindications that would prevent her from being a candidate for this drug regimen.

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[1] AUL model legislation is available at aul.org/what-we-do/legislation.
[2] *Medical Abortion*, Mayo Clinic, (last visited May 14, 2020), www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687.
[3] *Mifeprex (Mifepristone) Information,* U.S. Food and Drug Admin., (Feb. 5, 2018), http://www.fda.gog/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.

The American College of Obstetricians and Gynecologists (ACOG), a pro-abortion trade group, filed a lawsuit in early 2020 seeking to invalidate the FDA's "in-person dispensing requirement"[4] under the guise of COVID-19 prevention. Despite publishing practice manuals as recently as 2019 that advise physicians to evaluate patients in-person prior to prescribing mifepristone, ACOG is now suing the FDA to strike down this requirement so doctors can prescribe chemical abortion pills over video chat and administer them through the mail.[5]

Led by Congressman Bob Latta (OH-05), AUL filed a brief in the Fourth Circuit Court of Appeals on behalf of 102 Members of Congress urging the Court to recognize the importance of the "in-person dispensing requirement" to make sure women are receiving adequate medical care.[6] Ohioans Senator Rob Portman, Steve Chabot (OH-01), Warren Davidson (OH-08), Jim Jordan (OH-04), and Brad Wenstrup (OH-02) joined Mr. Latta in supporting this important federal policy.

State lawmakers can ensure that, regardless of what happens at the federal level, Ohioans are protected and given medically-sound care by passing SB 260 and codifying the "in-person dispensing requirement" in Ohio law.

Ohio's in-person dispensing requirement is a necessary medical safeguard that mirrors two decades of federal policy.

In 2000, the federal Food and Drug Administration (FDA) approved the new drug application for Mifeprex ("RU–486"), the first and only drug approved to terminate early pregnancy.[7] However, it did so with important restrictions intended to protect women experiencing abortion, including that it be obtained in person directly from a clinician licensed to prescribe and administer these drugs.

One of the regulations that has been in place since 2000 is the "in-person dispensing requirement."[8] This means that a physician must meet with her patient in-person to prescribe and administer the abortion-inducing drug regimen, or "chemical abortion pill."

What we colloquially call the "chemical abortion pill" (abortion advocates prefer the term "medical abortion") is actually a regimen of two drugs, mifepristone

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[4] *Id.*
[5] *Am. Coll. of Obstetricians and Gynecologists v. U.S. Food and Drug Admin.*, No. TDC-20-1320, 2020 U.S. Dist. LEXIS 122017 (D. Md. July 13, 2020).
[6] Brief Amici Curiae of 102 Members of Congress in Support of Defendant-Appellant FDA and Reversal of the Lower Court, *Am. Coll. of Obstetricians and Gynecologists v. U.S. Food and Drug Admin.*, Nos. 20-1784, 20-1824, & 20-1970 (D. Md. Nov. 2, 2020), https://aul.org/wp-content/uploads/2020/11/2020-11-02-ACOG-v-FDA-No-20-1784-Amicus-Brief-of-Members-of-Congress.pdf.
[7] *Mifeprex (Mifepristone) Information*, *supra* note 3.
[8] *Id.*

and misoprostol.[9] According to the FDA label, the woman takes mifepristone first, most often at the clinic directly from a doctor or clinician.[10] Mifepristone blocks the hormone progesterone, ending the pregnancy because the unborn child is starved of nutrients when the uterine lining breaks down. Several hours later she then takes misoprostol at home, which causes contractions and delivery of the deceased fetus without medical involvement or supervision.[11]

According to most current protocols, for either an in-clinic or telemedicine abortion, a woman must consult with a doctor in person. Medical institutions are in agreement about this; according to the world-renowned University of California-San Francisco Health Center, "a medical abortion involves at least two visits to a doctor's office or clinic."[12] Before the abortion, a healthcare provider must first confirm she is a medically appropriate candidate for chemical abortion.[13] Even the "TelAbortion Study" sponsored by Gynuity Health Projects requires at least two in-person appointments, one before and one after the abortion.[14]

A number of medical conditions make a woman ineligible to take the chemical abortion pill, including having a potentially dangerous ectopic pregnancy (a pregnancy outside of the uterus).[15] An ultrasound is necessary to rule out ectopic pregnancy prior to performing a chemical abortion[16] and must be done in-person. Chemical abortion cannot terminate an ectopic pregnancy,[17] and rupture of the tissue containing the fetus (most often the Fallopian tube) is most common between 6 and 16 weeks.[18] If a woman is not assessed for ectopic pregnancy prior to taking abortion-inducing drugs, she will unknowingly enter the timeframe for rupture. Rupture requires emergency surgery, and the blood loss can be fatal if not treated in time.[19]

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[9] You may have heard this called Mifeprex, RU-486, or Cytotec. These are trade names for the drugs used in the chemical abortion process. *Questions and Answers on Mifeprex*. U.S. Food and Drug Administration, 12 Apr. 2019, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex.

