

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.

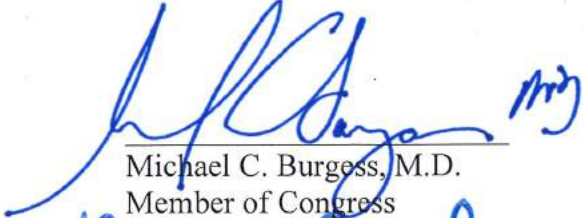
On October 18, 2018, an article published in *The Atlantic*ⁱ revealed that Aid Access, a foreign company, has been established to distribute mail-order chemical abortion drugs to U.S. customers in violation of the FDA's safety protocols. Aid Access allows chemical abortion pills to be prescribed by an 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

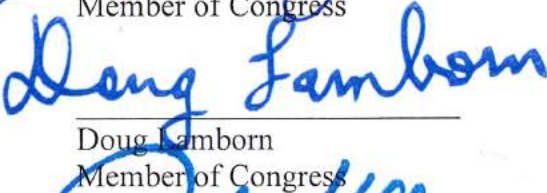
As noted in the warning letters, Mifeprex, also known as RU-486 or mifepristone, is the only chemical abortion drug approved in the U.S., and is used in combination with another FDA-approved drug, misoprostol. The FDA has approved chemical abortion for use up to 10 weeks gestation, but due to the risks, 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.

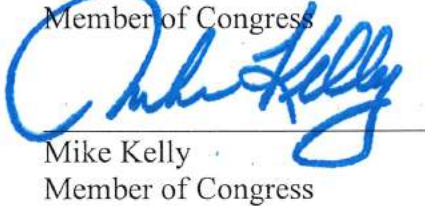
Furthermore, according to the FDA, "it is illegal for individuals to import drugs into the United States for personal use." Aid Access claims that their activities are permissible under FDA exceptions. FDA's exceptions, however, are limited to very narrow circumstances that Aid Access cannot meet. For 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

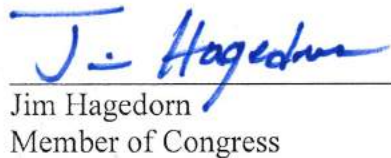
As the FDA has recognized, by shipping chemical abortion drugs from India to the United States, Aid Access circumvents the Food and Drug Administration's safety requirements, placing the lives of women and their children at risk. Once again, we would like to thank you for your recent actions to address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

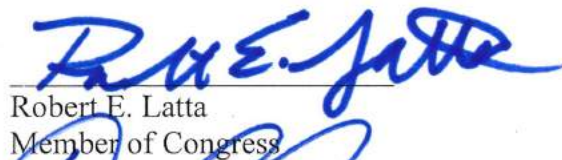
Sincerely,

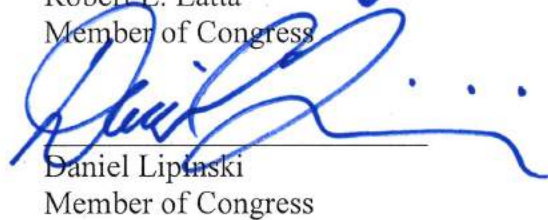

Michael C. Burgess, M.D.
Member of Congress


Doug Lamborn
Member of Congress

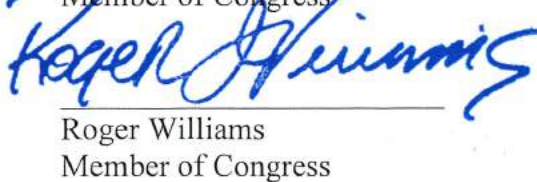

Mike Kelly
Member of Congress


Jim Hagedorn
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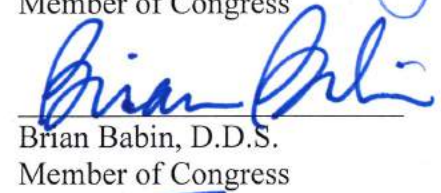

