Congress of the United States
Washington, DC 20510

January 11, 2023

The Honorable Robert Califf, MD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We are writing to share our deep concerns after the U.S. Food and Drug Administration's (FDA) decision to modify the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone. This change, intended to increase access to a chemical abortion drug for the purpose of inducing an elective abortion, will fundamentally harm the pharmacist-patient relationship and is contrary to the FDA's mission statement of protecting public health by ensuring the safe use of pharmaceuticals.

As you know, mifepristone is approved for use ten weeks or less from a woman's last menstrual period to terminate a pregnancy. In addition to killing her unborn baby, consuming mifepristone poses significant health risks for pregnant women. By expanding access to retail pharmacies and removing the in-person requirement for dispensing mifepristone, the FDA has sacrificed important safeguards against potential misuse and harm, jeopardizing the safety of patients.

As explained by the American Association of Pro-Life OBGYNS (AAPLOG), "An in-person visit is medically necessary and sound medical practice because it ensures that every woman receives a full evaluation for any contraindications to a medication abortion."[1] The evaluation includes an ultrasound to rule out ectopic pregnancy, the provision of Rhogam to women with an Rh negative blood type to prevent future pregnancy complications, and accurate dating of the pregnancy. Even when the in-person dispensing requirement for mifepristone was in place, the drug threatened the health of women.

Between 2000 and 2022, over 4,200 adverse events were reported to the FDA, including at least 28 deaths, more than 1,000 life-threatening complications, and over 2,100 severe complications.[2] Chemical abortion data in the United States is severely incomplete[3], so a comprehensive dataset provided in a Finnish study provides a clearer picture of the danger. It found that women who underwent a chemical abortion were four times more likely to experience an adverse event than women who had another type of abortion.[4]

[1] https://aaplog.org/wp-content/uploads/2021/04/AAPLOG-Statement-on-FDA-removing-mifepristone-REMS-April-2021-1.pdf
[2] https://www.fda.gov/media/164331/download
[3] https://journals.sagepub.com/doi/full/10.1177/23333928211068919
[4] https://pubmed.ncbi.nlm.nih.gov/19888037/

Modifying the REMS to remove the in-person dispensing requirement will turn many post offices and pharmacies into abortion clinics. It is not in the best interest of patients, including the mother and unborn child. It shows a complete disregard for protecting mothers and unborn children that will result in more innocent lives lost. Instead, the FDA should be focused on protecting life.

These decisions are dangerous and will have disastrous consequences. We urge you to rescind this approved modification immediately.

Sincerely,

Earl L. "Buddy" Carter
Member of Congress

Jeff Duncan
Member of Congress

Brad R. Wenstrup, D.P.M.
Member of Congress

August Pfluger
Member of Congress

William R. Timmons, IV
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Debbie Lesko
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