



AAPLOG Statement on FDA removing Mifepristone safety protocols (REMS)

As women's healthcare experts, we fight hard every day for the health of our patients. And when political agendas supersede the health of our patients, it is our responsibility to speak up. The FDA's announcement yesterday that they plan to lift safety restrictions that govern the dispensing of medication abortions makes women's health simply a pawn in the effort to push for more abortion. The American Association of Pro-life Obstetricians and Gynecologists (AAPLOG) represents approximately 7,000 women's healthcare practitioners who will not allow our patients' lives to be put in jeopardy in order to appease the abortion industry and their allies.

When Mifepristone was first approved in 2000, it was only approved with safety regulations in place (known later as REMS) that would attempt to minimize the significant risk of hemorrhage, tissue not removed, and infection. These REMS were relaxed in 2016 by the FDA, without any further safety testing and despite evidence of significant adverse events, as well as maternal deaths. Inexplicably in 2016, the FDA stopped collecting data on non-fatal adverse events and has only collected data on maternal deaths related to Mifepristone. They have chosen to completely ignore the thousands of women who are showing up in their local emergency rooms due to heavy bleeding, retained tissue, infection, or other complications as a result of medication abortions. A recent analysis of the Adverse Events submitted to the FDA with the REMS in place shows over 3000 women suffering with complications, of which 24 of these women died, and another 500 would have died if they had not reached emergency medical care in time. These numbers will only increase if the current REMS, which require that a woman be seen and evaluated by a licensed healthcare practitioner prior to receiving the medications for an abortion, are removed. This requirement is not restrictive – it is protective.

It is critical that a woman be seen in person before being given Mifepristone for an abortion for numerous reasons, including:

- 1) Her doctor(s) will know her actual risks;
- 2) her doctor(s) will be able to rule out contraindications like ectopic pregnancies; and
- 3) her doctor(s) will be able to give her Rhogam if she is Rh negative.

Requiring that a woman be seen in person in order to undergo medication abortion ensures that she is able to give her fully informed consent – a basic tenet of medical ethics. Many women are pressured into abortions by their partner, a family member, or a trafficker. Oftentimes, their visit with a physician in early pregnancy is the only chance these women will have to expose this pressure they're facing. As compassionate physicians, we should do everything we can to ensure that a woman is not being unduly pressured to have an abortion she does not want. Screening for abuse and trafficking is inadequate during a telemed visit because the physician cannot control

the environment of the woman on the other end of the screen, or know who is hovering behind the computer screen.

An in-person visit is medically necessary and sound medical practice because it ensures that every woman receives a full evaluation for any contraindications to a medication abortion. First, it ensures that the gestational age of her pregnancy can be confirmed. Mifepristone is only approved for use through 10 weeks gestation and the complication rates associated with it increase significantly after this gestational age. According to a [Committee Opinion](#) from the American College of OB/GYN's (ACOG) on dating pregnancies, up to 50% of women will be wrong about their gestational age when relying only on recall of their last menstrual period. For this reason, a pregnancy that has not had a first trimester ultrasound is considered sub optimally dated. A woman's risk of dying from an abortion [increases by 38%](#) for every week beyond 8 weeks gestation, and so confirmation of her gestational age is critical.

An ultrasound is also crucial to rule out an ectopic pregnancy, which can be life threatening if not detected. This cannot be diagnosed via a televisit or through symptom/risk factor screenings over the phone, as stated by [ACOG](#) – it requires an in person visit with an exam and ultrasound. This is particularly important since the symptoms of a life-threatening ruptured ectopic pregnancy mimic those of a medication abortion. Claims that allowing women to have Mifepristone delivered through the mail will put women who live hours from the closest medical care unit in danger – a woman experiencing hemorrhage related to her abortion or a ruptured ectopic pregnancy does not have hours and could die before she reaches a hospital.

Women who have an Rh negative blood type require an in person visit to receive a medication called Rhogam to prevent complications in future pregnancies. Even ACOG [admits](#) that it is standard medical care for women to receive Rhogam after a miscarriage or an abortion. Claims that this step can be skipped will potentially lead to the loss of future pregnancies from a disease known as rhesus isoimmunization.

These are not hypothetical scenarios. One of the largest [studies](#) to date analyzed high-quality registry data obtained from nearly 50,000 women in Finland who underwent abortions from 2000-2006 with a gestational duration of 9 weeks or less. This study found that the overall incidence of immediate adverse events is four-fold higher for medical abortions than for surgical abortions. In particular, this study indicated that hemorrhage and incomplete abortion are more common after medical abortions; the incidence of hemorrhage was 15.6 percent following medical abortions, compared to 2.1 percent for surgical abortions, and 6.7 percent of medical abortions resulted in incomplete abortion, compared with 1.6 percent of surgical abortions. This means that nearly 7% of women will need surgical intervention - a significant number when you consider how many abortions happen everyday in the U.S.

These figures do not tell the whole story, either. The true number of complications from use of a Mifepristone abortion regimen is much larger, since many studies show that on average 5-8% of women need emergency room visits for complications, and this does not even include the

number of surgeries done in the abortion clinics. [5% of the 3.7 million women who have used Mifepristone according to FDA estimates](#) means at least 185,000 women have suffered and needed surgery and medical treatment as a result. The FDA Mifepristone Adverse Event Reports represent only 1.73% of these women. And no one is systematically collecting data on the women hurt or killed by Mifepristone complications. The FDA knows that there are widespread inadequacies in reporting and the FDA itself [admits](#), for example, that it “does not receive reports for every adverse event... that occurs with a product.” This is in part because healthcare professionals are not required to report adverse events; rather, such reporting is voluntary.

It is impossible for a physician who is states away to safely, compassionately and fully care for a woman and ensure she has appropriate follow up. Abandoning our patients to the closest clinic or emergency room is not good medicine. We would like the FDA and ACOG to explain why women seeking abortions deserve substandard medical care that places their lives at risk. Mifepristone is a potentially dangerous medication for women, as evidenced by its black box warning label. Women deserve excellent healthcare – not the gross negligence that this decision by the FDA, at ACOG’s encouragement, provides.

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