

Congress of the United States
Washington, DC 20515

May 10, 2018

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

Dear Acting Commissioner Sharpless,

We write to thank you for taking action to address the sale of illegal mail-order abortion drugs to the United States (U.S.). The actions of Aidaccess.org and Rablon are of great concern to us, and we are encouraged to see that the Food and Drug Administration (FDA) has sent warning letters to these two online entities. We would like to urge the FDA, both under your leadership and the leadership of future FDA Commissioners, to continue to conduct oversight of these entities to ensure that they comply with the Food, Drug, and Cosmetic Act.

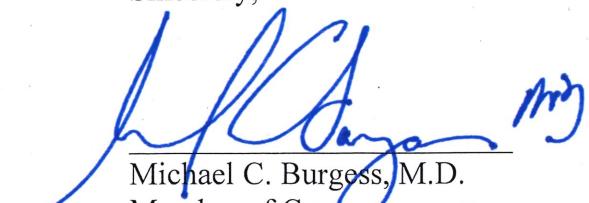
On October 18, 2018, an article published in The Atlanticⁱ revealed that Aid Access, a foreign company, has been established to distribute mail-order chemical abortion drugs to U.S. customers in violation of the FDA's safety protocols. Aid Access allows chemical abortion pills to be prescribed by an abortionist in the Netherlands, filled by a pharmacy in India, and shipped to stateside customers. While this case is particularly high profile, it is not singular. A March 2018 Fact Sheet by the Charlotte Lozier Institute revealed at least 72 unique websites purporting to sell chemical abortion drugs online in violation of FDA requirements. In some cases, these sites even advertise bulk sales without any clear intent to sell only to pregnant women.ⁱⁱ

As noted in the warning letters, Mifeprex, also known as RU-486 or mifepristone, is the only chemical abortion drug approved in the U.S., 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 risks, the FDA requires that only a certified prescriber dispense the drugs. The involvement of a physician or other certified prescriber who knows the state of a woman's pregnancy and health is critical, as patient safety is of utmost importance. Before the drugs are administered, it is crucial that a trained and certified healthcare provider screen for ectopic pregnancy, determine the gestational age of the baby, and monitor the patient for possible adverse events like severe hemorrhaging.

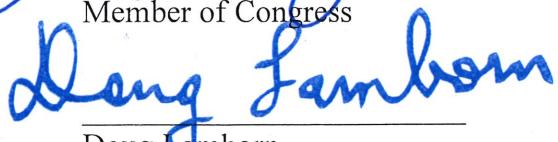
Furthermore, according to the FDA, "it is illegal for individuals to import drugs into the United States for personal use." Aid Access claims that their activities are permissible under FDA exceptions. FDA's exceptions, however, are limited to very narrow circumstances that Aid Access cannot meet. For example, the drug must be for a condition for which treatment is not available domestically, and there must not be any known promotion of the product to persons residing in the United States. Since chemical and surgical abortion are available in the U.S. and Aid Access is clearly promoting sale of the drugs online, the Aid Access system does not meet the first two requirements for an exception.ⁱⁱⁱ

As the FDA has recognized, by shipping chemical abortion drugs from India to the United States, Aid Access circumvents the Food and Drug Administration's safety requirements, placing the lives of women and their children at risk. Once again, we would like to thank you for your recent actions to address this issue, and to voice our support for ongoing oversight of this and any other rogue mail-order abortion operation.

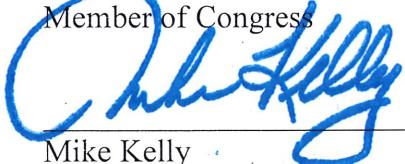
Sincerely,



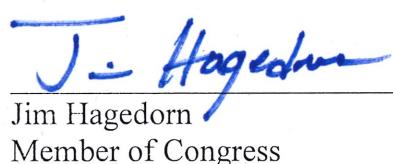
Michael C. Burgess, M.D.
Member of Congress



