

May 14th, 2025

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

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

Dear Secretary Kennedy and Commissioner Makary:

We write with gratitude to thank you for what you are doing to safeguard the lives, health, and wellbeing of all Americans. In the face of a dangerous drug, American women deserve the same resolve.

The recent revelation of commercial insurance data from 865,727 prescribed chemical abortions between 2017 and 2023 showing 94,605 women suffered serious adverse events indicates that more than one out of ten women are put at risk by mifepristone. This real-world rate is twenty-two times greater than the rate claimed by the FDA.

The danger this drug poses to women and girls is clear. Nearly 11% of women taking mifepristone experience sepsis, infection, hemorrhage, or another serious adverse event within 45 days of taking the drug. Yet the FDA under the Obama and Biden administrations not only removed the Risk Evaluation and Mitigation Strategy (REMS) requirements to report these serious consequences, it also removed protections like requiring a provider to meet with a woman in person before prescribing the drug to rule out dangerous conditions like ectopic pregnancies. The FDA also removed requirements for the provider to follow up with a woman in person to check on her condition after she ingests mifepristone. It even removed the requirement that a doctor be involved at any stage in the chemical abortion process.

The FDA exists to “protect[] the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices,” and its guidelines are intended to “help[] the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.”¹ In short, the FDA’s purpose is to safeguard the health and safety of Americans. In the case of mifepristone, these bedrock principles—necessary not only for the trust of Americans, but also for the safety of women—have been undermined by political whims that obscured the growing evidence of mifepristone’s harm.

We encourage the Administration and FDA to put the safety of women first and take a serious look at the data showing chemical abortion is neither safe nor effective. To start, the FDA should reinstate the previous protections for women prescribed mifepristone. The evidence

¹ *What We Do*, Food and Drug Administration, <https://www.fda.gov/about-fda/what-we-do>.

strongly suggests that mifepristone is unacceptably dangerous, and those who removed such protections put American women directly in harm's way.

Thank you for ending the political games of the past and working to promote the health and wellbeing of all Americans.

Respectfully,

Americans United for Life
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Ethics and Public Policy Center
Ryan Anderson, President

1792 Exchange
Douglas H. Napier, Executive Chairman

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