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December 10, 2025

Dr. Marty Makary
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Commissioner Makary:

Six months ago, you told me you were "committed to conducting a review of mifepristone," the chemical abortion drug. You repeated this commitment to state attorneys general and other members of Congress. Yet according to news reports yesterday, you have ordered this promised safety review delayed until after the midterms. Indeed, it is unclear whether you are conducting an independent safety review at all.

This is totally unacceptable. I cannot emphasize enough the danger of playing politics with women's health. In President Trump's first term, HHS required an in-person visit with a licensed physician before dispensing the chemical abortion drug. The safety rules also required in-person dispensing of the drug in a clinical setting. But Joe Biden removed those guardrails. Now, new studies from more than 865,000 insurance claims report that nearly 11% of women using mifepristone suffer a serious adverse health event—like sepsis or hemorrhaging—within 45 days.[1] That is 22 times the likelihood of risk currently listed on mifepristone's "black box" warning. The safety regulations from President Trump's first term should be reinstated.

But you have not done so. And news reports indicate you are attempting to sideline any review of mifepristone safety. In fact, you have repeatedly wavered in public on whether you are conducting a safety review at all. On April 24, you told an interviewer you had "no plans to take action" on mifepristone.[2] You wrote to me on June 2, however, that you were "committed to conducting a review of mifepristone." Then, a few months later, you reversed course again and inexplicably approved a *new* generic abortion drug, with no meaningful safety guardrails or conditions. Despite your claims to the contrary, that approval was in no way compelled by law.

Yesterday, in response to the latest reports, you said, "There has been an ongoing review of mifepristone. It's actually required as part of a policy called REMS."[3] But that is not what you promised. You promised a new and comprehensive study taking account of all available safety data, not the standard monitoring FDA already performs for countless drugs.

There are more abortions in America now than when *Roe* was still law. And this is largely because of the chemical abortion drug and its generics, like the one you approved. Chemical abortions account for almost 70 percent of all abortions nationwide. The science is clear. The chemical abortion drug is not safe.

It is time for direct answers about what, precisely, FDA is doing. Please answer the following questions by no later than Monday, December 15, 2025:

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[1] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf
[2] https://www.semafor.com/article/04/24/2025/fdas-marty-makary-no-plans-to-pull-abortion-pill-mifepristone
[3] https://x.com/TheElizMitchell/status/1998527302011924941

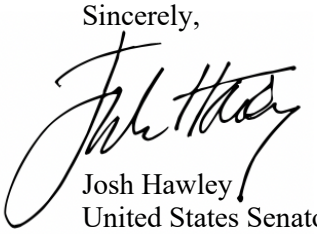
1. Is the FDA conducting a comprehensive safety review of mifepristone separate from the REMS process?
    a. When did it begin?
    b. Please provide a specific timeline for its completion.

2. If you are conducting a comprehensive safety review, did you order it to be delayed?
    a. Why?
    b. Until when?

3. Does the FDA have any plans to update the Mifepristone Risk Evaluation and Mitigation Strategy (REMS) to restore basic safety guardrails from President Trump's first term, such as in-person dispensing?

I await your responses.

Sincerely,



Josh Hawley
United States Senator