AAPLOG

July 19, 2025

Martin A. Makary, M.D., M.P.H.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Commissioner Makary,

The American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) submits this comment in opposition to citizen petition FDA-2025-P-0377-0001, regarding the U.S. Food and Drug Administration's (FDA) regulation of mifepristone.

AAPLOG is a fifty-year-old professional medical organization that represents approximately 8,000 women's healthcare professionals across the country. We were founded to represent the vast majority of OB/GYNs who do not perform induced abortion, which intends the death of our fetal patients. We recognize based on the medical evidence that this practice is not healthcare, and we are passionate about providing excellent, evidence-based healthcare to ALL our patients.

Petitioners' erroneous claim re: maternal mortality

This citizen petition makes many false claims about the safety and necessity of mifepristone. One of the claims in the citizen petition is that access to mifepristone must be sustained or expanded to address the rising instance of maternal mortality across our country. However, in an emergency that requires an immediate end to a pregnancy (such as hemorrhage), surgical intervention is a faster life-saving intervention.[i]

Petitioners' erroneous claim re: mifepristone safety and complication reporting

Another false claim is "[t]here is no evidence that eliminating any of the former REMS restrictions (or changing the label indications) reduced mifepristone's safety" and "the ongoing requirement that mifepristone prescribers report the miniscule number of deaths following mifepristone use is extraneous." There is not a comprehensive understanding of the adverse events associated with mifepristone use because in 2016, the requirement to report all adverse events was removed – leaving only a requirement to report fatalities. Even when the mandate was in effect, it was frequently ignored. The passive Federal Adverse Events Reporting System (FAERS) is an unwieldy, voluntary reporting system and has also been documented to report only a small minority of drug adverse events. Reporting of ALL adverse events, including

fatalities, is needed to present an informed, full picture of mifepristone use to women, medical professionals, and the public.

Characterizing the deaths of women at the hands of mifepristone as "miniscule" and "extraneous" does not align with the excellent healthcare American women deserve. It ignores the reality that dozens of families mourn the loss of a loved one from a drug given for an elective indication and that they were assured was safe. Additionally, this kind of characterization by organizations that claim to care for women and their healthcare is problematic and troubling. Before any new action is taken regarding mifepristone, the FDA must conduct an impartial analysis of real-world data to assess the drug's safety and true complication rate.

Two reports were released in May analyzing insurance claims data on mifepristone, and their conclusions should serve as an urgent safety signal.[ii] These reports analyzed anonymized information from health insurance records covering 330 million U.S. patients across all payor types from 2017-2023. The reports detail an extensive analysis of data identifying more than 860,000 prescriptions of mifepristone for induced abortions. The analysis utilized specific diagnosis and healthcare codes (ICD-10) to measure the occurrence of emergency room visits and severe adverse medical conditions correlated with abortion in the 45 days after mifepristone use. According to the data, 10.93% of women experienced sepsis, infection, hemorrhaging, surgical intervention, or another serious adverse event (including undiagnosed ectopic pregnancy) within 45 days following mifepristone use in an abortion.

This is the most extensive analysis of *real-world data* on mifepristone use, and shows real patients experience very real medical emergencies at an alarming rate – a rate consistent with what our members are seeing in their clinical practice. The data strongly suggest that mifepristone poses a far greater risk of causing harm than previously stated. According to this data, as many as 1 out of every 9 women who use this drug suffered serious adverse events. This data is replicable, and we urge the FDA to review robust, high quality insurance-based data sources in assessing mifepristone's real world complication rate.

Given the significant changes that have been made to how mifepristone is dispensed and the patient screening that occurs before it is dispensed, the FDA should be conducting thorough post-marketing surveillance under current use with robust education of medical professionals most likely to see women who have taken mifepristone. Per the FDA's own website, this is a crucial component of ensuring any safety signals are detected related to a drug's use: "Because all possible side effects of a drug can't be anticipated based on preapproval studies involving only several hundred to several thousand patients, FDA maintains a system of postmarketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug approval process. FDA monitors adverse events such as adverse reactions and

poisonings. The Agency uses this information to update drug labeling, and, on rare occasions, to reevaluate the approval or marketing decision."[iii]

Petitioners' erroneous claim re: "safer than Tylenol"

Another of the petitioners' false claims is that mifepristone is "safer than Tylenol." However, as a recent peer-reviewed paper that did an in-depth analysis of this claim noted, "...these are entirely inappropriate comparisons that have never been...investigated in the rigorous scientific manner rightfully demanded of medical information...These are, therefore, dangerous and unfounded claims that are yet being presented to patients, policymakers, jurists, and the public as 'consensus' facts..."[iv]

In fact, even making this claim about the safety of mifepristone is a violation of the FDA's own guidelines on claims made in the public square via pharmaceutical advertisements. According to a legal analysis of the FDA's guidance on these kinds of claims, "Comparative claims regarding a drug's efficacy or safety are generally permitted if they are based on the approved indication of a drug to the same approved indication of another drug and are supported by scientifically appropriate and statistically sound data (e.g., head-to-head study, clinically relevant to patients, not false or misleading). Comparative claims should not suggest superior efficacy or safety based solely on the differences in product labeling or the results of two different studies."[v]

Petitioners' erroneous claim re: safety of "telehealth" abortion

Another of the claims in the citizens petition is that the elimination of in-person dispensing did not impact the safety of mifepristone and "telehealth protocols for medication abortion offer the same patient protections as in-person dispensing and provide an equivalent level of patient care." The former claim cannot be fully defended because there is not required reporting for all adverse events. Many studies comparing the two methods of distribution are plagued by large numbers of women lost to follow-up for whom outcomes and complications are unknown. Additionally, these abortion industry studies did not replicate the conditions of use the FDA has allowed. Whereas many of these studies utilized standard pre-abortion testing including ultrasound (and differed only in whether the woman was handed the pills in-person or whether they were mailed to her) or a hybrid model whereby a woman who screened positive for ectopic risk factors or advanced gestational age was offered an ultrasound, today many of the websites offering mifepristone do not perform any screening and do not have the ability to order an ultrasound.

