ProLife OB|GYNS
AAPLOG American Association of Pro-life Obstetricians & Gynecologists

Chairman Lipps
House Health Committee
Re: Testimony on Senate Bill 260 = SUPPORT
Tues December 8, 2020

Chairman Lipps, Vice Chair Holmes, Ranking Member Boyd, and members of the committee,

The American Association of Pro-Life Obstetricians and Gynecologists is a national professional association of over 4000 obgyns and other reproductive health care specialists who practice according to the Hippocratic Oath, which causes us to advocate for both pregnant mothers and their unborn children. As such we urge the Committee to support Senate Bill 260, which is designed to safeguard pregnant women from patient abandonment by the abortion industry which will occur during the routine use of telemedicine to distribute the dangerous abortion regimen of mifeprex and misoprostol. Medical abortion carries significant risks, including hemorrhage, retained tissue, and need for emergency surgical intervention. Telemedicine is not appropriate for the distribution of these drugs.

FDA Warnings and Adverse Events Reporting

Both the FDA and drug manufacturers have acknowledged that the use of Mifeprex/misoprostol regimens to induce an abortion poses health risks for pregnant women. The final printed labeling (FPL) shaped and approved by the FDA warns that "About 85% of patients report at least one adverse reaction following administration of MIFEPREX and misoprostol, and many can be expected to report more than one such reaction."[1] These reactions include, but are not limited to, vomiting, headache, uterine hemorrhage, viral infections, and pelvic inflammatory disease.

The FDA considers Mifeprex complications serious and frequent enough to issue a black box warning to prescribers titled **"WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING."**[2] In addition, the FDA has instituted a Risk Evaluation and Mitigation Strategy (REMS) for Mifeprex.[3] According to the FDA, REMS "is a drug safety program" that the FDA "can require for certain medications with serious safety concerns."[4] The FDA goes on to emphasize that "[w]hile all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS."[5] Mifeprex is one of those few medications: in its own words, in 2018 "the agency determined that a REMS . . . continues to be necessary to ensure the safe use of Mifeprex."[6] The REMS prohibits use of Mifeprex in ways other than allowed by the FDA. Moreover, the FDA reports that, as of December 31, 2018, over 4,000 women in the United States have experienced "adverse events" after using mifepristone for the termination of pregnancy. [7] Among those adverse events were 24 deaths, 1,042 hospitalizations, 599 blood transfusions, and 412 infections. This last figure includes 69 severe infections, which the FDA says "generally result in death or hospitalization for at least 2-3 days, require intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days…." The same report indicates that there have been "11 additional reported deaths in women in foreign countries who used mifepristone for medical termination of pregnancy."

[1] FDA Mifeprex label. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf
[2] *Id.* at 1-2.
[3] FDA, *Mifeprex (mifepristone) Information*, Feb. 5, 2018, https://www.fda.gov/drugs/postmarket-drug-safetyinformation-patients-and-providers/mifeprex-mifepristone-information;.
[4] FDA, *Risk Evaluation and Mitigation Strategies* (*REMS*) 1 (2019), https://www.fda.gov/drugs/drug-safety-andavailability/risk-evaluation-and-mitigation-strategies-rems.
[5] *Id.*
[6] FDA Mifeprex Info available at:
[7] FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 12/31/2018*, https://www.fda.gov/media/112118/download,

These figures do not tell the whole story, either. The true number of complications from use of a Mifeprex abortion regimen is unknown, as there are widespread inadequacies in reporting. The FDA itself admits, for example, that it "does not receive reports for every adverse event … that occurs with a product."[8] This is in part because healthcare professionals are not required to report adverse events; rather, such reporting is voluntary.[9] On top of that, a 2006 review of official Adverse Event Reports (AERs) submitted to the FDA related to the use of the Mifeprex drug regimen, found that "AERs relied upon by the FDA to monitor mifepristone's postmarketing safety are grossly deficient due to extremely poor quality."[10] The review concluded, "[A] majority of the AERs analyzed do not provide enough information to accurately code the severity of the adverse event in question. The deficiencies were so egregious in some instances as to preclude analysis."[11]

One source of potential underestimation of the true number of complications from the use of the Mifeprex abortion regimen is patients who seek hospital treatment for complications and do not inform the hospital that the complications stem from an abortion attempt. Because miscarriage and abortion may present initially with the same symptoms,[12] this is relatively easy to do, and it is condoned or even encouraged by some. One international organization of medical professionals and others dedicated to "access to abortion," for example, advises that a woman who seeks medical care because of complications from a Mifeprex abortion "does not need to tell a health care provider that she took abortion pills."[13]