[10] *Highlights of Prescribing Information: Mifeprex*. *Danco Laboratories*, *LLC*, (revised Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

[11] *Medical Abortion*, *supra* note 2.

[12] *Medical Abortion*, University of California San Francisco, UCSF Health (2020), www.ucsfhealth.org/treatments/medical-abortion.

[13] In most states, this consultation is with a physician. In a few states, like California, it can be done by a midlevel provider, such as a nurse practitioner, certified nurse-midwife, or physician assistant. Steven H. Aden, *Defending Life 2020: Everyone Counts,* Americans United for Life, (2019), at 45.

[14] *FAQs*, The TelAbortion Project, (2020), https://telabortion.org/faqs.

[15] *Ectopic Pregnancy*, Mayo Clinic, (Feb. 28, 2020), www.mayoclinic.org/diseases-conditions/ectopic-pregnancy/diagnosis-treatment/drc-20372093.

[16] *Id.*

[17] Dulay, Antonette T. *Ectopic Pregnancy*. Merck Manual Consumer Version, Aug. 2019. https://www.merckmanuals.com/home/women-s-health-issues/complications-of-pregnancy/ectopic-pregnancy.

[18] *Id.*

[19] *Ectopic Pregnancy*, *supra* note 15.

The ultrasound is also used to determine gestational age of the baby.[20] Chemical abortion pills cannot be taken after 70 days (10 weeks) of pregnancy due to heightened risks to the mother's health and increasing failure rates.[21] At-home abortion means that the gestational age is simply the woman's best guess and the timeline extends as she waits for the pills to arrive by mail.

Rh negative blood type and its impact on future pregnancies is another factor that cannot be assessed or treated by video chat. If a pregnant woman has an Rh negative blood type, her doctor should ensure that she receives a RhoGAM shot to prevent her body from developing antibodies that complicate, and may even prevent, future pregnancies.[22] Blood typing and administering RhoGAM is common practice for obstetricians, but not all abortion doctors see this as an ethical obligation, placing the burden on the woman to independently obtain this treatment from another doctor.[23] No matter how early in pregnancy an abortion occurs, an Rh-negative woman still needs RhoGAM.[24]

A major claim of the abortion industry is that an abortion will not impact future pregnancies,[25] yet by divorcing themselves from the mandates of obstetrics, abortion doctors risk the health, safety, and fertility of the women they claim to serve.

Women should not be abandoned to "self-manage" at-home abortions when the data show that chemical abortion is unsafe.

To be clear, chemical abortion is never "safe." Even with current meager safeguards in place, around 5% of women end up at the Emergency Room with complications, and as often as 9% of the time the pills do not work, meaning the woman will still be pregnant.[26]

Ohio is one of just a handful of states to collect and publicize records on RU-486 "adverse events," a category that ranges from "incomplete abortion/no comment"

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[20] Comm. on Obstetric Practice Am. Inst. of Ultrasound in Med. Soc'y for Maternal-Fetal Medicine, *Methods for Estimating the Due Date*, Committee Op. No. 700, (May 2017), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date.

[21] *Mifeprex (Mifepristone) Information*, *supra* note 3.

[22] *Frequently Asked Questions*, RhoGAM Ultra-Filtered PLUS, (Apr. 2019), http://www.rhogam.com/faq/.

[23] *FAQs*, *supra* note 14.

[24] *Frequently Asked Questions*, *supra* note 22.

[25] *How Safe is the Abortion Pill?*, Planned Parenthood, (2020), https://www.plannedparenthood.org/learn/abortion/the-abortion-pill/how-safe-is-the-abortion-pill.

[26] Irving M. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 New England Journal of Medicine, (Apr. 30, 1998), 1241, doi:10.1056/nejm199804303381801.

to emergency transfer for blood transfusions.[27] AUL submitted a public records request for Ohio's chemical abortion adverse events reports (AERs) and received over 400 reports across an 8-year period.[28]

Every single report recorded a chemical abortion gone wrong. Most included zero follow up information, even whether the woman carried her pregnancy to term. Many listed "completed surgically" as the outcome (meaning the woman had to go through the emotional and physical burden of a second abortion), while others listed events that required emergency care like "severe bleeding" and "hemorrhage" and "retained products [of conception]."[29] "Retained products of conception (POC)" is medical-speak for when some of the pre-born baby's tissue remains in the uterus and needs to be removed to prevent infection, and it occurs much more frequently after abortion than after completed birth.[30] It is worth noting that this reporting only addresses the physical impact and does not measure the emotional, psychological, or spiritual impacts of taking these drugs and having a chemical abortion.

