



CLI Fact Sheet: An Abundance of Neglect FDA's Suspension of Medical Management of Abortion Pills

The decision by the U.S. Food and Drug Administration to suspend certain Risk Evaluation and Mitigation Strategies (REMS) for distribution of the abortion pill regimen is both unnecessary and medically unsound. The immediate impact of the decision will be to deprive women of [vital medical information](#) about their pregnancy and the health consequences of the mifepristone-misoprostol combination, which, international and domestic studies have shown, are associated with elevated rates of medical complications and emergency room visits when compared with surgical abortion. By focusing solely on COVID-19 infection and a handful of biased studies conducted since the beginning of the pandemic, the FDA's abdication of full enforcement of the REMS ignores an array of profound concerns.

1. Domestic and international studies alike demonstrate that the risks to women's health from the abortion pill regimen are higher than for surgical abortion, including a longer resolution (lasting on average 9-16 days), more pain and bleeding, possible visualization of the unborn human, and potential need for surgical completion due to retained pregnancy tissue, excessive bleeding, or failure to kill the fetus. A high-quality, records-linkage study of 42,000 abortions documented that 7% of women experiencing chemical abortions required surgery, and complications were four times more frequent in medical than in surgical abortions.¹
2. The FDA's suspension of enforcement of portions of the REMS follows its prior [mistaken decision](#) in the last year of the Obama administration to end the obligation of abortion pill providers to report adverse health events (AERS) to the FDA if those events are non-fatal. This egregious step was taken with the full knowledge that such events include hemorrhaging, infection, hospitalization, and the need for surgical abortion when the Mifeprex regimen fails to end the life of the unborn or to fully expel the developing child from the womb.
3. Contrary to the FDA's claim that it conducted a full literature search prior to its decision, a peer-reviewed [study of AERS published in January 2021](#) found a variety of serious and life-threatening conditions that were reported to the FDA and withheld from public knowledge. In addition to the FDA's laissez-faire attitude toward anything but fatal complications, most states fail to effectively track abortion complications generally, suffering from the fact that treatment of many complications, especially emergency room visits in the aftermath of abortion, are not traced back to the induced abortion.
4. Some women decide, when they are aware or made aware of the option, to attempt reversal of the abortion pill process by choosing not to consume the second pill in the regimen – misoprostol – but instead to take, under medical management, a course of progesterone to re-establish the fetal-maternal bond. Over [2,000 women](#) – as many as [two-thirds](#) of the women choosing this option – have proceeded to have their babies. Women are entitled to informed consent about the abortion pill, including the availability of this option. The FDA's negligence on this question will do nothing to alert women to their right to seek this remedial step.

¹ Niinimäki M., et al. (2009). Immediate Complications After Medical Compared with Surgical Termination of Pregnancy. *Obstetrics & Gynecology*, 114(4),795-804. doi: 10.1097/AOG.0b013e3181b5ccf9.

5. Previous [studies](#) of abortion pills by mail have acknowledged serious problems with the content of the pills shipped, the manufacturing quality of illegal overseas providers (whose price undercutting practices may encourage more women to purchase them), damaged packaging, lack of informed consent, and other issues. FDA's suspension will expose more women to these shipments if the lack of enforcement encourages the already-significant black market in abortion pills. Additionally, failure to perform a physical exam, ultrasound and labs before chemical abortions will increase the risk of failures due to underestimation of gestational age, ruptured ectopic pregnancies due to failure to make this diagnosis, and Rh isoimmunization when RhoGAM therapy is indicated but not given, which can result in stillbirth or brain injury to future children.
6. In addition to the medical issues cited above which can only be addressed by the kind of in-person, attentive medical care to which women are entitled, the FDA announcement turns a blind eye to the reality that abortion pills are a vehicle by which women can be subjected to chemical abortions without their knowledge or consent. The [sale of pills in bulk](#) also makes possible the intervention of sex traffickers who are left free to subject women and girls in their thrall to induced abortions in order to extend their servitude. These are criminal acts (see [here](#), [here](#), and [here](#)) that will be facilitated by the normalization of distribution of the pills via the mail.
7. [Evidence suggests](#) that the number and rate of abortions via Mifeprex are increasing in most states, alongside increases in total abortions. The FDA action to suspend enforcement of a portion of the REMS is likely to increase both numbers further, particularly with the FDA's blessing with respect to safety. State health agencies should take steps now to alert hospital ERs to this possibility, the potential that some women may have been advised not to share the truth about the cause of their medical condition, and the possibility of underlying conditions like ectopic pregnancy that may be life-threatening. The monitoring should lead to improved care in providing treatment and better data collection to assess the full impact of the FDA's rash and reckless step in suspending protocols that have existed to date under administrations regardless of political party.