Congress of the United States
Washington, DC 20515

April 22, 2021

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

Dear Acting Commissioner Woodcock:

We write to express our concerns with the recent action by the Food and Drug Administration (FDA) not to enforce the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone for the remainder of the COVID-19 public health emergency. Proponents of removing the REMS ignore both the extremely limited data available from the FDA regarding the potential health impacts on women and the international data indicating that one in five women who undergo chemical abortions are likely to experience adverse events. To protect the health of women, the REMS should be strictly enforced, both during the public health emergency and after it ends.

Mifepristone, first approved in the United States in 2000, is the first part of a two-drug chemical abortion process. It blocks progesterone, a hormone that nurtures the developing child throughout the pregnancy. A second medication, misoprostol, is consumed to force the uterus to contract and expel the unborn baby. Taking mifepristone to induce a chemical abortion is not a simple process. It 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, mifepristone presents serious health risks to the mother, including "serious and sometimes fatal infections" and "prolonged, heavy bleeding".[2] For that reason, the FDA put in place a Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, indicating it is a medication with serious safety concerns. Currently, the REMS for mifepristone requires 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. Prescribers must also be able to diagnose an ectopic pregnancy (pregnancy outside the womb) and provide surgical intervention if necessary.[3] If the chemical

---

[1] https://www.fda.gov/media/72923/download
[2] Mifeprex label, 2016. Food & Drug Administration. Revised March, 2016. <https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf>
[3] (Risk Evaluation and Mitigation Strategies \ REMS. Food & Drug Administration. <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems>

abortion drug is taken with an undiagnosed ectopic pregnancy, it can kill the woman, or at minimum require invasive, life changing surgery.

In the years since FDA approval, Mifeprex has been used by over 4 million women in the United States.[4] The most complete analysis of the adverse events received by the FDA has been published most recently in 2021.[5] The drug company that manufactures Mifeprex acknowledges that 2-7% of women will need a follow up surgical procedure[6], and a systematic review by abortion advocacy researchers similarly confirmed this to be 5% of women needing a follow-up surgical completion.[7]

The most widely accepted definition for the frequency of drug complications is given by the Council for International Organizations of Medical Sciences (CIOMS), an international, non-governmental, non-profit organization established jointly by World Health Organization and United Nations Educational, Scientific and Cultural Organization in 1949. The CIOMS training manual on medicine safety states that "adverse drug reactions" are "very common" if they occur in over 10% of cases and "common (frequent)" if they occur between 1 and 10% of the time.[8]

Published studies show that serious complications from drug-induced abortions are in the range of 3-5%, if not greater. An Australian study, for example, found that 3.3% of patients who used mifepristone in the first trimester required emergency hospital treatment.[9] And a study from Finland found that 15.6% of women experienced hemorrhage after a medical abortion, that 6.7% of women had incomplete abortions, and that 5.9% required surgery to complete the abortion.[10] Using the CIOMS criteria, this means complications from chemical abortions are "common" or "frequent."

Unfortunately, FDA data on the potential health risks that mifepristone poses is limited.[11] Adverse event reporting is voluntary and sporadic. Over 95% of the adverse events reported to the FDA came from the manufacturer, which would seemingly have no incentive to accurately report complications.[12] Even worse, since 2016, the only data that must be reported to the FDA is known deaths.[13] When looking at the data published by the FDA, we must acknowledge that this number of adverse events is clearly a gross underestimation of the actual number of complications occurring in American women, as the expected complication rate of

---

[4] https://www.earlyoptionpill.com/what-is-mifeprex/mifeprex-in-the-united-states/

[5] Aultman K., et al. "Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019," *Issues in Law & Medicine.* Spring 2021; 36(1): 1-25.

[6] https://www.earlyoptionpill.com/what-can-i-expect/

[7] Raymond E., et al. (2013). First trimester medical abortion with mifepristone 200 mg and misoprostol. Contraception, 87(1), 26-37. doi: 10.1016/j.contraception.2012.06.011.