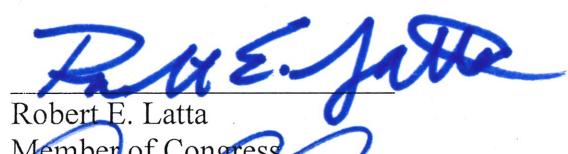
Doug Lamborn
Member of Congress



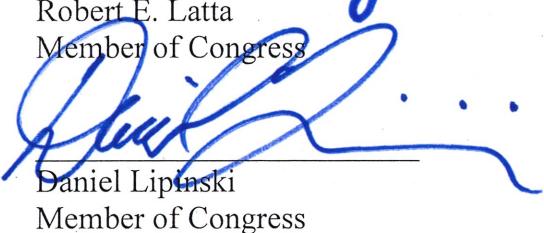
Mike Kelly
Member of Congress



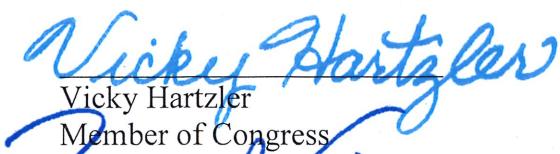
Jim Hagedorn
Member of Congress



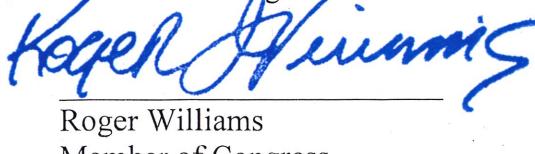
Robert E. Latta
Member of Congress



Daniel Lipinski
Member of Congress



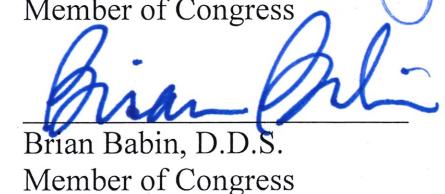
Vicky Hartzler
Member of Congress



Roger Williams
Member of Congress



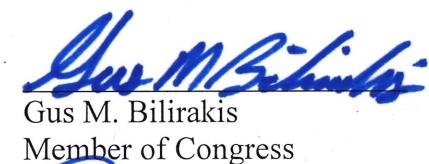
Martha Roby
Member of Congress



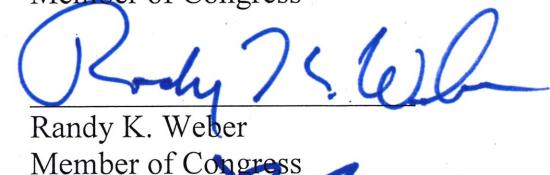
Brian Babin, D.D.S.
Member of Congress



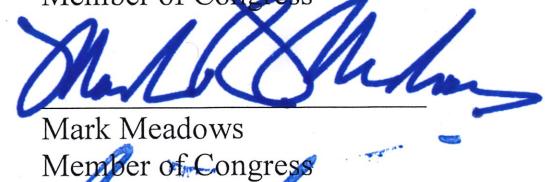
Ted Budd
Member of Congress



Gus M. Bilirakis
Member of Congress



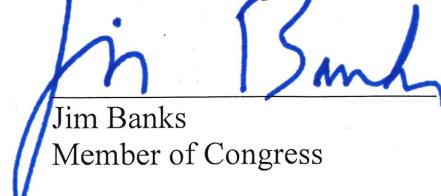
Randy K. Weber
Member of Congress



Mark Meadows
Member of Congress



Ron Wright
Member of Congress



Jim Banks
Member of Congress

Mike Johnson

Mike Johnson
Member of Congress

Mark Walker

Mark Walker
Member of Congress

Greg Gianforte

Greg Gianforte
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Richard Hudson

Richard Hudson
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Chris Smith

Christopher H. Smith
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Jack Bergman

