

Congress of the United States
Washington, DC 20510

February 18, 2022

The Honorable Robert Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Califf:

We write to express our deep concern regarding the December action by the Food and Drug Administration (FDA) to permanently eliminate longstanding patient safeguards associated with the chemical abortion drug mifepristone.

Removing the in-person dispensing requirements from the drug's Risk Evaluation and Mitigation Strategy (REMS) and permitting mail-order dispensing of this drug will increase risks to women. This action recklessly ignores the clear data showing the dangers of chemical abortions and abandons FDA's responsibility for ensuring safety of drugs.

Mifepristone is the first part of the two-drug chemical abortion process. It blocks progesterone, a hormone that nurtures the developing child throughout the pregnancy. It is prescribed in combination with a second drug, misoprostol, which forces the uterus to contract and expel the unborn baby. This chemical abortion process is a multi-day progression of bleeding, cramping, and contracting that according to the Mifeprex [®] medication guide may take up to 30 days to complete.¹

In addition to the loss of the unborn child, chemical abortion drugs present serious risk to the health of the mother, including severe bleeding, infection, the need for surgical intervention, and even death.² In fact, chemical abortions are four times more dangerous than surgical abortions.³ These health risks necessitate, at minimum, in-person screening by a physician. Pregnant mothers need to be screened in-person for contraindications like an ectopic pregnancy and the age of their baby to prevent life-threatening complications. They should also be tested for blood type and Rh factor to protect their fertility,⁴ examined after taking the drugs because of

¹ <https://www.fda.gov/media/72923/download>

² <https://lozierinstitute.org/the-no-test-medication-abortion-protocol-experimenting-with-womens-health>

³ <https://pubmed.ncbi.nlm.nih.gov/19888037/>

⁴ Ingrid Skop, M.D., "The 'No-Test Medication Abortion' Protocol: Experimenting with Women's Health", July 30, 2020, Charlotte Lozier Institute, <https://lozierinstitute.org/the-no-test-medication-abortion-protocol-experimenting-with-womens-health>.

the risk of infection from an incomplete abortion.⁵ Furthermore, allowing these drugs to be dispensed without physician oversight makes it easier for the drug to fall into the hands of abusers who may give them to pregnant women without their knowledge and consent.⁶

Recognizing these grave risks, FDA put in place rules to protect the women who take these drugs by implementing a REMS for mifepristone. FDA can require a REMS when a drug has “serious safety concerns” and the REMS are necessary to address the “specific serious risk” associated with the drug.⁷

Under the mifepristone REMS, the drug had to be ordered, prescribed, and dispensed by a qualified healthcare provider in a clinic, medical office, or hospital.⁸ FDA’s action to indefinitely repeal basic, commonsense safeguards is reckless and exposes women to unnecessary risks.

Even with the stronger REMS in place, mifepristone posed serious risks that have been increasing over time. A first-of-its-kind longitudinal study, published in November 2021 found that the rate of abortion-related emergency room visits following a chemical abortion increased by more than 500 percent from 2002 through 2015.⁹ This study looked at Medicaid claims data from the 17 states where taxpayer funds pay for abortion and is consistent with similar studies of chemical abortion in Finland¹⁰ and Sweden.¹¹ The FDA decision ignores these studies, which all confirm the risks from mifepristone are serious and increasing.

Make no mistake: the relaxation of these requirements will hasten a new regime of mail-order abortion, where women ingest these dangerous medications alone without any meaningful oversight from a doctor. Without physician involvement and the associated quick access to care in the case of adverse events, women are likely to face additional complications from these do-it-yourself chemical abortions.

Indefinitely eliminating the REMS in-person requirement eliminates the minimal guardrails established to protect women’s health. This action promotes mail-order abortion-on-demand and disregards the growing threat to women’s health posed by chemical abortion drugs. Further, the agency abandons vulnerable pregnant women to the reckless and predatory actions of the abortion industry. In light of comprehensive data showing increasing risks to women, the FDA should strengthen the REMS, rather than loosen them. Therefore, we call on FDA to immediately rescind its removal of the in-person dispensing requirement and to strengthen the REMS in order to protect women’s health.