[8] World Health Organization, *Medication Safety Training Course* at 10, https://www.who.int/medicines/areas/quality_safety/safety_efficacy/trainingcourses/definitions.pdf.

[9] Mulligan E, Messenger H. Mifepristone in South Australia – the first 1343 tablets. *Aust Fam Physician.* 2011;40(5):342-345.

[10] Niinimaki M, et al. Immediate complications after medical compared with surgical termination of pregnancy. *Obstet Gynecol.* 2009;114(4):795-804.

[11] Aultman, et al. "Deaths and Severe Adverse Events."

[12] Aultman, et al. "Deaths and Severe Adverse Events."

[13] Aultman, et al. "Deaths and Severe Adverse Events."

approximately 3-8% established in the medical literature would yield 120,000 (4 million x 0.03) to 320,000 (4 million x 0.08) women with severe, life threatening and fatal adverse events.

However, some conclusions can draw from the data made available to FDA.[14] Of the adverse events reported to the FDA:

1. Over 20% were life threatening or resulted in death.
2. 70.16% required follow up surgery, including total hysterectomy.
3. Abortion providers did not handle many of their complications, but rather left the women to find care at the emergency room on their own.[15]

Many of the adverse events reported to the FDA were due to ectopic pregnancies; one resulted in the death of the mother. According to the Centers for Disease Control (CDC), ectopic pregnancy accounts for 2% of all reported pregnancies. Half of those women do not have any known risk factors.[16] Prescribers must exclude the possibility of an ectopic pregnancy before prescribing the chemical abortion regimen, which can only be done using an ultrasound.

While the limited FDA data available suggests the risk that mifepristone presents to women's health, data from other countries is more reliable and offers a much clearer picture of the danger. For example, in 2009, the Finnish study of 42,619 women found that women who have had chemical abortions are almost four times more likely (20.0% compared with 5.6%) to experience adverse events.[17] The study covered "almost all abortions performed in Finland during the years 2000-2006."[18]

The FDA should not remove or weaken the existing REMS on mifepristone when the insufficient data available suggests that mifepristone endangers women's health. Requests to remove the in-person requirements for chemical abortion look the other way on women's health and scientific data for the sake of advancing a political agenda. Recognizing and addressing the need for comprehensive data on any health risks associated with mifepristone should be a bipartisan concern. Instead of making an uninformed decision to remove the REMS, we urge the FDA to mandate collecting complete, accurate information on all adverse events related to the drug.

Although there are many disagreements about the ethics of abortion, there must be total agreement that pregnant women deserve the highest standard of medical care.[19] As stated above, the FDA's medical data surrounding mifepristone is scant. However, what we do know is alarming. It shows that significant morbidity and mortality have occurred following the use of mifepristone. Allowing this drug to be available without medical supervision will have dire consequences for women and children.

---

[14] https://www.fda.gov/media/112118/download
[15] Aultman, et al, "Deaths and Severe Adverse Events."
[16] https://www.acog.org/womens-health/faqs/ectopic-pregnancy#:~:text=About%20one%20half%20of%20all,symptoms%20of%20an%20ectopic%20pregnancy
[17] Niinimaki et al., "Immediate Complications."
[18] Ibid. Page 779.
[19] Aultman, et al. "Deaths and Severe Adverse Events."

