

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),¹ 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

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

enabled these crimes.² However, AidAccess³ 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,

Marjorie Dannenfelser
President
Susan B. Anthony List

Donna J. Harrison, MD
Executive Director
American Association of Pro-Life
Obstetricians and Gynecologists

Kristan Hawkins
President
Students for Life of America &
Students for Life Action

Catherine Glenn Foster
President & CEO
Americans United for Life

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

³ 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).

Jeanne Mancini
President
March for Life

Lila Rose
President and Founder
Live Action

Penny Young Nance
CEO and President
Concerned Women for America LAC

Carol Tobias
President
National Right to Life

Jeffrey Barrows, DO, MA
Senior VP, Bioethics and Public Policy
Christian Medical & Dental Associations

Kris Held, MD
President
Association of American Physicians and Surgeons

Fr. Frank Pavone
National Director
Priests for Life

Eunie Smith
President
Eagle Forum

Thomas A. Glessner
President
National Institute of of Family & Life Advocates
(NIFLA)

Greg Schleppenbach
Associate Director
USCCB Secretariat of Pro-Life Activities

Jessica Anderson
Executive Director
Heritage Action

Jordan Sekulow
Executive Director
American Center for Law & Justice

Travis S. Weber
Vice President for Policy and Government Affairs
Family Research Council

Jor-El Godsey
President
Heartbeat International

Russell Moore
President
Southern Baptist Ethics &
Religious Liberty Commission

Dorinda C. Bordlee
Chief Counsel
Bioethics Defense Fund

Ellen Gianoli, BSN, MA, RN
President
National Association of Catholic Nurses, U.S.A.

Michelle Cretella
Executive Director
American College of Pediatricians

Bradley Mattes
President
Life Issues Institute

Tom Brejcha
President and Chief Counsel
Thomas More Society

Roland C. Warren
President & CEO
Care Net

Brian Fisher
President
Human Coalition

Tami Fitzgerald
Executive Director
NC Values Coalition

Michael Gonidakis
President
Ohio Right to Life

Cheryl Sullenger
Senior Vice President
Operation Rescue

Allan Parker
President
The Justice Foundation

Autumn Leva
Vice President, Strategy
Family Policy Alliance

Judie Brown
President
American Life League

Jim Sedlak
Founder
STOPP International

Esther Ripplinger
Executive Director
Human Life of Washington

Cynthia Collins
Global Advisor
Operation Outcry

Lois Anderson
Executive Director
Oregon Right to Life

Marc Tuttle
President
Right to Life of Indianapolis

John Helmberger
Chief Executive Officer
Minnesota Family Council

Julaine K. Appling
President
Wisconsin Family Action

Steven Ertelt
Editor
LifeNews.com

Mark Harrington
President
Created Equal

Eva Andrade
President
Hawaii Family Forum

Alexandra Snyder, Esq
Executive Director
Life Legal Defense Foundation

Bev Cielnicky
President
Crusade for Life

Lauren Muzyka
Executive Director
Sidewalk Advocates for Life

Eric J. Scheidler
Executive Director
Pro-Life Action League

Peggy Nienaber
Vice President
Faith & Liberty

Joe Langfield
Executive Director
Human Life Alliance

Samuel H. Lee
Director
Campaign Life Missouri

Bethany Bomberger
Executive Director
The Radiance Foundation

Connie Eller
Founder
Missouri Blacks for Life

David Fowler, Esq.
President
The Family Action Council of Tennessee, Inc.

Kelsey Hazzard
President
Secular Pro-Life

Christopher Bell
President
Good Counsel, Homes for Mothers and Babies

Cathie Humbarger
Executive Director
Right to Life of Northeast Indiana

Bryan Kemper
President
Stand True Youth Pro-life Outreach