Even with inadequate reporting and likely underreporting, the existing medical evidence shows that there are more complications from medical abortions than from surgical abortions. Studies comparing the outcome of surgical versus medical abortion have repeatedly demonstrated that medical abortions have a greater risk of hemorrhage, infection, continued pregnancies, retained tissue, and need for emergency reoperation than surgical abortions. [14] [15] [16]

Hemorrhage

It is undeniable that hemorrhaging is a risk of using Mifeprex for abortion. This risk comes from mifepristone action at the cellular level, which blocks the ability of the uterus to control hemorrhage.[17] Again, the Niinimaki study cited above indicated that 15.6 percent of women experienced hemorrhage after a medical abortion,[18] and the FDA has reported that at least 599 women have required blood transfusions after medical abortion.[19]
A recent and well-publicized clinical trial attempt by Dr. Mitchell Creinin is an example of the common risk of hemorrhage following Mifeprex abortion. This trial, designed to test the efficacy of medication abortion "reversal" protocols, was halted for safety considerations due to hemorrhaging.[20] Five women were given mifepristone alone, and two of those five (40%) had massive hemorrhage requiring emergency surgery, one of which required a blood transfusion. By contrast, in the comparison group with women taking mifepristone plus additional progesterone, only one woman had excessive bleeding, which stopped spontaneously without surgery. [21] (Progesterone counteracts the effect of mifepristone.)

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[8] FDA, *Questions and Answers on FDA's Adverse Event Reporting System (FAERS)*, 2 (2018), https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers.
[9] *Id.* at 1.
[10] Margaret M. Gary & Donna J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, 40 ANNALS PHARMACOTHERAPY 2, 1 (Feb. 2006),
[11] *Id.* at 5.
[12] Women's Health Network, *Health Facts: Abortion with Pills and Spontaneous Miscarriage* (Aug. 2019), https://nwhn.org/abortion-pills-vs-miscarriage-demystifying-experience/.
[13] Women Help Women, *Will a doctor be able to tell if you've taken abortion pills* (Sept. 2019), https://womenhelp.org/en/page/1093/will-a-doctor-be-able-to-tell-if-you-ve-taken-abortion-pills.
[14] Ushma D. Upadhyah et al., Incidence of Emergency Department Visits and Complications After Abortion, 125 J. OBSTET. GYNECOL. 1, 175, 181 (Jan. 2015).
[15] Ea Mulligan and Haley Messenger, Mifepristone in South Australia: The First 1343 Tablets. Australian Family Physician 5 343 (May 2011).
[16] Maarit Niinimaki, et. al., Immediate Complications After Medical Compared with Surgical Termination of Pregnancy, 40 J. OBSTET. GYNECOL. 4, 795 (Oct. 2009),.
[17] Ralph P. Miech, *Pathopharmacology of excessive hemorrhage in mifepristone abortions*, 41 ANNALS PHARMOCOTHERAPY 12, 2002-07 (Dec. 2007).
[18] Niinimaki op cit. fn 18
[19] FDA Mifepristone Adverse Events Summary cited at fn 7.
[20] Mitchell D. Crenin, et al., *Mifepristone Antagonization With Progesterone*, 135 J. OBSTET. GYNECOL. 1, 158165 (Jan. 2020).
[21] *Id.*

Infection/sepsis

The risk of infection is also significant, since both Mifeprex[22] [23] and misoprostol[24] depress a woman's immune response to infection, which can allow simple infections to become overwhelming and lead to fatal sepsis. In fact, this concern about serious infections led Planned Parenthood to abandon the off-label use of misoprostol in the vagina and substitute instead the off-label use of misoprostol in the cheek (buccal administration) and to give prophylactic antibiotics.[25]

Ectopic Pregnancy

An ectopic pregnancy occurs when a woman's embryo implants outside of the uterus, most often in the woman's fallopian tube. A woman who has an ectopic pregnancy may experience the same symptoms as a woman who has an early pregnancy in her womb. Ruptured ectopic pregnancy is a leading cause of maternal mortality in the first trimester of pregnancy. Critically important, the only way to accurately diagnose an ectopic pregnancy is by the use of ultrasound to visualize the inside of the womb and locate the fetal pole.

