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July 22, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Dear Secretary Kennedy:

I write to thank you for your expressed commitment to review the safety data on mifepristone following the publication of alarming new safety studies and to once again request swift action on this matter to protect American women.

On April 28, I sent a letter to Food and Drug Administration (FDA) Commissioner, Dr. Marty Makary, asking for a timely review of the safety of mifepristone in response to shocking new data showing high adverse event rates for mifepristone. Dr. Makary sent me a letter in response expressing a commitment to conducting such a review. I am grateful to both you and Dr. Makary for undertaking this critical work.

As I have shared with you, recent studies using insurance claims data to conduct post-market safety analyses have raised serious concerns about the chemical abortion drug. Researchers with the Foundation for the Restoration of America and Ethics and Public Policy Center found that about 11% of women who take mifepristone for an abortion experience a serious adverse health event—a rate 22 times higher than the FDA claims.[1] Additionally, a follow-up Ethics and Public Policy Center study based on the same data shows that for pregnancy termination, mifepristone had a 5.26% failure rate, which is significantly higher than the rate listed on the FDA label.[2]

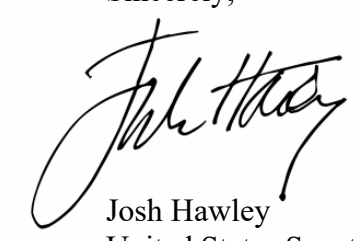
Despite these documented safety risks, online providers continue to distribute mifepristone in violation of FDA guidelines and State laws. Recent investigative reporting has demonstrated that abortion drugs can be easily obtained online in a manner outside of the FDA's approved use or without confirming a pregnancy at all.[3] This environment poses serious and potentially life-threatening consequences for American women.

[1] https://www.ffroa.com/chemical-abortion-research/
[2] https://eppc.org/news/new-study-of-abortion-pill-reveals-startling-failure-rate/
[3] https://dailycaller.com/2025/06/19/chemical-abortion-pill-order-online/

I eagerly await the results of your review of mifepristone safety data. In the meantime, I urge you to reverse changes to the mifepristone Risk Evaluation and Mitigation Strategy (REMS) made during Democrat presidential administrations that weakened protections for women. Previous requirements such as in-person visits with a provider, follow-up visits, and adverse event reporting must be immediately reinstated to protect women against serious complications and bolster informed consent. Furthermore, I ask that you take swift action against abortion drug providers that distribute mifepristone contrary to federal regulations. These actions would go a long way toward protecting women's health and safety.

Thank you for your attention to this important matter.

Sincerely,



Josh Hawley
United States Senator