HB24-1106

Provide Information About Abortion Pill Reversal

In Support (Dr Catherine Wheeler)

As a board member of AAPLOG, I represent thousands of physicians nationwide who support women receiving fully informed consent, including about APR.

As an OB-GYN physician who performed abortions, I reflect on how differently we offer informed consent with abortion compared to other medical procedures.

With tubal ligations, I informed women of the risk of failure, the potential for reversal, but without guarantee of being able to conceive normally.

With hysterectomy, I described the procedure in detail, with risks, benefits and alternatives, including finality of loss of fertility.

With abortion, I did NOT describe the procedure in detail, nor how I would dismember the preborn baby. This was wrong, and it is the standard "informed consent practice" for abortions. There is a notion that the woman might feel "guilty" or "bad" – that we should spare her the details. However, knowing all the facts is a woman's RIGHT. Sure, she might make a different choice if she knew all the details. But isn't that what informed consent is about – having ALL the relevant information? Who are we to infantize and deceive women in this way?

For a woman who begins a medication, or chemical, abortion, and changes her mind, natural progesterone taken within 72 hours of mifepristone, provides a 67% chance of saving her baby's life. Who would deny this desperate woman that opportunity? The FDA classifies progesterone as safe during pregnancy, research consistently shows that progesterone is effective, and more than 4500 babies' lives have been saved with progesterone as APR.

A dear friend of mine recently succumbed to a severe form of multiple myeloma. As one treatment after another failed, her physician offered off-label treatments. A large proportion of medications are used off-label. Doctors are very capable of explaining this to our patients. We can't guarantee the effectiveness of any medications or surgeries. During informed consent we explain the available options, relative safety and effectiveness in similar situations, and risks.

Offering women ALL the relative information is essential, and our DUTY, especially when a life is at stake. It is frankly cruel to not tell women of this life-saving, safe option.

Please vote in favor of HB24-1106.

SB23-190 Rebuttal of ACOG to the Stakeholders Meeting Comments by Dr. Catherine Wheeler (4/Aug/2023)

To the Members of the Boards of Medicine, Nursing and Pharmacy
Because so much emphasis is being placed on ACOG and AMA claims that progesterone to reverse the effects of mifepristone abortion is not effective, is not standard of care, and is harmful, I would like to comment on the combined testimony submitted by the American College of Ob/Gyn (ACOG), SMFM (Society of Maternal-Fetal Medicine), and SFP (Society for Family Planning).

I am a board-certified Ob/Gyn physician, and practiced for 24 years.
As background, Ob/Gyn physicians are not required to be members of ACOG. Surveys have shown that only 7 to 14 % of Ob/gyn physicians would provide an abortion for patients who requested it.[1] Thus, ACOG's statements regarding abortion do not represent the majority of Ob/Gyn physicians, who are not surveyed by ACOG to determine its stance on abortion.
AMA only recently changed its neutral stance on abortion, joining ACOG and other abortion advocates by cosigning an amicus brief in the Supreme Court's Dobbs v Jackson Women's Health case. Of the 1,341,682 practicing physicians in this country, only 132,133 are AMA members.(2) Thus, AMA represents only 10% of U.S. physicians. When ACOG and AMA declare there is no scientific evidence for the safety and effectiveness of natural progesterone to reverse mifepristone, they are ignoring a significant body of scientific evidence, which many physicians have presented to the Boards. While this is low to moderate quality evidence, it all consistently points to the safety and efficacy of APR. The evidence presented also meets the standard for evidenced-based medicine, and respect for patient autonomy, as well as the serious ethical responsibility of physicians to be honest about all the body of evidence in obtaining informed consent. ACOG guidelines and opinions are just that – guidelines and opinions. Physicians are not robots, or vending machines, nor are we required to follow strict checklists and protocols. We practice by evidence-based medicine – starting with a question, searching the literature, critically evaluating the literature, and individualizing to the patient's situation and values, using informed consent as the model. This is exactly what APR proponents have presented to the Boards as evidence. Rather than simply take statements at face value, I ask you to critically evaluate the evidence for yourself.

I am thankful ACOG presented what they are relying on for evidence to support their statements. In response to ACOG's comments and evidence for their position:

1. ACOG erroneously stated that Dr. Delgado did not have IRB approval for his "retrospective analysis of clinical data of 754 patients who decided to attempt to reverse the medical abortion process after taking mifepristone but before taking the second drug in the protocol misoprostol."[3] The study clearly states in the methods section it was reviewed and approved by the institutional review board. (4] Dr. Delgado reviewed the rationale for progesterone for APR, and prior studies, both for progesterone as APR, and continuing pregnancies after mifepristone. The historical controls came from a review of 30 articles studying mifepristone monotherapy, 12 of which utilized ultrasound to determine incomplete or missed abortion and embryo survival. He used the high-end embryo survival rate with mifepristone monotherapy, in order not to overestimate the benefit of progesterone.

