

# Congress of the United States

Washington, DC 20510

April 14, 2020

The Honorable Stephen Hahn, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Hahn,

In this difficult time our country faces, we are grateful for your tremendous leadership at the Food and Drug Administration (FDA) as you work to defend our nation from the effects of the Coronavirus Disease 2019 (COVID-19), and to ensure Americans have access to life-affirming medications and cures.

Unfortunately, there are some who seek to exploit this time of crisis to push for the weakening or overturning of critical Risk Evaluation and Mitigation Strategy (REMS) associated with medication abortion drugs, which would put women at significant risk. Your predecessor, Acting Commissioner Sharpless, began to address the ongoing problem of the sale of illegal mail-order abortion drugs in the United States. We write to urge you to continue to robustly enforce the REMS for medication abortion and end dangerous runarounds of these protections under the guise of medical research.

Mifeprex, also known as RU-486 or mifepristone, is the only chemical abortion drug approved in the United States, and is used in combination with another FDA-approved drug, misoprostol. The FDA has approved chemical abortion for use up to 10 weeks gestation, but due to the attendant risks to the mother, FDA requires that only a certified prescriber dispense the drugs after confirming the gestational age, ruling out ectopic pregnancy, and that the woman herself sign and retain a copy of the prescribers agreement. The involvement of a physician or other certified prescriber, who knows the state of a woman's pregnancy and health, is critical for patient safety.

As you may know, the *New York Times* editorial board and others have called for making medication abortion more widely accessible with far less oversight – via an overturning of the REMS and an expansion of the stage of pregnancy at which Mifeprex may be prescribed. These demands are both reckless and dangerous. The FDA should stand confidently for the protection of women.

Despite claims that medication abortion is safe and easy, research proves that as many as five to seven percent of women who take abortion drugs will require follow-up surgery,<sup>1</sup> and three percent could end up in the emergency room.<sup>2</sup> Self-managed abortions from home are especially dangerous; in fact, half of abortion providers do not consider them safe, according to a 2019 survey published in the journal *Contraception*.<sup>3</sup> Further, medication abortion becomes even more dangerous in situations where women cannot access emergency medical care. This is especially concerning during the COVID-19 pandemic as emergency rooms are currently being overwhelmed.

---

<sup>1</sup> <https://www.ncbi.nlm.nih.gov/pubmed/19888037>

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pubmed/?term=Mifepristone+in+South+Australia:+The+First+1343+Tablets>

<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pubmed/31002777>

Before medication abortion drugs are administered, under the current protocols, trained and certified healthcare providers must screen for ectopic pregnancy, determine the gestational age of the baby, check for contraindications in the woman's medical history, and monitor the patient for possible adverse events like severe hemorrhaging. If the REMS are lifted and these drugs are made more widely available in pharmacies or via mail-order, women will be put in danger without these critical screenings.

Because Mifeprex does not treat ectopic pregnancies and the effects of the drug can mimic those of a rupturing ectopic pregnancy, many women who have died from medication abortions have died because of missing this diagnosis. Symptoms of a ruptured ectopic pregnancy, such as bleeding and cramping, are the same symptoms women experience after taking medication abortion drugs. Without medical oversight, women may not recognize the rupturing ectopic until she collapses from massive blood loss. In cases where she cannot get immediate medical care, she is at great risk of dying. As of December 31, 2018, at least 97 women with ectopic pregnancies in the United States had been given Mifeprex. Of these women, at least two bled to death from an undiagnosed ectopic pregnancy.<sup>4</sup>

While hospitals are being pushed to their limits because of the growing number of people severely ill as a result of COVID-19, we should minimize, not increase, unrelated pressures on our health care providers.

Additionally, we encourage FDA to conduct oversight into ongoing studies to remotely dispense medication abortion to women, which is a violation of the REMS. Specifically, Gynuity's TelAbortion project, which started in 2015 to test direct-to-consumer medication abortion by mail, has been extended continuously and now prescribes medication abortion in a growing list of states.<sup>5</sup> Currently, Gynuity is conducting this study in the following 13 states: Colorado, Georgia, Hawaii, Illinois, Iowa, Maine, Maryland, Minnesota, Montana, New Mexico, New York, Oregon, and Washington, with the expressed desire to keep adding states. This study is transmuting into a national policy, without adequate evaluation or oversight.

