

May 4, 2020

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

Dear Commissioner Hahn,

We are writing to urge you to seize the website domains for [AidAccess](#), Rablon, and any other entities illegally prescribing and/or selling mifepristone in the United States, and to further investigate their practices as discussed below. Just as FDA acted in December 2019 to protect Americans from websites advertising [the sale of illicit vaping cartridges](#), we urge FDA to protect women from the distributors of abortion-inducing drugs who place lives at risk by circumventing your agency's regulatory safeguards.

It has been over a year since FDA sent warning letters to AidAccess and Rablon stating that the websites are in violation of U.S. law. Yet, these websites remain active and continue to dispense abortion-inducing drugs, including mifepristone, through internet prescriptions or orders that are purportedly filled by pharmacies in India, and then shipped to customers in the United States. Their actions brazenly flout FDA-required protections for women using abortion-inducing drugs.

In the warning letters, dated March 8, 2019, FDA stated that [AidAccess](#) “cause[s] the introduction into interstate commerce of misbranded and unapproved new drugs,” and [Rablon](#) “introduces into interstate commerce misbranded and unapproved new drugs,” both in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The letters warn that “[f]ailure to correct these violations may result in FDA regulatory action, including seizure or injunction, without further notice.”

Mifeprex (or its recently-approved generic),<sup>1</sup> used in combination with misoprostol, is the only FDA-approved regimen for drug-induced abortion. Mifeprex is subject to a Risk Evaluation and Mitigation Strategy (REMS), which, as stated in the warning letters, “is intended to mitigate the risk of serious complications associated with Mifeprex.” Further, “[c]onsistent with the REMS, Mifeprex is not sold through retail pharmacies or over the internet.”

In fact, the Mifeprex REMS requires that the drug be dispensed only at a healthcare facility, by or under the supervision of a certified prescriber, after a patient signs an agreement form. These requirements also protect women and unborn children from predators who would force or trick pregnant women into taking Mifeprex. Tragically, internet access to abortion-inducing drugs has

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<sup>1</sup> All references to Mifeprex are intended to include the generic, which is subject to the same REMS.

enabled these crimes.<sup>2</sup> However, AidAccess<sup>3</sup> and websites within Rablon’s network continue to flagrantly subvert the REMS by marketing mifepristone to U.S. customers. FDA’s [Motion to Dismiss](#) a lawsuit filed by the founder of AidAccess, Dr. Rebecca Gomperts, explains:

The mifepristone that Dr. Gomperts prescribes is neither FDA-approved Mifeprex nor the FDA-approved generic version. . . .Nor is it dispensed in a clinic, medical office, or hospital, as FDA-approved Mifeprex must be. Instead, the unapproved product is exported from India by N N Agencies and shipped to patients (*Gomperts v. Azar*, No. 1:19-cv-00345-DCN (Dist. of Idaho)).

Further, the website Plan C, which provides a [report card](#) ranking the “best” sources for obtaining abortion-inducing drugs online, states that at least three of their highest-ranked sources appear to ship from within the United States—abortionrx.com, abortionpills247.com, and nopregnancy.net—all of which are in Rablon’s network. We urge you to investigate the source of the drugs distributed by these websites, given that only two domestic companies are authorized to distribute Mifeprex in the U.S. (Danco Labs LLC and GenBioPro), and these entities are required to comply with the Mifeprex REMS.

We appreciate that FDA is seriously defending the necessary safeguards contained in the Mifeprex REMS in litigation. These safeguards are meaningless, however, if opportunistic entities can sell abortion-inducing drugs over the internet with impunity. We urge the FDA to act now to stop this predatory and dangerous practice.

Sincerely,

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<sup>2</sup> <https://dailycaller.com/2018/01/15/the-metoo-movement-ignores-the-most-offensive-form-of-partner-violence-that-exists/>.

<sup>3</sup> The [AidAccess website](#), as of April 22, 2020, includes a statement that “[b]ecause of Covid-19 (Corona Virus) the Government of India has decided to close all international airports to prevent corona virus outbreak. Therefore the pharmacy in India cannot send the medicines until further notice.” They also claim that they are only prescribing misoprostol for “miscarriage management” at this time. However, the website [Plan C](#) states that AidAccess recommends that women interested in obtaining abortion drugs “try to find it locally and check back on their website in a few days.” Further, in their [May 16, 2019 response](#) to the FDA warning letter, Dr. Gomperts’ attorney asserts that she will continue to “consult” with U.S. women (*i.e.*, write prescriptions for abortion-inducing drugs and facilitate access to the drugs through a pharmacy in India).

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