2. ACOG also criticizes the study for using ultrasounds to select for living embryos before the first progesterone dose. Dr. Delgado appropriately explains in the document, that if possible, women would have an ultrasound for viability prior to beginning progesterone, and notes this is a potential confounding factor. He also notes that some women started progesterone prior to ultrasound documentation of a living embryo (due to the 72 hour urgency after consuming mifepristone). This

group "would have included some women with embryonic demise, which would falsely lower success rate of progesterone therapy."

3. ACOG recommends that the only course for women who change their mind after taking mifepristone is expectant management. However, when one evaluates ACOG' practice bulletin #255, it states: "The following recommendations are based primarily on consensus and expert opinion (Level C): In the very rare case that patients change their mind about having an abortion after taking mifepristone and want to continue the pregnancy, they should be monitored expectantly."[5] Thus, ACOG's recommendation for expectant management is itself low level, and actually not based on evidence, but consensus and opinion.

4. ACOG references rely heavily on courts and state agencies to determine adequacy of medical practice, which does not prove scientific integrity nor evaluation of evidence in an unbiased, scientific fashion. It is unfortunate that political agendas are attempting to coerce and control the evidence-based practice of medicine. Additionally, the Louisiana legislative report cited was published in 2017, prior to Dr. Delgado's large case series being published; thus, it is outdated and one cannot rely on the statements of there being no evidence for APR effectiveness.

5. ACOG does NOT comment on the prospective randomized controlled rat study published in June 2023, which affirmed that reversal of mifepristone abortifacient effects with high dose progesterone is not only possible, but in this study was 81% effective (livebirth), even when given after the rats began to bleed (i.e. begin to abort).

6. ACOG adamantly states progesterone is ineffective, yet real world experience says otherwise. There are more than 4500 livebirths after progesterone to reverse the effects of mifepristone recorded with the APR Network registry, including women from every state in the U.S. and across the globe.

7. ACOG adamantly states that women do not regret their abortions, including medication abortion. They cite one study, but there are many other studies ACOG ignores which reveal abortion regret. One of the tests for truth in reported scientific outcomes is, does it match or explain reality. The fact that at least 4500 women have sought reversal through APR clearly reveals women do regret their abortion choice and desperately seek help. We have heard their testimonies both at the first Shareholder Meeting, and during legislative testimony. Doctors who prescribe APR have witnessed to this fact. My 24-year practice regularly witnessed to this fact. The single study that ACOG sites is "up to 5-year follow-up". For some women the regret is immediate. For some, decades. And certainly not all women experience regret – but many do.

One group that has not been considered is the group of women who are coerced and forced to have abortions. This is especially true for women being trafficked and forced into abortion, or given medication without their knowledge.

8. ACOG states boldly that APR "poses a threat to mental and physical health", without presenting the evidence to support that claim. All medications carry some risk, including medication abortion, which has been associated with at least 26 known maternal deaths in the U.S. The FDA completed a review of progesterone and progestin use in pregnancy, and concluded that natural progesterone is low risk, and does not pose increased risk of fetal anomalies. [6] The American Society of Reproductive Medicine affirms this.[7] The regimen used for APR is the same regimen used for women who require luteal phase support for ovarian (corpus luteum) loss or infertility. Cochrane Review has also concluded that progesterone is safe for luteal support in pregnancy.(8]

The study cited by ACOG is actually a 2003 study of a synthetic progestin, not progesterone, and therefore, does not support their claim. I am including the reference I cited in previous comments for the second shareholder meeting, a review of the difference between progesterone and progestin in obstetrics, which also affirms that it is the progestins, not progesterone, which are associated with hypospadias.[9]

Mifepristone, on the other hand, has a black box warning for serious and fatal infections and heavy bleeding.[10] In addition, the common adverse effects include: nausea (51-75%), weakness (55-58%), fever/chills (48%), vomiting (37-48%), headache (41-48%), diarrhea (18-43%), dizziness (39-41%). Product information also states: "Women should expect to experience vaginal bleeding or spotting for an average of 9 to 16 days. Women report experiencing heavy bleeding for a median duration of 2 days. Up to 8% of all subjects may experience some type of bleeding for 30 days or more."