Robert E. Latta
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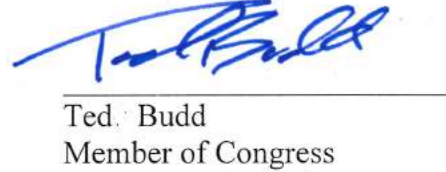

Daniel Liptanski
Member of Congress


Vicky Hartzler
Member of Congress

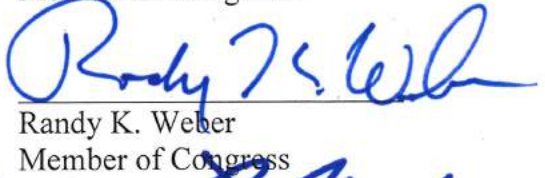

Roger Williams
Member of Congress

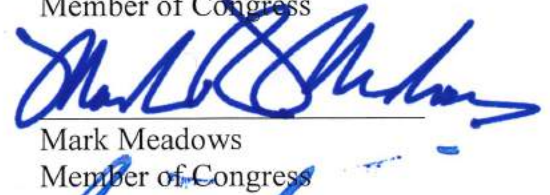

Martha Roby
Member of Congress

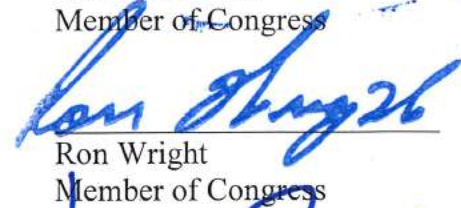

Brian Babin, D.D.S.
Member of Congress

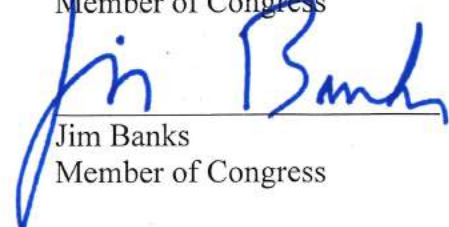

Ted Budd
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Gus M. Bilirakis
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Member of Congress


Ron Wright
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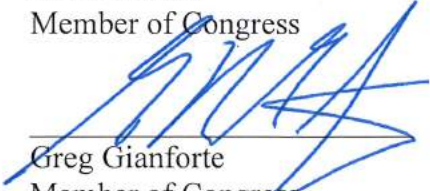

Jim Banks
Member of Congress



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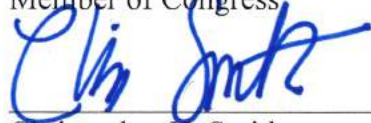
Mark Walker
Member of Congress



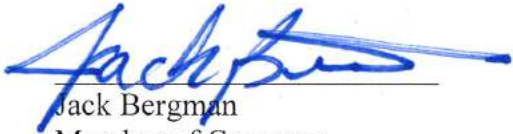
Greg Gianforte
Member of Congress



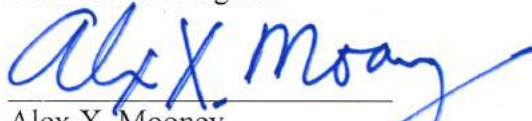
Richard Hudson
Member of Congress



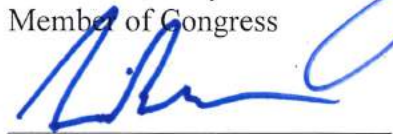
Christopher H. Smith
Member of Congress



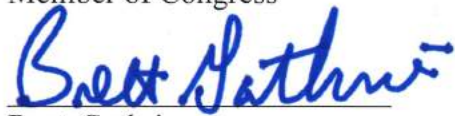
Jack Bergman
Member of Congress



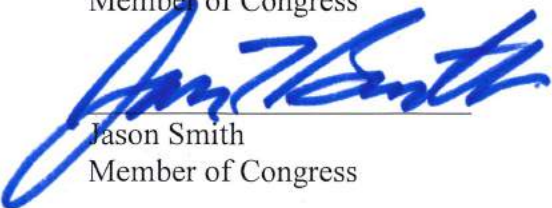
Alex X. Mooney
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Tim Burchett
Member of Congress



