## Congress of the United States Washington, DC 20515

May 10, 2019

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<sup>i</sup> 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.<sup>ii</sup>

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 Jamborn Member of Congres Mike Kelly 🕡 Member of Congress Jim Hagedorn • Member of Congress Robert E. Latta Member of Congress Daniel Lipinski Member of Congress

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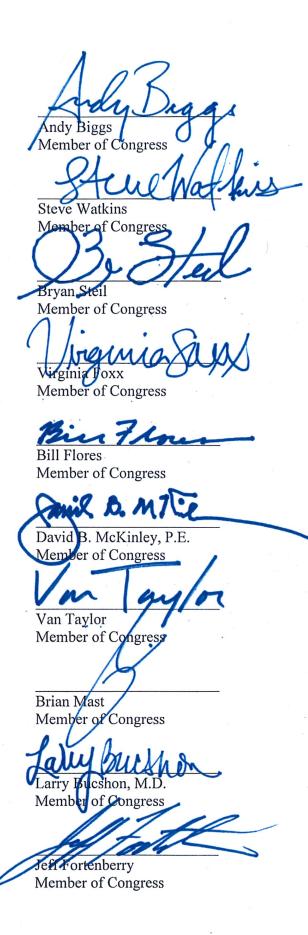
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https://www.theatlantic.com/health/archive/2018/10/women-on-web-safe-abortion-mail/573322/

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

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