January 8, 2026

The Honorable Martin A. Makary, M.D., M.P.H.

Commissioner, U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

The Honorable Robert F. Kennedy Jr.

Secretary, U.S. Department of Health and Human Services

200 Independence Avenue, S.W.

Washington, DC 20201

Dear Commissioner Makary and Secretary Kennedy,

As representatives of tens of thousands of pro-life obstetricians/gynecologists, pediatricians, family physicians, and other medical professionals dedicated to evidence-based care for women and their preborn children, we are deeply concerned to hear the news that the U.S. Food and Drug Administration (FDA) may be delaying its full review of the safety of mifepristone.

In congressional hearings and subsequent letters to state attorneys general and members of Congress over the past year, the FDA committed to conducting a thorough, independent review of real-world safety data for this abortion drug—data that recent papers indicate reveal serious complication rates far higher than previously disclosed on the FDA label, including hemorrhage, sepsis, and incomplete abortions requiring surgical intervention.

Two reports analyzing insurance claims for 330 million U.S. patients (2017–2023) identified more than 860,000 mifepristone prescriptions and tracked adverse events within 45 days of use. **Alarmingly, 10.93% of women experienced severe complications, including infection, hemorrhage, surgical intervention, or undiagnosed ectopic pregnancy.**[1] This rate is consistent with what our clinicians observe and suggests the true risk may be *22 times higher* than previously disclosed.

As we stated in our previous letter sent in July of this year, when the FDA approved mifepristone in 2000 under Subpart H, it did so with safeguards designed to reduce these risks.[2] These

[1] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf

[2] FDA-Letter-July-2025_FINAL-1.pdf.pdf

essential safeguards were eventually formalized under the REMS program due to ongoing safety concerns (including the addition of a black box warning related to fatal infections in 2006). Over time, those safeguards have been dismantled, leaving women with little to no medical oversight before or after taking the drug – most egregiously when the Biden administration made this high-risk drug available through the mail with no medical evaluation or ongoing care. Today, at least 63% of abortions are done with this drug, amplifying the public health impact of these changes.[3] Without a national abortion reporting law and in the absence of adequate safeguards, the actual impact on public health is likely even higher.

Despite admitting that removal of in-person dispensing requirement would likely lead to more emergency room visits and complications, the FDA, nearly one year into the current administration, has yet to produce an analysis of the public health impact of this change or the previous 2016 changes, all while quietly approving a second generic drug and continuing to cite a serious complication rate of less than 0.5% (which ignores key data such as hemorrhage rates).

Such blatant disregard for the health and safety of women and willful ignorance of what is occurring in emergency departments across the country undermines informed consent and public trust. Claims that mifepristone is "safer than Tylenol" are not only scientifically unfounded but also violate FDA guidelines on comparative safety claims.[4]

We were promised a thorough review, but instead the medical community has received empty words and delayed actions. Commissioner Makary has stated that ongoing evaluations (which are a requirement of the REMS program) are occurring and that one of the reasons for that is to identify any new complications that were not previously documented. How can this be?[5] The FDA stopped collecting data on mifepristone complications in 2016, despite making major changes at that time and again in 2021 that would affect the rate of complications. Additionally, if ongoing safety evaluations have been occurring, where are the results of those evaluations, and what data is the FDA relying on? As clinicians who are actively providing care to women experiencing serious complications related to this drug, not only do we deserve these answers, but they are also indispensable for providing fully informed consent to our patients.

We ask the FDA to do its job and give us accurate (and real-world) data to provide women with correct medical information. The continued availability of these drugs without rigorous oversight—particularly via mail-order distribution—increases risk for harm for our patients,

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[3] https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020
[4] The Origins and Proliferation of Unfounded Comparisons Regarding the Safety of Mifepristone | MDPI
[5] https://www.dailysignal.com/2025/12/09/exclusive-makary-responds-report-saying-he-slow-walked-abortion-pill-safety-review/

empowers coercion and abuse, and leaves women abandoned to their local emergency room (many of which are already extremely full) for care when they experience severe complications. It is the ultimate example of patient abandonment.

On December 18, at a press conference regarding sex-denying interventions, Secretary Kennedy said the following: "This is not medicine – it is malpractice. We're done with junk science driven by ideological pursuits, not the well-being of children."[6] We agree and ask that this same commitment to evidence-based healthcare for women and children be applied to this issue.

As physicians who uphold the Hippocratic oath to do no harm, we oppose any delay in a much-needed safety review of mifepristone that prioritizes political expediency over patient safety.

This administration has the chance to do right by women and undo the previous administration's damage immediately. We urge the FDA to:

- **Immediately reinstate the in-person dispensing requirement for mifepristone, which would restore the regulations in place under the first Trump administration.**
- **Immediately reinstate required reporting of all adverse events directly to the FDA by any medical professional caring for the patient.** The manufacturers should not be relied upon to report these.
- **Conduct an urgent, thorough review of mifepristone's safety, which should include a comprehensive evaluation of real-world safety data** in partnership with NIH, using Medicaid, Tricare, and commercial insurance claims.
- **Restore pre-2016 REMS safeguards**, including:
    - Limiting use to seven weeks gestation (as the rates of complications increase significantly starting at eight weeks gestation)
    - Requiring in-person follow-up care
- **Require ultrasounds** to confirm gestational age and rule out ectopic pregnancy.[7]

It's time for this administration to fulfill its commitment to women and the medical community and address this public health crisis with the seriousness and urgency it requires.

We stand ready to provide expert input and data from our members to support this process.

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[6] Robert F. Kennedy Jr. says HHS won't fund 'sex-rejecting procedures': 'It is malpractice' | New York Post

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

Respectfully,

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