



June 27, 2019

Thomas Christl
Director
Office of Drug Security, Integrity, and Response
Center for Drug Evaluation and Research
Food and Drug Administration

RE: Warning Letters Against Online Providers of Abortion Medications

Mr. Christl:

On March 8, 2019, the FDA issued warning letters to AidAccess.org, Dr. Rebecca Gomperts, and Rablon asserting that they are violating the Federal Food, Drug, and Cosmetic Act by allegedly offering mifepristone and misoprostol directly to U.S. consumers seeking to end a pregnancy. The FDA demanded that these websites immediately cease offering these critical, life-saving medications within the U.S. Because targeting these safe and effective medications through selective enforcement is a misuse of FDA resources and undermines the FDA's mission to advance and protect the public health,ⁱ the undersigned experts and organizations urge your office to stop targeting mifepristone and misoprostol, withdraw the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, and withdraw the threatened actions against AidAccess.org and Rablon.

The use of mifepristone and misoprostol does not threaten public health.ⁱⁱ In fact access to these medications provides public health benefits to the thousands of women who are already and will increasingly be denied access to other forms of safe and effective abortion care, as a result of laws and policies designed to deprive people with the capacity for pregnancy of critical health care.ⁱⁱⁱ Targeting these -- of the many medications that may be supplied to U.S. consumers from outside the U.S. -- does not further the FDA's mission to advance and protect the public health.

Of the vast number of medications available for sale through U.S. and foreign websites, this action singles out mifepristone and misoprostol, which are well known and proven to be safe and effective. Pregnant individuals are capable of using them and assessing when they need follow-up care when provided with information, and so the question remains: *why is the FDA seeking to restrict access to specific medications, in a way that harms a particular group – women?*

More than 100 lawmakers, led by members of the Congressional anti-abortion caucus, have submitted a letter to FDA Acting Commissioner Sharpless applauding the agency's actions against Rablon and AidAccess.org. Many of these lawmakers represent the very states that have

recently passed laws attempting to legislate legal abortion out of existence – including Alabama, Georgia, Kentucky, Mississippi, and Ohio. This agency’s warning letters and threatened actions will further these efforts to keep abortion inaccessible. The FDA’s obligation is to protect public health for all people in the U.S., not to be partisan or political. We strongly urge you to work on advancing the FDA’s mission, not to be a part of a political agenda to deprive women in the U.S. of access to legal, safe and effective abortion care.

Misoprostol and Mifepristone are Safe and Effective Medications

The World Health Organization and medical research establish that these medications are used safely around the world^{iv} for a variety of obstetric and gynecological health care needs, including treatment of postpartum hemorrhage and safe termination of pregnancy.^v

Today, after decades of use in the United States and throughout the world, it is clear that medication abortion is an exceedingly safe and effective way to end a pregnancy.^{vi} Since mifepristone became available in the US in 2000, there have been 3.7 million users with an extremely low associated mortality rate of 0.0006%. The most rigorous study of medication abortion safety included prospective cohort data with no loss to follow up from 11,319 Medi-Cal patients in California.^{vii} In this study, only 35 (0.31%) had a major complication, defined as hospitalization, blood transfusion, or surgery.

It is also a method that many people prefer, accounting for nearly half of U.S. abortions before nine weeks’ gestation.^{viii} But it has been over-regulated^{ix} and pushed out of reach for many people by state restrictions -- both those named above, and by additional politically-motivated restrictions that are not evidence-based, such as bans on telemedicine abortion.^x Worse yet, people who self-manage abortions or who are accused of attempting to do so have been criminalized, subjected to interrogations and wrongful prosecutions.^{xi} Neither overregulation nor criminalization advance the public health goals this agency purports to serve.

The Constitutional and Human Right to Access Abortion

The U.S. Supreme Court as well as international bodies have recognized and reaffirmed the right to have an abortion. In 1973, the landmark case of *Roe v. Wade* held state action could not violate one’s “right to privacy,” specifically a woman’s unqualified right to terminate her pregnancy during the first trimester.^{xii} Further, the United Nations, Human Rights Committee has concluded that government “parties [which includes the U.S.] should not introduce new barriers and should remove existing barriers that deny effective access by women and girls to safe and legal abortion.”^{xiii} Such barriers undermine pregnant people’s fundamental right to life. As explained below, the FDA’s actions – with no evidence that the targeted entities are harming women – only serve to further a medically dangerous political agenda, in violation of the U.S.’s obligation to remove barriers to safe abortion care, and are in fact contradictory to the public health.

