Congress of the United States
Washington, DC 20515

September 25, 2019

Norman Sharpless, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, MD 20993

Dear Acting Commissioner Sharpless,

We write to express our concerns about the effectiveness of the current Risk Evaluation and Mitigation Strategy (REMS) for mifepristone in light of the recent approval of a generic version and growing calls from abortion providers and advocates to remove restrictions. The use of mifepristone as a method to kill unborn babies has increased despite its proven health risks to women, and we are concerned that having this drug more readily available will have deeply troubling results.

Mifepristone, first approved in the United States in 2000, was previously only marketed under the brand name Mifeprex. Mifepristone is the first part of a two-drug chemical abortion process. It blocks progesterone, a hormone that nurtures the developing child throughout the pregnancy. By blocking the progesterone, mifepristone causes the mother's body to stop nourishing her unborn child. A second medication, misoprostol, is consumed to force the uterus to contract and expel the unborn baby.[1] Taking mifepristone to induce a chemical abortion is not a simple process. It is a multi-day progression of bleeding, cramping, contracting that, according to the Mifeprex ® medication guide may take up to 30 days to complete.[2]

In addition to the tragedy of aborting the unborn child, mifepristone presents serious health risks to the mother. The FDA has put in place REMS for mifepristone. REMS are required by the FDA for medications with serious safety concerns.[3] The REMS for mifepristone require it to only be dispensed by a certified prescriber in a clinic, medical office or hospital, and requires women to be informed of the potential complications associated with taking the drug. Healthcare providers who wish to become a certified prescriber must follow all guidelines listed in the REMS including a comprehensive review of the prescribing information and must sign a Prescriber Agreement Form to certify their ability to assess the gestation period accurately. Prescribers must also be able to diagnose an ectopic pregnancy (pregnancy outside the womb) and provide surgical intervention if necessary.[3]

These REMS, which now include the new generic mifepristone, do not go far enough to protect patient health. According to one study, women who have chemical abortions experience roughly four times the rate of adverse events as women whose babies are surgically aborted.[4]Although complete data is not available, the FDA reports that, since mifepristone was first approved on September 28, 2000, twenty-four women have died and thousands of women have experienced adverse events.[5] These include hospitalization, blood loss requiring a transfusion, severe or fatal infection, or ruptured ectopic pregnancies.[6] Even though the REMS require a provider who dispenses mifepristone to test for ectopic pregnancy, the FDA reports that at least 97 women with ectopic pregnancies have been given mifepristone; at least two women died

---

[1] Medication Guide (7/19/05), U.S. Food and Drug Administration, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020687s015MedG.pdf.
[2] Medication Guide (7/19/05), U.S. Food and Drug Administration, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020687s015MedG.pdf.
[3] Risk Evaluation and Mitigation Strategies (8/8/19), U.S. Food & Drug Administration, https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems.
[4] Maarit Niinimäki, M.D., et al., "Immediate Complications after Medical Compared with Surgical Termination of Pregnancy," 114 *Obstetrics & Gynecology* (Oct. 2009): 795-804. This study uses abortion outcome data collected in Finland, where medical registries used to track the government-based health care provided.
[5] Mifeprex Label, Reference ID: 3909592 (3/16), U.S. Food and Drug Administration, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[6] Mifeprex Label, Reference ID: 3909592 (3/16), U.S. Food and Drug Administration, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

from ruptured ectopic pregnancy.[7] According to one study, an incomplete abortion can happen at least up to 10 percent of the time during chemical abortions and the risk increases after the 9th week of pregnancy.[8]

We vigorously oppose calls by Planned Parenthood[9] and other pro-abortion advocates[10] to remove the REMS for mifepristone. Allowing the drug to be available without medical supervision will have dire consequences for women and children. On the contrary, we agree with the American Academy of Pro-Life Obstetricians and Gynecologist (AAPLOG) that the current REMS offer insufficient protection for patients. At the least, it should be limited to 49 days' gestation (instead of the current 70 day limit), it should be administered under the supervision of a physician (instead of the currently-mandated "health care provider" who may be unable to rule out ectopic pregnancy and provide adequate care), and it should require three office visits by the patient.[11] To better understand the extent of the threat mifepristone poses to patients, the FDA should also mandate collecting complete, accurate information on all adverse events related to the drug. Since 2016, prescribers are only required to report deaths associated with mifepristone. Please consider reestablishing all four of these components from the 2000 REMS for mifepristone.