On October 31, 2019: "Patient took misoprostol incorrectly and failed the abortion. She was sent to Women's Med Center in Dayton, Ohio for a D&C." We *only* have this information because Ohio requires it be collected and made available to the public, and in-person chemical abortion protocol requires a follow up visit. How many more "failed abortions" will there be when abortionists wash their hands of responsibility and leave women to fend for themselves? How many more "failed abortions" would there be if all fifty states recorded and shared this information? Removing chemical abortion from the medical context increases the likelihood of complications and adverse events while simultaneously signaling to women that this is their problem to solve alone.

The in-person dispensing requirement prevents forced abortion and other forms of reproductive control.

Ohio has a legitimate interest in preventing domestic violence and reproductive control. Intimate partner violence (IPV) and reproductive control are domestic violence concerns for women seeking an abortion. IPV includes physical violence, sexual violence, stalking, and psychological aggression by a current or former intimate partner.[31]

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[27] Ohio Reports of RU-486 Events are available to the public under Ohio Sunshine Laws. Records sent to Americans United for Life by the State Med. Board of Ohio Dep't of Health are available upon request.

[28] *Id.*

[29] *Id.*

[30] Mark A. Sellmyer et al., *Physiologic, Histologic, and Imaging Features of Retained Products of Conception*, 33 RadioGraphics 3, (May 3, 2013), https://doi.org/10.1148/rg.333125177.

[31] *Preventing Intimate Partner Violence*, Ctrs. For Disease Control and Prevention (Feb. 26, 2019), https://www.cdc.gov/violenceprevention/intimatepartnerviolence/fastfact.html.

The Centers for Disease Control and Prevention (CDC) notes that "IPV is a significant public health issue that has many individual and societal costs."[32] IPV may produce chronic health conditions affecting survivors' heart, digestive, reproductive, muscle and bones, and nervous systems.[33] IPV survivors may experience depression and post-traumatic stress disorder. Survivors also are at higher risk for engaging in health risk behaviors, such as smoking, binge drinking, and sexual risk behaviors.[34] The CDC estimates the lifetime medical, lost work productivity, and criminal justice costs are $3.6 trillion.[35] The lifetime cost for a female victim of IPV is $103,767.[36] Thus, there are steep individual and societal costs for IPV.

Unfortunately, IPV is common. One in four women have experienced IPV, and nearly one in five women have experienced severe physical violence by an intimate partner.[37] "Unintended" pregnancy, which may be a reason to seek an abortion, raises the risk of IPV. Women with unintended pregnancies are four times as likely to experience IPV as women with intended pregnancies.[38] Notably, half of all pregnancies are characterized as "unintended".[39]

Abortion also increases the risk of IPV. There are "[h]igh rates of physical, sexual, and emotional IPV . . . among women seeking a[n abortion]."[40] For women seeking abortion, the prevalence of IPV is nearly three times greater than women continuing a pregnancy.[41] Post-abortive IPV victims also have a "significant association" with "psychosocial problems including depression, suicidal ideation, stress, and disturbing thoughts."[42]

Notably, a survey in the American Journal of Public Health indicated IPV perpetrators are more likely than nonabusive men to be involved in a pregnancy that ended in abortion.[43] The surveyed male IPV perpetrators were likely to be in conflict

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[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] Comm. on Health Care for Underserved Women, *Reproductive and Sexual Coercion*, Comm. Op. No. 554, at 2 (Feb. 2013) (internal citation omitted).
[39] Comm. on Gynecologic Practice Long-Acting Reversible Contraception Working Group, *Increasing Access to Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy*, Comm. Op. No. 645, at 1 (reaffirmed 2018).
[40] Megan Hall et al., *Associations Between Intimate Partner Violence and Termination of Pregnancy: A Systematic Review and Meta-Analysis*, 11 PLoS Med. 1, 15 (Jan. 2014).
[41] *Reproductive and Sexual Coercion*, *supra*, at 2.
[42] Hall, *supra*, at 11.
[43] Jay G. Silverman et al., *Male Perpetration of Intimate Partner Violence and Involvement in Abortions and Abortion-Related Conflict*, 100 Am. J. of Pub. Health 1415, 1416 (Aug. 2010).

with their female partner particularly over her abortion decision when the violence occurred.[44]

With the prevalence of IPV, ACOG acknowledges that "[b]ecause of the known link between reproductive health and violence, health care providers should screen women and adolescent girls for intimate partner violence and reproductive and sexual coercion at periodic intervals."[45] IPV is therefore a grave concern for women seeking abortion.