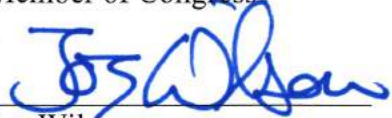
Brett Guthrie
Member of Congress



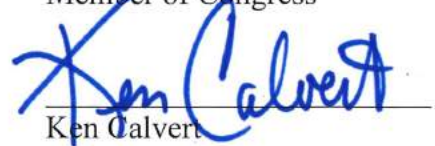
Jason Smith
Member of Congress



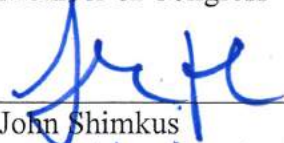
John Ratcliffe
Member of Congress



Joe Wilson
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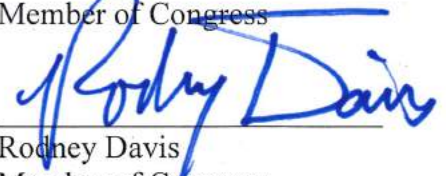
Ken Calvert
Member of Congress



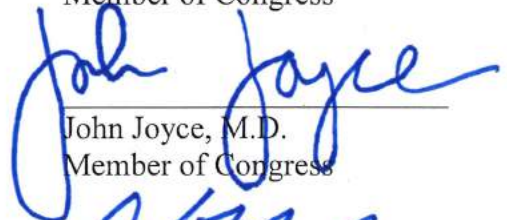
John Shimkus
Member of Congress



Lance Gooden
Member of Congress



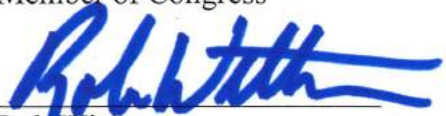
Rodney Davis
Member of Congress



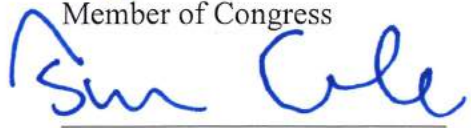
John Joyce, M.D.
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John R. Moolenaar
Member of Congress



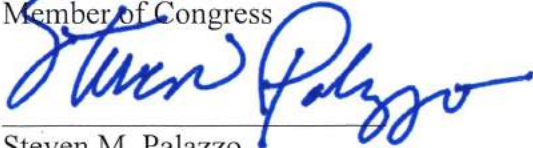
Rob Wittman
Member of Congress



Tom Cole
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Adam Kinzinger
Member of Congress



Steven M. Palazzo
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Carol D. Miller
Member of Congress