If a woman who has an ectopic pregnancy is given mifepristone, she is in significant danger of the ectopic pregnancy rupturing, which will cause massive internal bleeding. Thus, if the location of the pregnancy cannot be confirmed by ultrasound, that is an absolute contraindication to giving mifepristone for abortion.[26] This is especially so because the symptoms of a rupturing ectopic pregnancy are identical to the symptoms that a woman experiences when she has a mifepristone abortion: bleeding, cramping and severe abdominal pain. [27] In other words, if an ectopic pregnancy has been missed, a woman could be in significant danger after taking mifepristone because her assumption that the symptoms she is experiencing are normal for mifepristone abortion can and do result in delay in diagnosis of a rupturing ectopic pregnancy.

Overall complication rates

The abortion industry claims that complications from medication abortion are extremely low. However, most widely accepted definition for the frequency of drug complications is given by the Council for International Organizations of Medical Sciences (CIOMS), an international, non-governmental, non-profit organization established jointly by World Health Organization and UNESCO in 1949. The CIOMS training manual on medicine safety states that "adverse drug reactions" are "very common" if they occur in over 10% of cases and "common (frequent)" if they occur between 1 and 10% of the time.[28]

Published studies show that serious complications from drug-induced abortions are in the range of 3-5%, if not greater. The Mulligan study cited previously found that 3.3% of patients who used mifepristone in the first trimester required emergency hospital treatment.[29] And the study from Finland found that 15.6% of women experienced hemorrhage after a medical abortion, that 6.7% of women had incomplete abortions, and that 5.9% required surgery to complete the abortion.[30] Using the CIOMS criteria, this means complications from medical abortions are "common" not "rare".

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[22] Jeanette I. Webster & Ester M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, 181 J. ENDOCRINOLOGY, 21 (2004)

[23] Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, 39 ANNALS PHARMOCOTHERAPY (Sept. 2005).

[24] D.M. Aronoff, et al., *Misoprostol Impairs Female Reproductive Tract Innate Immunity against Clostridium sordellii*, 180 J. IMMUNOLOGY 12, 6 (June 2008).

[25] M. Fjerstad et al., *Rates of Serious Infection after Changes in Regimens for Medical Abortions*, 361 NEW ENG. J. MED., 145-51 (2010).

[26] FDA Mifeprex label. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf

[27] *Id.* at 6.

[28] World Health Organization, *Medication Safety Training Course* at 10, https://www.who.int/medicines/areas/quality_safety/safety_efficacy/trainingcourses/definitions.pdf.

[29] Mulligan op cit fn 17

[30] Niinimaki op cit fn 18.

Telemedicine is inadequate to address known patient risks with Mifeprex abortions.

Providing medical abortion through telemedicine is problematic for at least three reasons: (1) the seriousness and risks of medical abortion are trivialized by the telemedicine approach; (2) a thorough and definitive in-person examination is needed and better ensured by having a physician present and involved; (3) an in-person meeting with a physician encourages future interaction and availability for follow-up and complication management.

Seriousness and Risks of medical abortion are trivialized by telemedicine approach

As detailed above the decision to have a Mifeprex abortion is not only a decision to end the life of a completely separate human being, but also involves serious risks to the woman, including the risk of death. These risks increase as the pregnancy advances, and thus each woman should have a detailed discussion of the risks to her, tailored to her specific circumstances, by someone who is knowledgeable about her individual medical history, physical exam and individual risks. This is not a trivial discussion, and the vending machine approach of telemedicine abortion trivializes the seriousness of this decision-making process. The 2011 telemedicine paper by Grossman included a patient comment which illustrates this issue, stating "I am always generally more comfortable dealing with serious issues in person."[31]

Patients need for thorough evaluation by a physician before administering Mifeprex

Mifeprex is contraindicated in a number of instances, including when ectopic pregnancy is suspected or confirmed; when there is chronic adrenal failure; when there is concurrent long-term corticosteroid therapy or anti-coagulant therapy; when the patient is allergic to mifepristone, misoprostol, or other prostaglandins; when the patient has inherited porphyria; and when the patient has an IUD in place.[32] These contraindications require close attention to patient history and medications as well as a thorough physical examination by a physician capable of diagnosing hemorrhagic disorders, porphyria, adrenal failure, ectopic pregnancy, etc. A pelvic examination is required to rule out undiagnosed adnexal mass and look for the presence of an IUD, as well as to check for tenderness consistent with pelvic inflammatory disease. It is the responsibility of the prescribing physician to ensure that the patient does not have any of these contraindications prior to prescribing Mifeprex. The abortion industry claims that screening women for contraindications can be done with equal safety regardless of whether the physician is physically present, but they present no real evidence of this unbelievable claim especially for the diagnosis of pelvic infections, undiagnosed adnexal masses and uterine abnormalities making emergency surgical abortion more difficult. Further, even if an individual abortion clinic developed some safeguard to ensure the accurate diagnosis of all of the contraindications, that is no guarantee that it *will* be done with equal safety if medical abortion is thrown open to the practice of telemedicine.