⁵ Ibid.

⁶ Ibid.

⁷ <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems>

⁸ <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information>

⁹ <https://journals.sagepub.com/doi/full/10.1177/23333928211053965>

¹⁰ <https://pubmed.ncbi.nlm.nih.gov/19888037/>

¹¹ <https://pubmed.ncbi.nlm.nih.gov/30253769/>

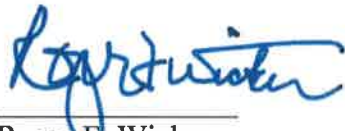
Sincerely,



Cindy Hyde-Smith
United States Senator



Robert E. Latta
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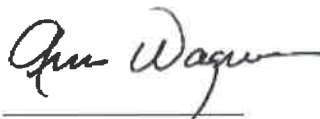
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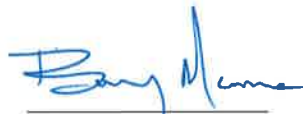
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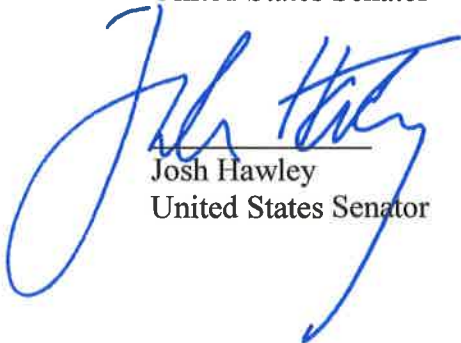
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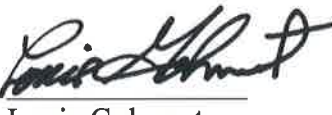

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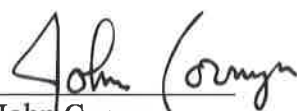

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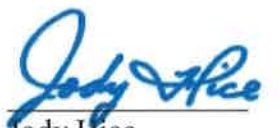

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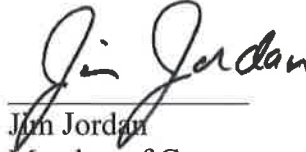
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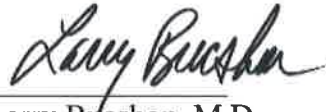
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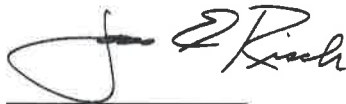
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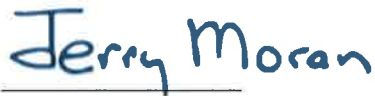
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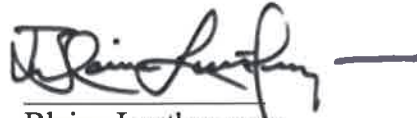
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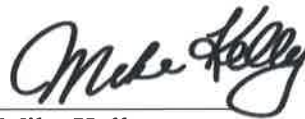
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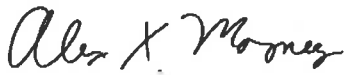
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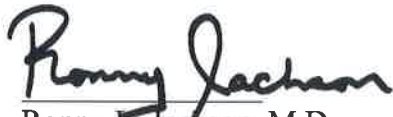
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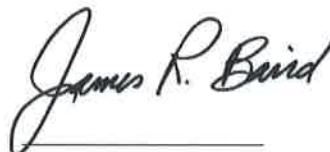
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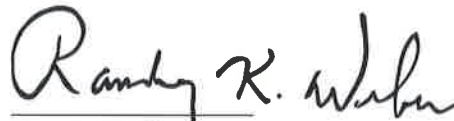
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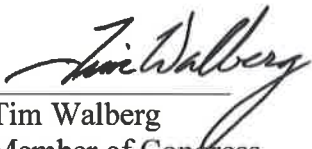


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