Sincerely,

Robert E. Latta
Member of Congress

Cindy Hyde-Smith
United States Senator

Dusty Johnson
Member of Congress

Marsha Blackburn
United States Senator

Debbie Lesko
Member of Congress

Roy Blunt
United States Senator

Tony Gonzales
Member of Congress

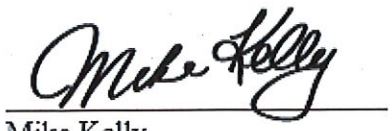
John Boozman
United States Senator

Andy Harris, M.D.
Member of Congress

Mike Braun
United States Senator

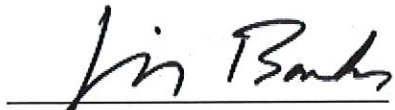
Christopher H. Smith
Member of Congress

Bill Cassidy, M.D.
United States Senator



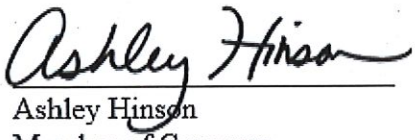
Mike Kelly
Member of Congress

Neal Dunn
Member of Congress



Jim Banks
Member of Congress

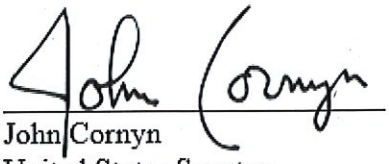
Gus M. Bilirakis
Member of Congress



Ashley Hinson
Member of Congress

Larry Bucshon, M.D.
Member of Congress

Steven M. Palazzo
Member of Congress

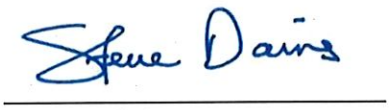


John Cornyn
United States Senator

Kevin Cramer
United States Senator

Mike Crapo
United States Senator

Ted Cruz
United States Senator

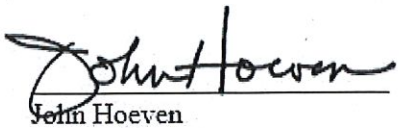


Steve Daines
United States Senator

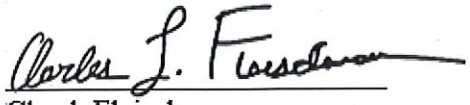
Deb Fischer
United States Senator

Josh Hawley
United States Senator

Doug LaMalfa
Member of Congress

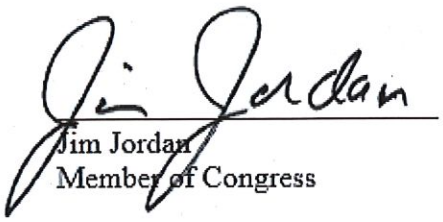


John Hoeven
United States Senator

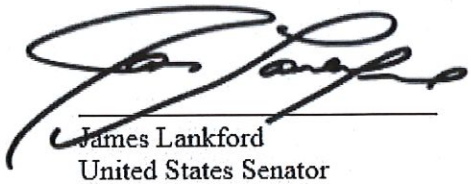


Chuck Fleischmann
Member of Congress

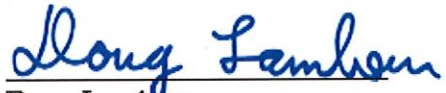
James M. Inhofe
United States Senator



Jim Jordan
Member of Congress

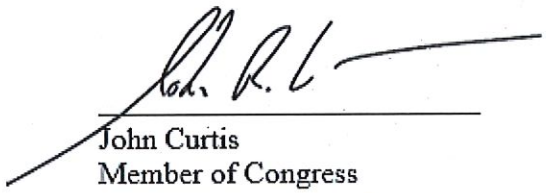


James Lankford
United States Senator

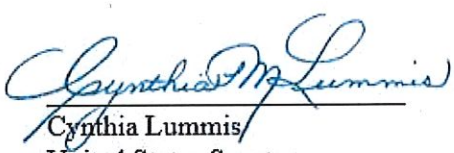


Doug Lamborn
Member of Congress

Mike Lee
United States Senator

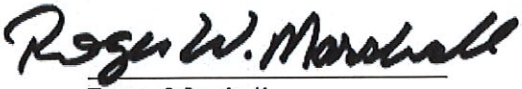


John Curtis
Member of Congress

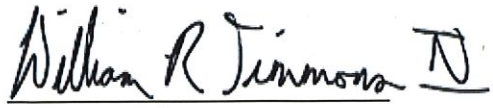


