

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,¹ and three percent could end up in the emergency room.² 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*.³ 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.

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

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

³ <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.⁴

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.⁵ 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

⁴ 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>.

⁵ <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