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Alex X. Mooney

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Tim Burchett

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Jason Smith

Jason Smith
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John Ratcliffe

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Joe Wilson

Joe Wilson
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Ken Calvert

Ken Calvert
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John Shimkus

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Lance Gooden

Lance Gooden
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Rodney Davis

Rodney Davis
Member of Congress

John Joyce

John Joyce, M.D.
Member of Congress

John R. Moolenaar

John R. Moolenaar
Member of Congress

Rob Wittman

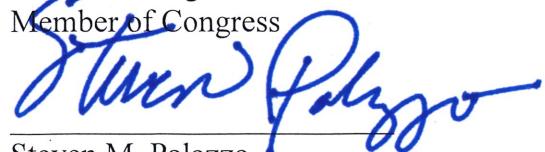
Rob Wittman
Member of Congress

Tom Cole

Tom Cole
Member of Congress



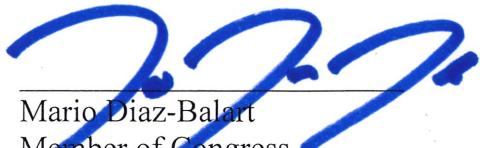
Adam Kinzinger
Member of Congress



Steven M. Palazzo
Member of Congress



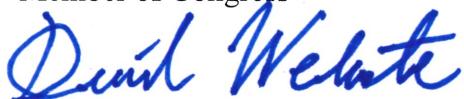
Carol D. Miller
Member of Congress



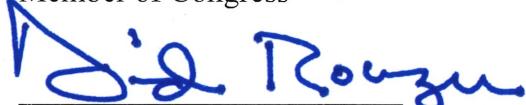
Mario Diaz-Balart
Member of Congress



Bruce Westerman
Member of Congress



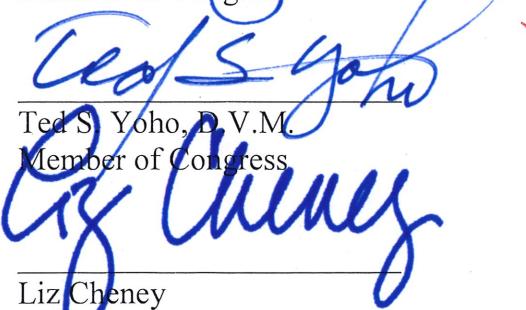
Daniel Webster
Member of Congress



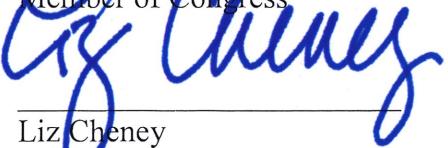
David Rouzer
Member of Congress



Bill Huizenga
Member of Congress



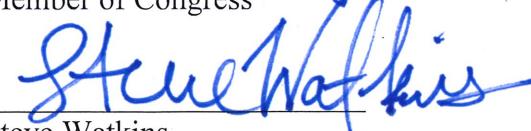
Ted S. Yoho, D.V.M.
Member of Congress



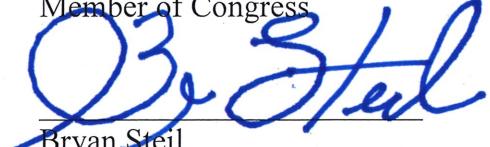
Liz Cheney
Member of Congress



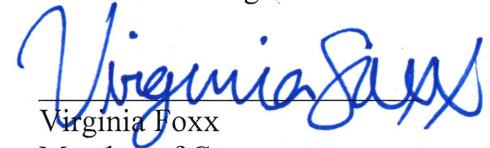
Andy Biggs
Member of Congress



Steve Watkins
Member of Congress



Bryan Steil
Member of Congress



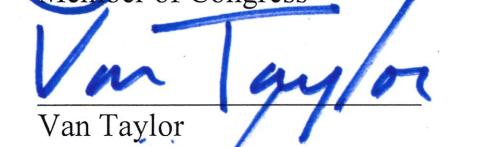
Virginia Foxx
Member of Congress



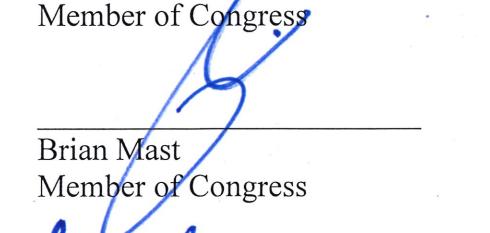
Bill Flores
Member of Congress



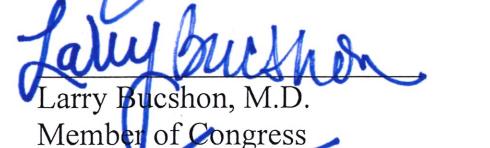
David B. McKinley, P.E.
Member of Congress