As to the latter assertion, claiming that online dispensing of mifepristone occurs via "telehealth" is misleading and implies that women are interacting with a qualified medical professional virtually and are able to be asked questions specific to their particular situation as well as ask questions of the person providing the drugs. In many, if not most, circumstances,

this is not occurring. Women answer a few questions via an online form and then mifepristone is shipped to them. Not only does this prevent any meaningful screening for contraindications to mifepristone (such as gestational age >10 weeks or ectopic pregnancy) but it also negates informed consent. Truly informed consent cannot occur without an in-person physician visit before a woman takes the drug. A basic tenet of medical ethics is informed consent – which requires a review of accurate risks and benefits of any proposed intervention that is specific to the patient sitting in front of us, which is based on actual data, not ideologically-driven rhetoric. The American College of OB/GYNs (ACOG) itself states that women will often wrongly determine their gestational age, and there is no way for a woman to determine if she has an ectopic pregnancy or not without an ultrasound.[vi] Direct, in-person medical supervision is necessary for women's safety.

The petitioners want the FDA to lessen restrictions on advanced practice clinicians (APCs) being able to provide abortion-inducing drugs where permitted by state law. Unfortunately the current reality doesn't line up with these claims. Already several pro-abortion states have laws in place that do not require the prescribing physician's name to be on abortion-inducing drugs – drugs sent across state lines into pro-life states, directly undercutting those state laws. Further loosening of restrictions by the FDA will not honor the *Dobbs v. Jackson Women's Health* decision to return the issue of abortion to the states nor what President Trump has indicated his stance on induced abortion to be, but rather would empower pro-abortion states to override the will of the people as determined by pro-life states' laws. Additionally, high quality studies document at least 3-8% of women require surgical completion for failed chemical abortion, so the inability of APCs to perform the intervention needed by their patients results in many injured women presenting for urgent care in our country's already-overwhelmed emergency room system.

"Telehealth" abortion, bolstered by these laws of pro-abortion states, will prevent the essential follow up healthcare women deserve and require after taking mifepristone. Women obtaining mifepristone online often receive the drug from a provider who is out of state and completely unable to ensure that she is seen in a timely fashion if she experiences a complication. Instead, patients are abandoned to their local emergency rooms with no continuity of care. This is not a bug of the current system – it is a feature. And it is unacceptable.

Recommendations

AAPLOG emphatically disagrees with the petitioners that the FDA has not gone far enough in eliminating restrictions on mifepristone. The recently reported deaths of Candi Miller, Amber Thurman, Alyona Dixon, and other women highlight how recklessly far the FDA has gone in removing common sense restrictions on this dangerous drug. **We urge the FDA to reject these attempts to further remove the remaining restrictions and thereby place women in even more danger. Instead, we strongly urge you to reinstate the pre-2016 REMS.** Americans must

be able to trust that no matter what, the FDA will rely on the most robust safety standards before and after approving any drug and that they can have truly informed consent by knowing what the risks to taking FDA-approved drugs are.

Unfortunately, the latest data strongly suggest that hundreds of thousands of women have been harmed by mifepristone while believing that it is "safer than Tylenol", and the petitioners seem unconcerned by the dangers countless women are facing as a result. We owe the women of this country better.

We urge you to deny this citizen petition and reinstate the pre-2016 Risk Evaluation and Mitigation Strategies (REMS), including reporting of ALL adverse events, limiting use of the drug to 7 weeks gestation, and requiring in-person dispensing as well as follow up. We also ask the FDA to conduct its own independent and nonpartisan evaluation of real-world data to determine the overall safety of mifepristone in both the adult and adolescent populations and if your findings confirm the complication rate indicated by recent analyses of insurance claims data, we would urge consideration of removal of mifepristone from the market.

All of this we ask for the safety of our patients and the good of our profession.

Respectfully submitted,

Dr. Christina Francis
CEO
American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG)

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[i] https://lozierinstitute.org/handbook-of-maternal-mortality-addressing-the-u-s-maternal-mortality-crisis-looking-beyond-ideology/

[ii] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf; https://www.ffroa.com/wp-content/uploads/2025/04/FFROA-Chemical-Abortion-Data-Review.pdf

[iii] https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs

[iv] Louttit C. The Origins and Proliferation of Unfounded Comparisons Regarding the Safety of Mifepristone. BioTech. 2025; 14(2):39. https://doi.org/10.3390/biotech14020039

[v] Reeves, N.; Lundy, S.H.; Bañuelos, H.; Russell, G. The Legal 500 Country Comparative Guides: United States Pharmaceutical Advertising. 2023. Available online: https://www.kslaw.com/attachments/000/011/319/original/The_Legal_500_Country_Comparative_Guides_-_United_States_Pharmaceutical_Advertising.pdf?1702050651 (accessed on 19 June 2025)

[vi] https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date