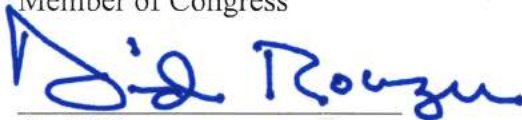
Mario Diaz-Balart
Member of Congress



Bruce Westerman
Member of Congress



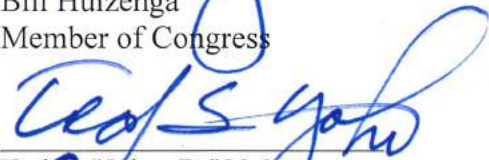
Daniel Webster
Member of Congress



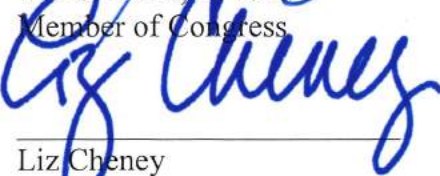
David Rouzer
Member of Congress



Bill Huizenga
Member of Congress



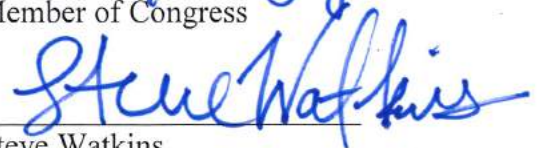
Ted S. Yoho, D.V.M.
Member of Congress



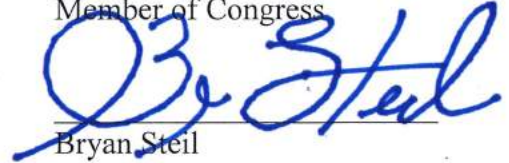
Liz Cheney
Member of Congress



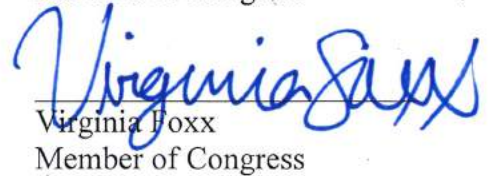
Andy Biggs
Member of Congress



Steve Watkins
Member of Congress



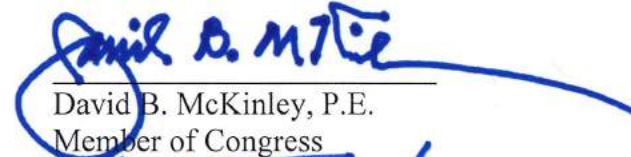
Bryan Steil
Member of Congress



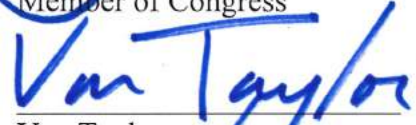
Virginia Foxx
Member of Congress



Bill Flores
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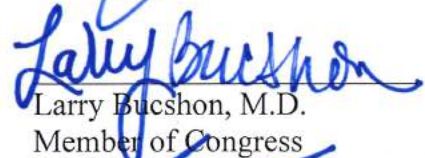


David B. McKinley, P.E.
Member of Congress

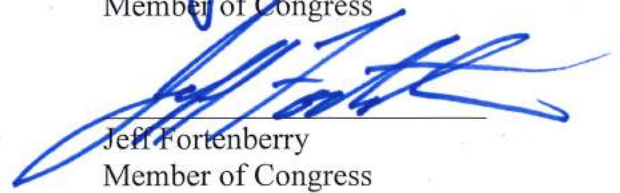


Van Taylor
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Brian Mast
Member of Congress



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Jeff Fortenberry
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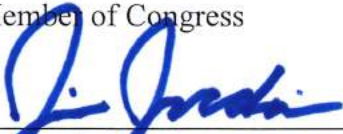
Adrian Smith
Member of Congress



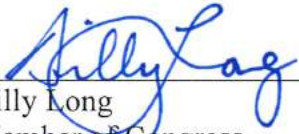
Gary Palmer
Member of Congress



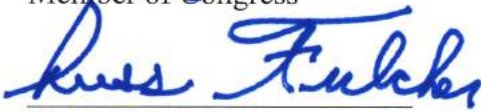
Kevin Hern
Member of Congress



Jim Jordan
Member of Congress



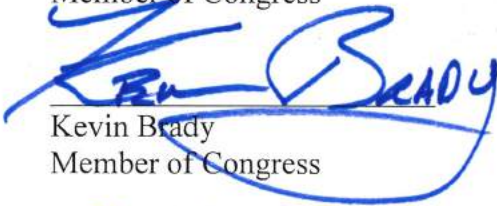
Billy Long
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Russ Fulcher
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Andy Harris, M.D.
Member of Congress