In order to discuss this matter further, we request a meeting with you by October 1, 2019. We appreciate your attention to these requests and look forward to reviewing a timely response.

Sincerely,

Jim Banks
Member of Congress

Robert E. Latta
Member of Congress

Doug Lamborn
Member of Congress

Mike Kelly
Member of Congress

Vicky Hartzler
Member of Congress

Jeff Fortenberry
Member of Congress

---

[7] RCM # 2007-525, NDA 20-687, Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018, U.S. Food and Drug Administration, https://www.fda.gov/media/112118/download.

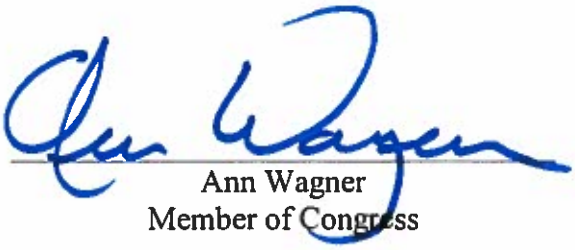
[8] P. Sanhueza Smith, et al., "Safety, Efficacy and Acceptability of Outpatient Mifepristone-Misoprostol Medical Abortion Through 70 Days Since Last Menstrual Period in Public Sector Facilities in Mexico City," Reproductive Health Matters 22 (2015): 75-82, accessed May 6, 2015, https://www.ncbi.nlm.nih.gov/pubmed/25702071

[9] Former FDA Chief, Planned Parenthood: Remove 'Abortion Pill' REMS (8/21/19), Inside Health Policy, https://insidehealthpolicy.com/inside-drug-pricing-daily-news/former-fda-chief-planned-parenthood-remove-'abortion-pill'-rems.

[10] Jane E. Henney, M.D., et al., "Time to Reevaluate U.S. Mifepristone Restrictions," 381;7 *The New England Journal of Medicine* (Aug. 2019): 597-598.

[11] Citizen Petition from American Association of Pro-Life Obstetricians and Gynecologists and American College of Pediatricians, March 29, 2019, https://www.regulations.gov/document?D=FDA-2019-P-1534-0001.