A theoretical telemedicine scenario is often presented in which the patient does even see the physician on the video screen until minutes before she is handed the mifepristone by the clinic staff. This scenario stands in sharp contrast to standard pre-surgical care in which the surgeon examines, diagnoses, and discusses treatment options with the woman prior to commitment to a surgical procedure or other course of treatment. This theoretical telemedicine scenario raises significant concern for the adequacy of informed consent and for the possibility of marketing coercion.

If the physician has not examined the patient, who will make the determination that she is even a candidate for telemedicine abortion? In many cases where telemedicine abortion is being implemented, the person doing the initial screening is a receptionist or other non-medical personnel. It is not clear what training this "scheduler" will have, and how this "scheduler" will determine who is and who is not a candidate for Mifeprex abortion, surgical abortion or both. The determination of who is a candidate for a Mifeprex abortion involves not only gestational age, but also ruling out contraindications as per the FDA label. This kind of discernment requires medical training.

Who will provide informed consent for this patient? An informed consent process should entail a discussion of specific risks for that particular patient, complications, and alternatives. Such patient specific consent necessitates

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[31] Daniel Grossman, *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 J. OBSTET. GYNECOL. 2, 302 (Aug. 2011).

[32] Mifeprex FDA label op cit fn 1.

a thorough history, a physical examination, and the ability to diagnose medical contraindications. Such skills are typically not in the ability of abortion clinic staff who are not formally trained in diagnosis and treatment.

The gestational age of the pregnancy is critically important to determine the specific risks of death and complications that the patient will face. How will this gestational age be determined if the physician is not doing a physical examination? The abortion industry claims that a trained ultrasound technician can be employed to do the ultrasound, but frequently there is no requirement that the sonographer have any recognized radiological or sonographic certification. An ambiguous phrase such as "a trained ultrasound technician" could include non-medical staff that has performed a few ultrasounds but is not actually certified. Errors in gestational age caused by poor sonographic dating can have tremendous implications when discussing risks, because the risks of a mifepristone abortion increase with increasing gestational age.

There are many other aspects to an ultrasound examination beyond gestational age, which bear on the risks that an individual woman will face during her abortion, including the location of the placenta, the position of the uterus, the presence of a uterine septum, whether or not a woman has fibroids, etc., all of which become important if the woman has a subsequent hemorrhage requiring emergency surgery. Will the person performing the ultrasound be qualified to evaluate these abnormalities? Such evaluation requires the training of the surgeon who is responsible for handling the complications of the procedure.

It is of grave concern that many clinics currently using telemedicine for abortion use minimally trained clinic staff for the informed consent process. Unlike the standard of medical care before other non-abortion procedures, the telemedicine patients do not have the opportunity for informed consent with the physician who will be responsible for taking care of them should complications arise. In fact, if "clinic staff" are doing the evaluation and consent for the abortion patient before they even meet the "doctor" over the internet, this puts the clinic staff doing a high level medical interaction with the patient, including apparently an informed consent discussion, as well as conveying medical information about the procedure, the risks and the expected complications. This is the kind of discussion that is expected between the surgeon and his or her patient in normal medical practice.

The issue of coercion in the telemed abortion process is also of concern. It appears that the first time the patient even virtually sees the treating physician is immediately before she is handed the mifepristone. At that point, the physical, psychological, and financial investment in the abortion would make it very difficult for a woman to choose any other option but to proceed with the abortion. The pressure on the patient at that point significantly compromises a patient's free and full informed consent prior to an elective procedure.