Kevin Brady
Member of Congress




George Holding
Member of Congress



Blaine Luetkemeyer
Member of Congress



Bill Posey
Member of Congress



Bradley Byrne
Member of Congress



Sean Duffy
Member of Congress



Doug LaMalfa
Member of Congress



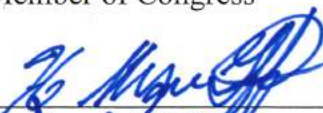
Chris Stewart
Member of Congress



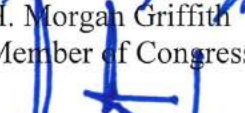
Jaime Herrera Beutler
Member of Congress



Chip Roy
Member of Congress



H. Morgan Griffith
Member of Congress




Trent Kelly
Member of Congress



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



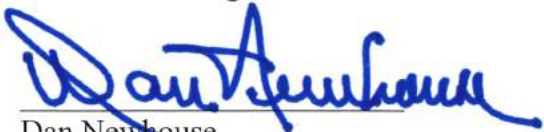
Pete Olson
Member of Congress



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



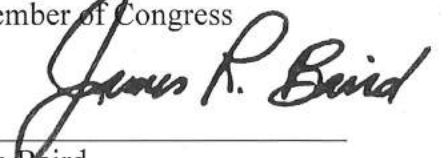
Steve Chabot
Member of Congress



Ross Spano
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Louie Gohmert
Member of Congress



Jim Baird
Member of Congress



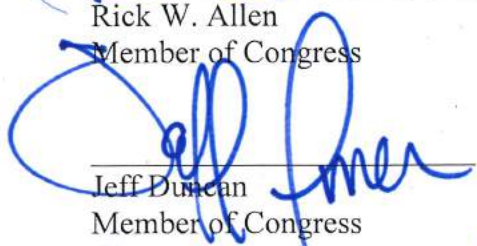
William R. Timmons IV
Member of Congress



Ralph Abraham, M.D.
Member of Congress



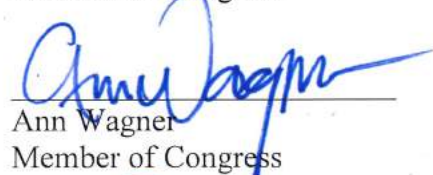
Rick W. Allen
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Jeff Duncan
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Roger Marshall, M.D.
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Ann Wagner
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Ralph Norman
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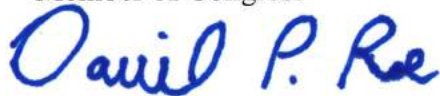
Ben Cline
Member of Congress



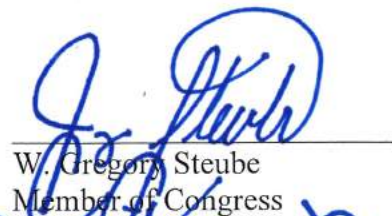
Jackie Walorski
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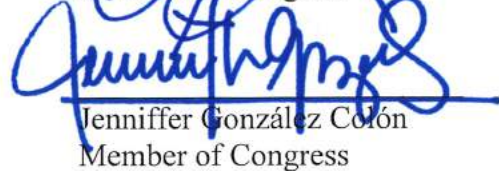
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W. Gregory Steube
Member of Congress



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Steve King
Member of Congress



Jody B. Hice
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Paul A. Gosar, D.D.S.
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Tom Graves
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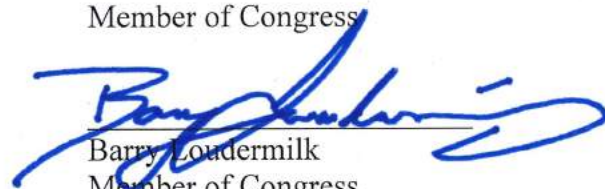
Rick Crawford
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Bob Gibbs
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Glenn Grothman
Member of Congress



Barry Loudermilk
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Patrick McHenry
Member of Congress


Ron Estes
Member of Congress


Tom Emmer
Member of Congress


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>