July 8, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

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

Dear Secretary Kennedy and Commissioner Makary:

We write to you as medical organizations who represent approximately 30,000 medical professionals that are passionate about providing excellent, evidence-based healthcare to ALL our patients. In any medical decision a woman makes, we want her to have fully informed consent, and safety guidelines rooted in reliable data are integral to such consent.

Mifepristone is a high-risk abortion-inducing drug that is known to cause serious adverse effects and medical emergencies, including hemorrhage, sepsis, and incomplete abortions requiring surgical intervention. In 2000, after fast-tracking the approval process through subpart H, the FDA approved mifepristone with specific safeguards in place to minimize the likelihood of these serious and potentially life-threatening adverse events. Since then, these safeguards have been progressively dismantled to the point where women are now receiving these drugs with little to no medical consultation beforehand and without any meaningful follow up care afterwards.[i] This has a significant public health impact as at least 63% of all abortions are now drug induced.[ii]

Two reports were released in May analyzing insurance claims data on mifepristone, and their conclusions should serve as an urgent safety signal.[iii] 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 the 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 that is 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. **In fact, the risk of serious complications may be 22 times higher than previously disclosed.**

The FDA has claimed that the rate of severe adverse effects from mifepristone is <0.5%, and yet in doing so they ignored some of their own data, including hemorrhage rates altogether. These recent real-world use reports signal the need for immediate further study and analysis of mifepristone's real-world risks. As you are aware, this kind of in-depth, follow-up safety review is common for a drug, as its real-world complication rate can differ greatly from clinical trials. **According to this data, as many as 1 out of every 9 women who use this drug suffered serious adverse events.**

Abortion proponents have often claimed 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]

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. Women deserve to know the true risk of serious adverse events and medical emergencies after using mifepristone – no matter how politically charged the discussion surrounding this drug. Such truly informed consent cannot occur without an in-person physician visit before a woman takes the drug. Direct, in-person medical supervision is necessary for women's safety.

**In light of all this, we urge the FDA to immediately reinstate reporting of ALL adverse events related to mifepristone use and reinstate the pre-2016 Risk Evaluation and Mitigation Strategies (REMS), including limiting use of the drug to 7 weeks gestation and requiring in-person dispensing as well as follow up. We also urge the FDA to require ultrasounds to confirm gestational age (crucial to accurately dating a pregnancy and determining the risk of complications) and to rule out ectopic pregnancy, which is a life-threatening condition.[vi]**

**This data is easily reproducible. We also ask the FDA to conduct its own evaluation of real-world data to determine the overall safety of mifepristone in both the adult and adolescent populations. This could be done through a partnership with NIH to evaluate insurance claims data from Medicaid, Tricare, and commercial insurance databases that would include data from across the country.**

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 suggests that

hundreds of thousands of women have been harmed by mifepristone while believing that it is "safer than Tylenol".

We urge you to address this public health crisis expeditiously, for the safety of our patients and the practice of good medicine.

Respectfully,

Christina Francis, MD, dip ABOG
CEO, American Association of Pro-Life OB/GYNs (AAPLOG)

Mike Chupp, MD, FACS
CEO, Christian Medical and Dental Associations (CMDA)

Michael Artigues, MD, FCP
President, American College of Pediatricians (ACPeds)

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Ayman Iskander, MD, FACC, FSCAI
Treasurer, Coptic Medical Association of North America (CMANA)

Donna Harrison, MD
Chair of the Board, Alliance for Hippocratic Medicine (AHM)

[i] https://www.supremecourt.gov/DocketPDF/23/23-235/279230/20230908165000535_USFDA%20et%20al.%20v.%20Alliance%20for%20Hippocratic%20Medicine%20et%20al.%20Petition.pdf

[ii] https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020

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

[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