Follow-up availability

The abortion industry claims that in-person treatment from a physician is irrelevant because when complications from a medical abortion do arise they occur *after* the patient has left the clinic. This presents a startlingly bleak and shallow picture of the physician-patient relationship, which is not supposed to end just because a patient goes home. Instead, a physician overseeing a procedure is supposed to be available to manage known complications from that procedure. This management does not happen with telemedicine abortion. It would be unethical for any surgeon to start a procedure and then be unavailable to manage known complications from that surgery. A surgeon who simply tells the patient to go to a local emergency room if there is a complication risks a malpractice suit for patient abandonment, as well as risking the loss of hospital privileges. But, passing off the management of complications from mifeprex abortions to the local Emergency Room is the apparent management plan for patients with complications after telemedicine abortions.

The FDA Adverse Event Reports and the scientific literature indicates that this type of patient abandonment approach is pervasive in the abortion industry. It is undeniable that many women report to emergency rooms rather than return to the clinic where they obtained the abortion, as illustrated in a recent article which states that "complication rates are underestimated by low follow-up rates"[33] and that "[p]ublished complication rates are considered incomplete because they usually do not include those diagnosed at sites other than the original source of care."[34] This trend is also why studies that include emergency room complications tend to show a larger rate of complications than do those that draw primarily from clinics, such as the Cleland study.[35] It is difficult to see how

[33] J.E. Kohn, D. Grossman, et al., Medication Abortion Provided Through Telemedicine in Four U.S. States, 00 J. OBSTET. GYNECOL., 1-8 (2019
[34] Op cit Upadhyah.
[35] K. Cleland et al., *Significant adverse events and outcomes after medical abortion,* 121 J. OBSTET. GYNECOL., 16671 (2013).

telemedicine could do anything but exacerbate this issue, as it weakens the link between women and their physicians even more. In fact, women who had telemedicine abortions were less likely to follow up with the abortion provider. [36] "It is possible," the authors conceded, "that meeting with a clinician virtually rather than in person may reduce one's likelihood to return for a follow-up visit."[37]

Telemedicine abortion is touted as being particularly helpful to rural areas, but that leads to a serious question. According to FDA records, many of the first 600 severe adverse event reports in the first four years after mifepristone approval in 2000 would have been fatalities except for prompt access to emergency intervention and adequate hospital access. [38] It is clear from the scientific literature that telemedicine abortions in remote areas will initiate a procedure that commonly results in hemorrhage, ER visits, need for emergency surgery, transfusions, etc., in precisely those areas where emergency services are the least accessible. This places the women in remote areas at the highest risk of turning a manageable complication into something life threatening or fatal.

False characterization of telemedicine abortion

The abortion industry argues that telemedicine is used in other states to deliver a broad range of healthcare services, for example addiction treatment, chronic disease management, high-risk pregnancy, oncology, radiology, and stroke treatments. But obviously none of these services are comparable to the administration of a medication abortion. Rather, the majority of these and other telemedicine services are likely to be conversation- or consultation-based, not procedure-based. None of the services listed here are either elective procedures, such as elective abortion, nor are they surgical services. None involve starting an invasive procedure such as a mifepristone abortion in clinical situations that do not have adequate medical infrastructure to handle known complications.

The abortion industry claims that medical abortion is non-invasive. This is not true. Mifepristone interferes with the natural physiological process of pregnancy, to result in the death of a separate human being, and it leads to the (commonly incomplete) painful expulsion of that human being and placenta from inside the woman's body. And, again, the risks associated with this procedure are greater than the risks associated with surgical abortion: infection, hemorrhage, and follow-up surgical abortions.

As women's health professionals, AAPLOG members care for women prior to surgery. We know that women expect appropriate pre-procedure medical care prior to initiating a procedure, including a medical abortion. It is surgical standard of care that the surgeon takes a history, does a physical examination and discusses not only the diagnosis, but also the risks and alternatives with a patient prior to any procedure. For a non-emergency surgery such as an elective abortion, it is standard of care for a woman to have some time to consider what the physician has communicated to her without pressure to complete a procedural path which has already been initiated. That's what women expect from medical care. And that is not provided by telemedicine abortions. We urge you to support Senate Bill 260.

Respectfully submitted,

Donna J. Harrison M.D. Executive Director
On behalf of the Board and membership of the
American Association of Pro-Life Obstetricians and Gynecologists

[36] J.E. Kohn, D. Grossman, et al., *Medication Abortion Provided Through Telemedicine in Four U.S. States*, 00 J. OBSTET. GYNECOL., 1-8 (2019), provided as Attachment N.
[37] *Id.* at 6.
[38] *Gary op cit fn* 12