Reproductive control, which overlaps IPV, is also a public policy concern for women seeking abortion. Reproductive control describes "actions that interfere with a woman's reproductive intentions."[46] Reproductive control occurs over "decisions around whether or not to start, continue or terminate a pregnancy, including deployment of contraception, and may be exercised at various times in relation to intercourse, conception, gestation and delivery."[47] Reproductive control includes intimate partners, family members, and sex traffickers asserting control over a woman's reproductive decisions.[48] Thus, in the context of abortion, reproductive control not only produces coerced abortions or continued pregnancies, it also affects whether the pregnancy was intended in the first place.[49]

Reproductive control is a prevalent issue for women. "As many as one-quarter of women of reproductive age attending for sexual and reproductive health services give a history of ever having suffered [reproductive control]."[50] In the United States, African American and multiracial women disproportionately experience reproductive control.[51] Younger women also are more at risk for reproductive control.[52] Coerced abortion particularly is a problem for victims, including minor victims, of sex trafficking in the United States.[53]

Women seeking abortion are susceptible to domestic violence in the forms of IPV and reproductive control. In turn, IPV and reproductive control may impair a woman's ability to provide consent to an abortion. Telemedicine only reduces the safeguards against domestic violence and coercion.

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[44] *Id.*
[45] *Reproductive and Sexual Coercion*, *supra*, at 1.
[46] Sam Rowlands & Susan Walker, *Reproductive Control by Others: Means, Perpetrators and Effects*, 45 BMJ Sexual & Reprod. Health 61, 62 (2019).
[47] *Id.*
[48] *Id.* at 65.
[49] *Id.* at 61–62.
[50] *Id.* at 62.
[51] Charvonne N. Holliday et al., *Racial/Ethnic Differences in Women's Experiences of Reproductive Coercion, Intimate Partner Violence, and Unintended Pregnancy*, 26 J. of Women's Health 828 (2017).
[52] Elizabeth Miller et al., *Recent Reproductive Coercion and Unintended Pregnancy Among Female Family Planning Clients*, 89 Contraception 122 (2014).
[53] Rowlands, *supra*, at 64.

The American Medical Association describes:

> While social distancing and quarantine measures are in place to protect the general public, domestic violence situations are likely to worsen as victims may be limited in seeking care or leaving the unsafe situation. Domestic violence is also a contributing factor to adverse health outcomes such as increased risk of chronic disease, depression, post- traumatic stress disorder, and substance use behaviors.[54]

ACOG echoes the concern of COVID-19's impact on domestic violence. According to ACOG, "The risk of intimate partner violence is increased in the context of recommendations to shelter in place, physical distancing, financial hardships, and potential isolation and quarantine. The severity of intimate partner violence may escalate during pregnancy or the postpartum period."[55] Notably, ACOG recommends healthcare providers screen patients multiple times because patients may not be able to disclose abuse each time they are screened.[56] In other words, although domestic violence screening may occur by telehealth, "screening for intimate partner violence by telehealth may not allow women the privacy or safety needed to disclose abuse."[57]

The very organization currently suing to remove the in-person dispensing requirement states that telehealth is an insufficient method of screening a woman for IPV, a deadly serious condition that could prevent a woman from freely consenting to seeking an abortion.

It is impossible to reach the medical certainty needed to prescribe abortion pills through a video chat.

Telemedicine abortion would increase the likelihood of coerced abortion or that the pills are taken by someone who is not medically eligible for the drug regimen and will suffer complications without a doctor's supervision. Ohio's adverse events reports show that chemical abortion is not "safe" and deregulating it further would only heighten the risks, leaving post-abortive women abandoned and alone to deal with complications.

Several states have already explicitly prohibited at-home abortions via telemedicine, recognizing the inherent risks to women.[58] And around twenty states

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[54] *COVID-19 Resource Guide: Women in Medicine*, Am. Med. Ass'n (Aug. 3, 2020), https://www.ama-assn.org/practice-management/physician-health/covid-19- resource-guide-women-medicine.
[55] *COVID-19 FAQs for Obstetrician-Gynecologists, Obstetrics*, Am. Coll. of Obstetricians and Gynecologists, https://www.acog.org/.
[56] *Id.*
[57] *Id.*
[58] These are: Arizona, Idaho, Oklahoma, West Virginia, and Wisconsin (currently in litigation).

have laws like SB 260, requiring that abortion-inducing drugs be prescribed and supplied directly from the physician in a clinical setting.[59]

While telemedicine has many beneficial applications, abortion will never be one of them. SB 260 ensures that no matter what happens to existing federal regulations, Ohioans are protected against dangerous at-home abortions.

Respectfully,

Katie Glenn

Government Affairs Counsel

Americans United for Life

[59] Amanda Stirone, *State Regulation of Telemedicine Abortion and Court Challenges to Those Regulations*, 24 On Point (July 2018), https://s27589.pcdn.co/wp-content/uploads/2018/07/State-Regulation-of-Telemedicine-Abortion-and-Court-Challenges-to-Those-Regulations.pdf.