We are grateful for all FDA's efforts to uphold the REMS, and we encourage continued vigilance to enforce the commonsense REMS associated with medication abortion. Furthermore, we urge FDA to act promptly to stop illegitimate and dangerous experiments with women's health.

Sincerely,



CINDY HYDE-SMITH  
United States Senator



ROBERT E. LATTA  
Member of Congress

MITCH MCCONNELL  
United States Senator

KEVIN MCCARTHY  
Member of Congress

<sup>4</sup> Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018, RCM # 2007-525, NDA 20-687, <https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM603000.pdf>.

<sup>5</sup> <https://telabortion.org/get-started/>

TOM COTTON  
United States Senator

JEFF DUNCAN  
Member of Congress

MARSHA BLACKBURN  
United States Senator

RANDY K. WEBER  
Member of Congress

PAT ROBERTS  
United States Senator

K. MICHAEL CONAWAY  
Member of Congress

STEVE DAINES  
United States Senator

JIM BANKS  
Member of Congress

MIKE BRAUN  
United States Senator

RALPH NORMAN  
Member of Congress

JAMES LANKFORD  
United States Senator

TED BUDD  
Member of Congress

TED CRUZ  
United States Senator

STEVE KING  
Member of Congress

JAMES E. RISCH  
United States Senator

ANN WAGNER  
Member of Congress

MIKE CRAPO  
United States Senator

TED S. YOHO, D.V.M.  
Member of Congress

JOSH HAWLEY  
United States Senator

BRIAN BABIN, D.D.S.  
Member of Congress

M. MICHAEL ROUNDS  
United States Senator

BILL POSEY  
Member of Congress

MIKE LEE  
United States Senator

PHIL ROE, M.D.  
Member of Congress

KELLY LOEFFLER  
United States Senator

ALEX X. MOONEY  
Member of Congress

KEVIN CRAMER  
United States Senator

DOUG LAMBORN  
Member of Congress

MARCO RUBIO  
United States Senator

BILLY LONG  
Member of Congress

TIM SCOTT  
United States Senator

STEVE WATKINS  
Member of Congress

JOHN KENNEDY  
United States Senator

DOUG LAMALFA  
Member of Congress

JOHN BOOZMAN  
United States Senator

TRENT KELLY  
Member of Congress



JONI K. ERNST  
United States Senator

BILL FLORES  
Member of Congress

JOHN THUNE  
United States Senator

STEVEN PALAZZO  
Member of Congress

ROGER F. WICKER  
United States Senator

JIM JORDAN  
Member of Congress

LINDSEY GRAHAM  
United States Senator

MARTHA ROBY  
Member of Congress

THOM TILLIS  
United States Senator

LOUIS GOHMERT  
Member of Congress

JAMES M. INHOFE  
United States Senator

TIM WALBERG  
Member of Congress

RICK SCOTT  
United States Senator

GLENN GROTHMAN  
Member of Congress

BEN SASSE  
United States Senator

MIKE JOHNSON  
Member of Congress

CHARLES E. GRASSLEY  
United States Senator

STEVE CHABOT  
Member of Congress

TODD YOUNG  
United States Senator

WARREN DAVIDSON  
Member of Congress

JERRY MORAN  
United States Senator

NEAL DUNN, M.D.  
Member of Congress

JOHN HOEVEN  
United States Senator

PETE OLSON  
Member of Congress

JOHN CORNYN  
United States Senator

JOHN JOYCE, M.D.  
Member of Congress

ROB PORTMAN  
United States Senator

LARRY BUCSHON, M.D.  
Member of Congress

JOHN BARRASSO  
United States Senator

MIKE BOST  
Member of Congress

DEB FISCHER  
United States Senator

MICHAEL C. BURGESS, M.D.  
Member of Congress