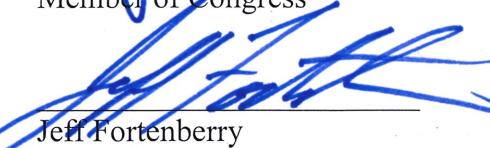
Van Taylor
Member of Congress



Brian Mast
Member of Congress



Larry Bucshon, M.D.
Member of Congress



Jeff Fortenberry
Member of Congress

Adrian Smith

Adrian Smith
Member of Congress

Gary Palmer

Gary Palmer
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Kevin Hern

Kevin Hern
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Jim Jordan

Jim Jordan
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Billy Long

Billy Long
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Russ Fulcher

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Andy Harris, M.D.

Andy Harris, M.D.
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Kevin Brady

Kevin Brady
Member of Congress

George Holding

George Holding
Member of Congress

Blaine Luetkemeyer

Blaine Luetkemeyer
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Bill Posey

Bill Posey
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Bradley Byrne

Bradley Byrne
Member of Congress

Sean Duffy

Sean Duffy
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Doug LaMalfa

Doug LaMalfa
Member of Congress

Chris Stewart

Chris Stewart
Member of Congress

Jaime Herrera Beutler

Jaime Herrera Beutler
Member of Congress

Chip Roy

Chip Roy
Member of Congress

H. Morgan Griffith

H. Morgan Griffith
Member of Congress

Trent Kelly

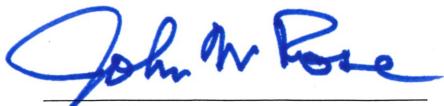
Trent Kelly
Member of Congress

Dusty Johnson

Dusty Johnson
Member of Congress



Mike Bost
Member of Congress



John Rose
Member of Congress



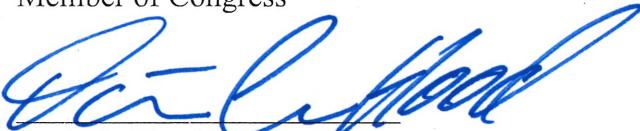
Daniel P. Meuser
Member of Congress



David Kustoff
Member of Congress



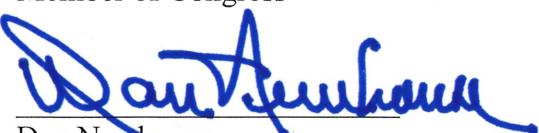
Pete Olson
Member of Congress



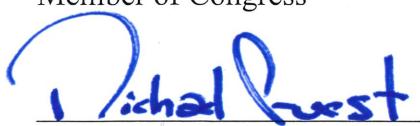
Darin LaHood
Member of Congress



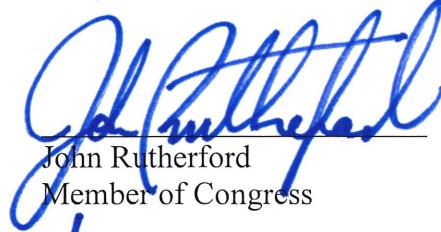
French Hill
Member of Congress



Dan Newhouse
Member of Congress



Michael Guest
Member of Congress



John Rutherford
Member of Congress



Mike Gallagher
Member of Congress



Earl L. "Buddy" Carter
Member of Congress



Michael Waltz
Member of Congress



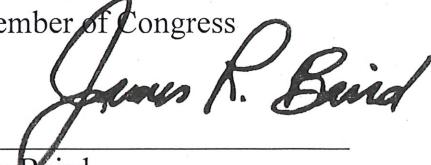
Steve Chabot
Member of Congress



Ross Spano
Member of Congress



Louie Gohmert
Member of Congress



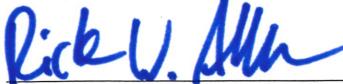
Jim Baird
Member of Congress



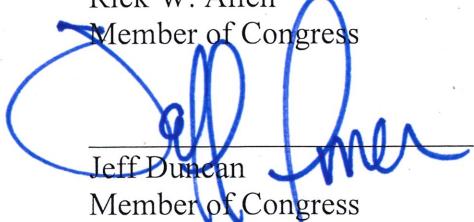
William R. Timmons IV
Member of Congress