Cynthia Lummis
United States Senator

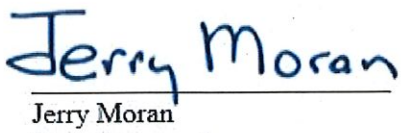
Gary Palmer
Member of Congress



Roger Marshall
United States Senator

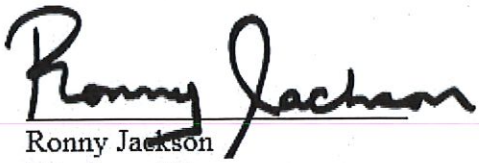


William Timmons
Member of Congress

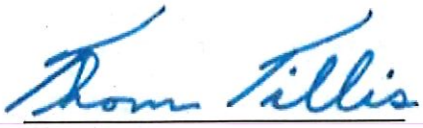


Jerry Moran
United States Senator

Rand Paul
United States Senator

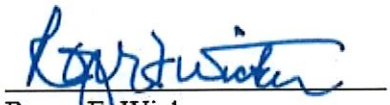


Ronny Jackson
Member of Congress

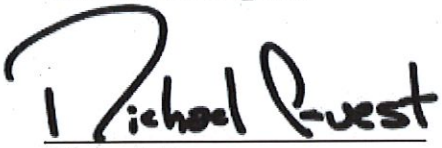


Thom Tillis
United States Senator

Billy Long
Member of Congress

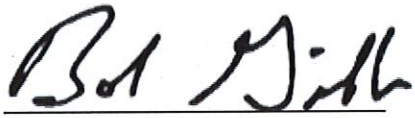


Roger F. Wicker
United States Senator



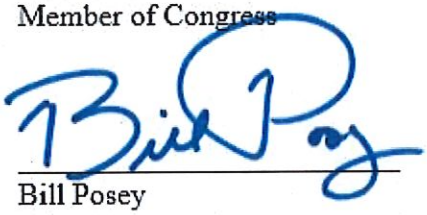
Michael Guest
Member of Congress

Ralph Norman
Member of Congress

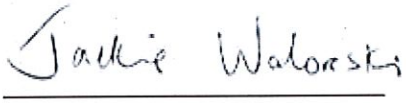


Bob Gibbs
Member of Congress

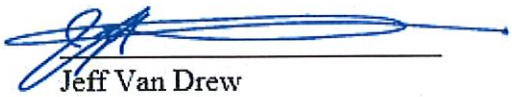
Michael Cloud
Member of Congress



Bill Posey
Member of Congress



Jackie Walorski
Member of Congress



Jeff Van Drew
Member of Congress

Brian Babin
Member of Congress

Randy Feenstra
Member of Congress

Bob Good
Member of Congress

Brett Guthrie
Member of Congress

Michael C. Burgess, M.D.
Member of Congress

Dan Bishop
Member of Congress

Warren Davidson
Member of Congress

Garret Graves
Member of Congress

Rick W. Allen
Member of Congress

John H. Rutherford
Member of Congress

Rob Portman
United States Senator

James E. Risch
United States Senator

M. Michael Rounds
United States Senator

Marco Rubio
United States Senator

Ben Sasse
United States Senator

Rick Scott
United States Senator

John Thune
United States Senator

Troy Balderson
Member of Congress

August Pfluger
Member of Congress

David Rouzer
Member of Congress

Joe Wilson
Member of Congress

Pat Fallon
Member of Congress

Tom Emmer
Member of Congress

Lisa McClain
Member of Congress

Ann Wagner
Member of Congress