Ralph Abraham, M.D.
Member of Congress



Ann Wagner
Member of Congress

Greg Gianforte
Member of Congress

Andy Harris, M.D.
Member of Congress

K. Michael Conaway
Member of Congress

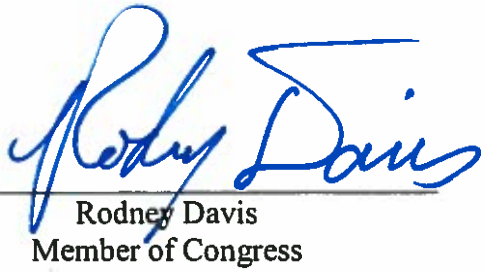
Ron Wright
Member of Congress

Steve Chabot
Member of Congress

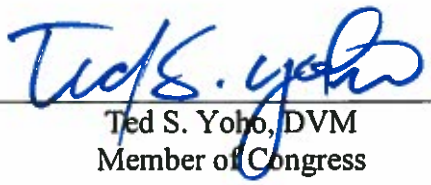
Jeff Duncan
Member of Congress

Bill Flores
Member of Congress

Gus M. Bilirakis
Member of Congress



Rodney Davis
Member of Congress



Ted S. Yoho, DVM
Member of Congress

Austin Scott
Member of Congress

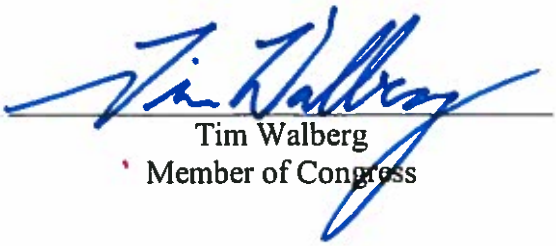
Roger Marshall, M.D.
Member of Congress

Glenn Grothman
Member of Congress

Bob Gibbs
Member of Congress

Ron Estes
Member of Congress

Bradley Byrne
Member of Congress



Tim Walberg
Member of Congress

Paul A. Gosar D.D.S.
Member of Congress

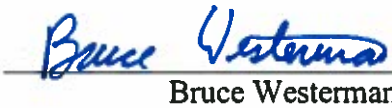
Doug LaMalfa
Member of Congress

Jim Jordan
Member of Congress

Jody Hice
Member of Congress

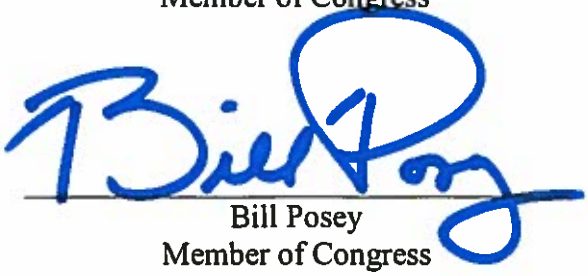
Andy Biggs
Member of Congress

Blaine Luetkemeyer
Member of Congress



Bruce Westerman
Member of Congress

Buddy Carter
Member of Congress



Bill Posey
Member of Congress

Mark Meadows
Member of Congress

Pete Olson
Member of Congress

Ralph Norman
Member of Congress

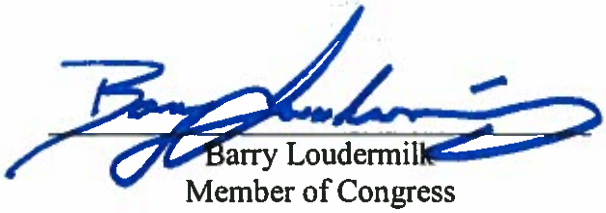
Randy Weber
Member of Congress

Rick W. Allen
Member of Congress

Roger Williams
Member of Congress

David Rouzer
Member of Congress

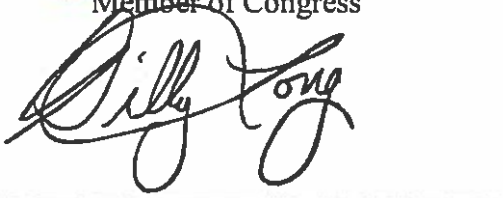
Brian Babin, D.D.S.
Member of Congress



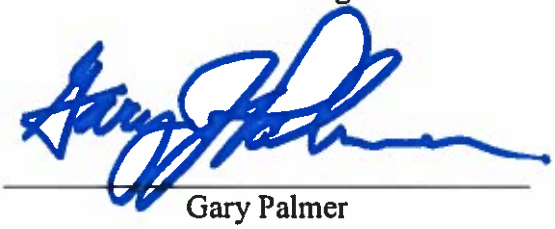
Barry Loudermilk
Member of Congress

John Ratcliffe
Member of Congress

Debbie Lesko
Member of Congress



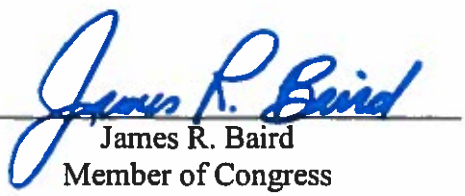
Billy Long
Member of Congress



Gary Palmer
Member of Congress

John Rutherford
Member of Congress

Steve Watkins
Member of Congress



James R. Baird
Member of Congress

Ted Budd
Member of Congress

Rick Crawford
Member of Congress

John Rose
Member of Congress