9. ACOG states that progesterone interrupts the "safe medication abortion process", and references the National Women's Health Network, which is not a scientific medical organization, as its source for the quoted <1% risk of serious complications for medication abortion. There are many claims that medication abortion is "safe". ACOG does not present the actual evidence they base that claim on. The U.S. does NOT collect accurate data of the number of abortions performed, nor of complications. The only countries that do so are ones with universal health coverage and registries of pregnancy, abortion, and death, allowing data linkage. ACOG has ignored such a study of all abortions in Finland (more than 42,000), which found that adverse events occurred in 20% of women having medication abortion, including 15.6% with severe hemorrhage, and 5.9% requiring surgical intervention. Adverse effects following medication abortion occurred at four times the rate of surgical abortion.[11]

ACOG also quotes Creinin's study, but does not provide all of the important details. As has been commented by many others who have evaluated the study, the patients with hemorrhage requiring surgery (2) and transfusion (1) were in the placebo group – who did not receive progesterone. This is a 40% severe complication rate from mifepristone. Only one patient in the progesterone group hemorrhaged as the medication abortion completed, and she did not require any intervention. Additionally, embryo survival rates in the progesterone group were double that of the placebo group, consistent with other scientific evidence that has been presented. The studypopulation was small; however, the safety concern was in the group who did NOT receive progesterone. ACOG states the hemorrhage was because the misoprostol was withheld by the women who wanted to save their babies. This is a twisted conclusion from the data. The data supports the conclusion that mifepristone abortion is associated with risk for hemorrhage; progesterone appears to decrease that risk, and increase embryo survival opportunity.

10. ACOG states that promoting APR "can pose a significant risk to patients' mental health," quoting a study assessing the impact of laws requiring information regarding possibility of reversal be given to women seeking medication abortion, suggesting that it may "pressure" women and "stigmatize" abortion. Thus, ACOG suggests withholding medical information that could save their baby's life, should they change their mind, in order to keep some women from feeling the stigma of their decision. There is NO comparison between death, and a woman feeling badly about her difficult abortion decision. This cited study does not research harm to women receiving progesterone, but a projected and assumed harm to other women considering abortion. The SB23-190 proposed regulations specifically apply to women being prescribed progesterone for APR. The negative mental health impact for women seeking APR, but being denied a low-risk medication to save their baby's life far outweighs the proposed concerns ACOG has described. For all of us women who have lost a baby to (spontaneous) miscarriage, we understand the profound grief and loss. This is not a trivial matter.

11. ACOG then states that offering APR "misleads patients". The evidence has been presented regarding the scientific evidence, the levels of evidence (see Dr. Perille's comments), the safety of progesterone, use of progesterone for threatened miscarriage and other obstetric indications, sanctioned by ACOG, ASRM, and other organizations, and how prescribing progesterone for APR meets the requirements for the evidence-based practice standards we employ day-in and day-out in medicine. Informed consent is a critical part of the process. Yes, we all hope for ongoing research. The evidence we have today supports informing patients of its availability and potential effectiveness, and offering progesterone to women who are seeking to reverse the mifepristone abortion process. It is a woman's right to know, and to choose.

What is at stake is death, and the lifelong impact on a mother who is denied her autonomy to choose to continue a pregnancy with a safe, legitimate treatment. Additionally, this legislation sets a precedent for government interference in any area of medicine; the integrity and practice of all medicine in Colorado is at stake. The evidence has been presented that clearly demonstrates that APR meets generally accepted standards for medical practice (EBM). Additionally, the responsibility for these lives are in your hands. Please review the evidence for yourself.

[1] Desai S, Jones R, Castle K. Estimating abortion provision and abortion referrals among United States obstetricians and gynecologists in private practice. Contraception 2018;97:297-302;
(2) Stuhlberg DB, Dude AM, Dahlquist I, Curlin FA. Abortion provision among practicing obstetrician-gynecologists. Obstet Gynecol 2011;118(3):609-614
(3) https://www.medpagetoday.com/blogs/campbells-scoop/80583
(4) G. Delgado, et al. A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone. Issues in Law and Medicine, 2018, 33(1):21-31.
(5) Ibid, p. 24
(6) ACOG Practice Bulletin #255, October 2020, Reaffirmed 2023. Medication Abortion up to 70 Days Gestation
(7) Federal Register;64(70): April 13, 1999. Proposed Rules. FR Document 99-9146.
(8) Progesterone Supplementation During the Luteal Phase and In Early Pregnancy in the Treatment of Infertility: An Educational Bulletin. The Practice Committee of the American Society for Reproductive Medicine. Fertil Steril 2008 April; 89(4): 789-792.
(9) Van der Lindeu, et al. Luteal Phase Support for Assisted Reproductive Cycles. Cochrane Data Base Syst Rev 2015 Jul; 2015(7):CD009154
(10) R. Romero, F. Stanczyk, Progesterone is not the same as 17 alpha-hydroxyprogesterone acetate: implications for obstetrical practice. Amer J Obstet Gynecol 2013 June; 208(6):421-426.
[11] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf
[12] Niinimäki M, Pouta A, Bloigu A, Gissler M, Hemminki E, Suhonen S, et al. Immediate complications after medical compared with surgical termination of pregnancy. Obstet Gynecol. 2009;114(4):795–804.