Barry Loudermilk
Member of Congress

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

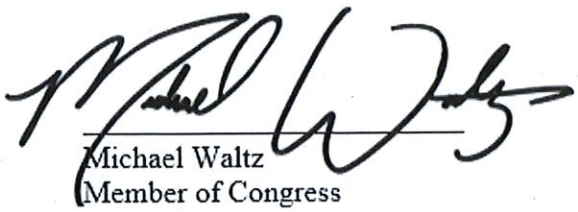
Don Bacon
Member of Congress

Jake LaTurner
Member of Congress

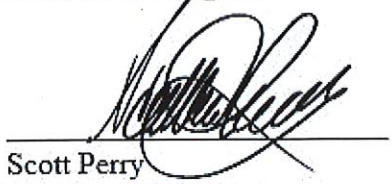
Glenn Grothman
Member of Congress

Richard Hudson
Member of Congress

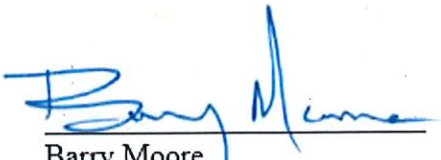
John Rose
Member of Congress



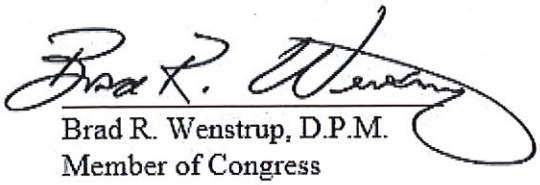
Michael Waltz
Member of Congress



Scott Perry
Member of Congress



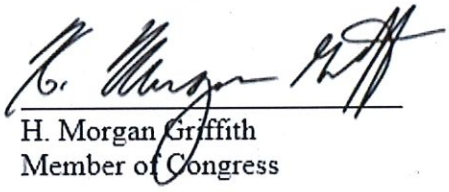
Barry Moore
Member of Congress



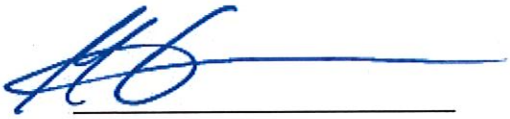
Brad R. Wenstrup, D.P.M.
Member of Congress

Vicky Hartzler
Member of Congress

Michelle Fischbach
Member of Congress

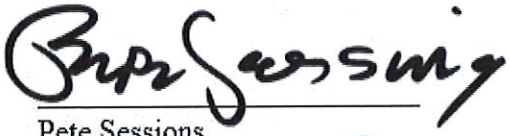


H. Morgan Griffith
Member of Congress



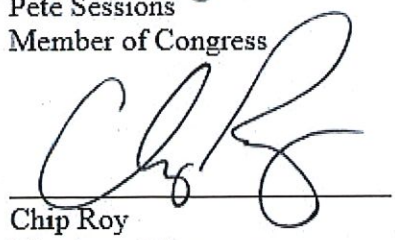
Mike Gallagher
Member of Congress

Darrell Issa
Member of Congress

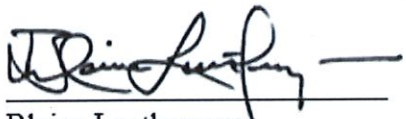


Pete Sessions
Member of Congress

Roger Williams
Member of Congress



Chip Roy
Member of Congress



Blaine Luetkemeyer
Member of Congress

Tracey Mann
Member of Congress

Jeff Duncan
Member of Congress

Louie Gohmert
Member of Congress

Alex X. Mooney
Member of Congress

Mike Johnson
Member of Congress

Trent Kelly
Member of Congress

Diana Harshbarger
Member of Congress

Gregory F. Murphy, M.D.
Member of Congress

Ted Budd
Member of Congress

Jody Hice
Member of Congress

David Schweikert
Member of Congress

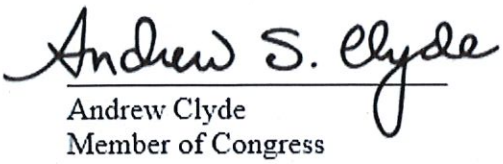
Jeff Fortenberry
Member of Congress

Ben Cline
Member of Congress

Steve Chabot
Member of Congress

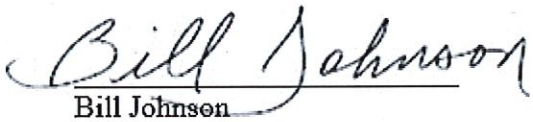
Andy Biggs
Member of Congress

Brian Mast
Member of Congress



Andrew Clyde
Member of Congress

David Kustoff
Member of Congress



Bill Johnson
Member of Congress