ROY BLUNT  
United States Senator

GREG GIANFORTE  
Member of Congress

BILL CASSIDY, M.D.  
United States Senator

DAN BISHOP  
Member of Congress

MIKE KELLY  
Member of Congress

H. MORGAN GRIFFITH  
Member of Congress

CATHY MCMORRIS RODGERS  
Member of Congress

JODY B. HICE  
Member of Congress

ANDY BIGGS  
Member of Congress

GARRETT GRAVES  
Member of Congress

BRUCE WESTERMAN  
Member of Congress

DUSTY JOHNSON  
Member of Congress

RICK W. ALLEN  
Member of Congress

CHRISTOPHER H. SMITH  
Member of Congress

MATT GAETZ  
Member of Congress

ROSS SPANO  
Member of Congress

DOUG COLLINS  
Member of Congress

ROGER MARSHALL, M.D.  
Member of Congress

JAMES COMER  
Member of Congress

JACKIE WALORSKI  
Member of Congress

KEVIN HERN  
Member of Congress

DAVID KUSTOFF  
Member of Congress

VICKY HARTZLER  
Member of Congress

JOHN SHIMKUS  
Member of Congress

RODNEY DAVIS  
Member of Congress

TOM EMMER  
Member of Congress

BILL HUIZENGA  
Member of Congress

CHIP ROY  
Member of Congress

AUSTIN SCOTT  
Member of Congress

RALPH ABRAHAM, M.D.  
Member of Congress

MICHAEL WALTZ  
Member of Congress

GUY RESCHENTHALER  
Member of Congress

BILL JOHNSON  
Member of Congress

GUS M. BILIRAKIS  
Member of Congress

JASON SMITH  
Member of Congress

JEFF FORTENBERRY  
Member of Congress

TIM BURCHETT  
Member of Congress

ROGER WILLIAMS  
Member of Congress

MICHAEL GUEST  
Member of Congress

DEBBIE LESKO  
Member of Congress



BARRY LOUDERMILK  
Member of Congress

ANTHONY GONZALEZ  
Member of Congress

JOHN R. CURTIS  
Member of Congress

BEN CLINE  
Member of Congress

TROY BALDERSON  
Member of Congress

WILLIAM R. TIMMONS, IV  
Member of Congress

GREGORY F. MURPHY, M.D.  
Member of Congress

PETE STAUBER  
Member of Congress

DAVID ROUZER  
Member of Congress

ANDY BARR  
Member of Congress

DAN CRENSHAW  
Member of Congress

VIRGINIA FOXX  
Member of Congress

CAROL MILLER  
Member of Congress

JOE WILSON  
Member of Congress

EARL L. "BUDDY" CARTER  
Member of Congress

TREY HOLLINGSWORTH  
Member of Congress

BRAD WENSTRUP, D.P.M.  
Member of Congress

KELLY ARMSTRONG  
Member of Congress

GLENN 'GT' THOMPSON  
Member of Congress

SCOTT PERRY  
Member of Congress

KEN BUCK  
Member of Congress

KEVIN BRADY  
Member of Congress

DARIN LAHOOD  
Member of Congress

KENNY MARCHANT  
Member of Congress

DAN MEUSER  
Member of Congress

GREG PENCE  
Member of Congress

COLLIN C. PETERSON  
Member of Congress

RICK CRAWFORD  
Member of Congress

JACK BERGMAN  
Member of Congress

BRYAN STEIL  
Member of Congress

RON ESTES  
Member of Congress

ANDY HARRIS, M.D.  
Member of Congress

ADRIAN SMITH  
Member of Congress

ELISE M. STEFANIK  
Member of Congress

JOHN ROSE  
Member of Congress

BRETT GUTHRIE  
Member of Congress

ROB BISHOP  
Member of Congress

FRED KELLER  
Member of Congress

GARY PALMER  
Member of Congress

MICHAEL CLOUD  
Member of Congress

JIM HAGEDORN  
Member of Congress

W. GREGORY STEUBE  
Member of Congress

MIKE GALLAGHER  
Member of Congress

JAIME HERRERA BEUTLER  
Member of Congress

BLAINE LUETKEMEYER  
Member of Congress

PAUL COOK  
Member of Congress

JOHN RUTHERFORD  
Member of Congress