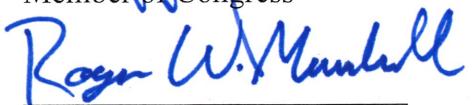
Ralph Abraham, M.D.
Member of Congress



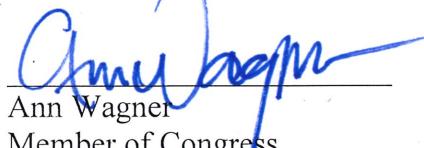
Rick W. Allen
Member of Congress



Jeff Duncan
Member of Congress



Roger W. Marshall
Member of Congress



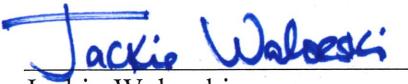
Ann Wagner
Member of Congress



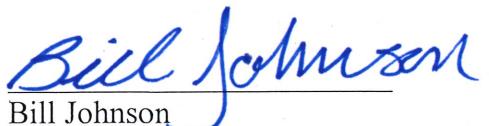
Ralph Norman
Member of Congress



Ben Cline
Member of Congress



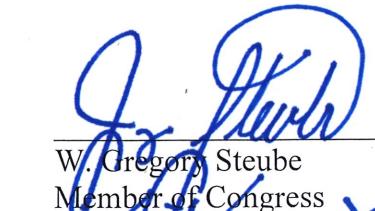
Jackie Walorski
Member of Congress



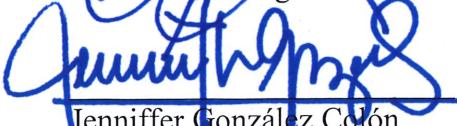
Bill Johnson
Member of Congress



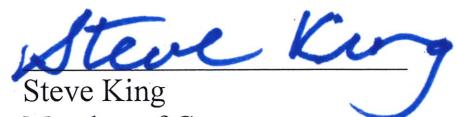
David P. Roe
Member of Congress



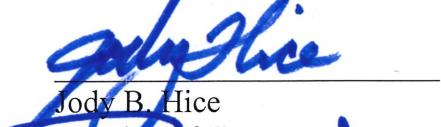
W. Gregory Steube
Member of Congress



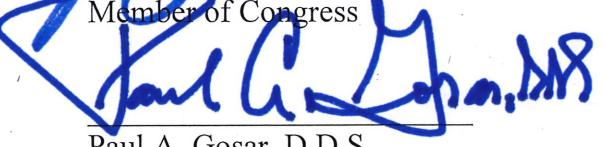
Jenniffer González Colón
Member of Congress



Steve King
Member of Congress



Jody B. Hice
Member of Congress



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



Tom Graves
Member of Congress



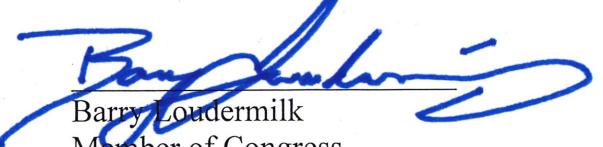
Rick Crawford
Member of Congress



Bob Gibbs
Member of Congress



Glenn Grothman
Member of Congress



Barry Loudermilk
Member of Congress

Patrick McHenry
Patrick McHenry
Member of Congress

Ron Estes
Ron Estes
Member of Congress

Tom Emmer
Tom Emmer
Member of Congress

Debbie Lesko
Debbie Lesko
Member of Congress

ⁱ <https://www.theatlantic.com/health/archive/2018/10/women-on-web-safe-abortion-mail/573322/>

ⁱⁱ <https://lozierinstitute.org/fact-sheet-online-sales-of-mifeprex-and-misoprostol-for-self-abortion/>

ⁱⁱⁱ <https://www.fda.gov/forindustry/importprogram/importbasics/ucm432661.htm>