Why Women Seek Online Sources of Care for Abortion

U.S. history as well as experience from countries where abortion is prohibited demonstrate that pregnant women deciding to end a pregnancy will find a way regardless of legality. Estimates of illegally induced abortions in the United States in the 1960’s (before state law protections and the *Roe* decision) ranged between 200,000 and 1,200,000 per year.^{xiv}

Access to abortion care of any kind, by any method, is under direct threat, with near-total bans on abortion care recently signed into law in Alabama, Georgia, Kentucky, Mississippi, and Ohio. This is happening in a context in which abortion is already inaccessible for many: 90% of U.S. counties have no abortion clinic,^{xv} and there are six states in which there is only one abortion provider.^{xvi} In addition to having to travel a long distance to the nearest abortion clinic, many people have to endure legally-mandated waiting periods. These medically-unnecessary waiting periods create further challenges for people who have to take time away from work or arrange for childcare.^{xvii} These hurdles may increase the cost of an abortion, which averages \$500 in the first trimester and only becomes more expensive as pregnancy progresses. In 35 states and the District of Columbia, Medicaid does not cover abortion except in rare cases, making abortion financially inaccessible for low-income people.^{xviii} Other legislatively-devised hurdles such as narrated and forced viewing of ultrasounds and biased counseling add unnecessary indignities to what is otherwise a safe and straightforward procedure.

In this context, it is unsurprising that people would turn to online telemedicine services and pharmacies to seek abortion care. Research conducted with people in the United States who sought abortion medications online revealed that the barriers to abortion care may lead people to seek self-managed options, and that a lack of online sources can lead to delays in care or consideration of less effective or safe alternatives.^{xix}

The Truth About Pregnancy and Medication Abortion in the U.S.

The warning letter states that Rablon’s “Abortion Pill Pack” and AidAccess.org’s “(b)(4),(b)(6)” (each a combination of mifepristone and misoprostol) “contain[s] prescription drugs intended for a condition that is not amenable to self-diagnosis and treatment by a layperson.” This overlooks the fact that millions of people each year self-diagnose pregnancies and are able to accurately determine the gestational length of the pregnancy,^{xx} and that AidAccess.org offers a screening and electronic consultation with a licensed physician. The intended effects of the medication are similar to a spontaneous abortion, which occurs in up to 25% of known pregnancies and is frequently managed by the patient with no intervention by a health care provider. Health websites directed at pregnant readers provide lists of the symptoms that might warrant calling a health care provider.

The letter further states that, because pregnancy is “not amenable” to self-diagnosis and treatment by a lay person “adequate directions cannot be written such that a layperson can use the product safely for its intended use.” To the contrary, research into outcomes from online telemedicine services indicates that patients are able to safely use the medications as directed, and self-refer to a health care provider when needed.^{xxi} In fact, most patients receiving medication abortions in U.S.-based clinics are provided with instructions to self-administer one or both medications.

For decades, paternalistic and disingenuous claims of concern for pregnant people’s well-being (such as the claims in the anti-abortion legislators’ letter to the FDA) have been used as a pretext to make abortion as inaccessible and expensive as possible. This approach was rejected by the U.S. Supreme Court in *Whole Woman’s Health v. Hellerstedt*, 579 U.S. ___ (2016) in which the court held that states may not place substantial obstacles in the path of people seeking abortion under the guise of protecting their health. Where, as here, the risks posed by the medications are no greater -- and in many cases significantly lower -- than the risks posed by some over-the-

counter medications,^{xxii} or of experiencing a spontaneous abortion, or by carrying a pregnancy to term, it appears that the “threat” the FDA is seeking to address is a political one: that pregnant people will be able to reclaim their autonomy by circumventing the obstacles intentionally placed in their path to safely access the abortion care they need.

Ensuring the Health of Pregnant People

The impact of FDA’s warning letters and any further selective enforcement action will be to endanger women’s safety and lives by closing off sources of medication that have been found to be safe and reliable.^{xxiii} For women who cannot currently access abortion in a medical setting and will find a way to terminate a pregnancy if they decide to do so, these threats will further limit access to proven safe alternatives. This selective enforcement is also based on the erroneous presumption that eliminating options eliminates risk. Even women who carry pregnancies to term face significant health risks throughout the pregnancy and in the postpartum period. The person best situated to assess the potential risks is the pregnant individual.

Targeting misoprostol and mifepristone for enforcement differently from other medications will also contribute to stigmatization of these medications and endangering women’s access to them from approved sources in the U.S. This has tragically already happened in the U.S. to women when pharmacists refused to fill prescriptions for misoprostol to women who had experienced miscarriages or were in the process of miscarrying.^{xxiv}

This office should not allow itself to be a part of a political agenda to deprive a specific subset of people – those who become pregnant – of their constitutional right to make intimate decisions about their pregnancies. We urge the FDA not to repeat mistakes of the past in which the public health was endangered by the agency’s refusing to support access to life-saving medications for another singled-out group of people – those with HIV or AIDS.^{xxv} Instead, the FDA should support the removal of the current unnecessary regulatory barriers, including the onerous REMS that make safe and effective abortion medications inaccessible, and withdraw the warnings against AidAccess.org and Rablon. Please contact Amber Khan at NAPW (azk@advocatesforpregnantwomen.org) or Farah Diaz-Tello at If/When/How (farah@ifwhenhow.org) with any follow-up.

Sincerely,

If/When/How: Lawyering for Reproductive Justice,
National Advocates for Pregnant Women,

and:

Reproductive Health Access Project
National Women’s Health Network
Ibis Reproductive Health
National Latina Institute for Reproductive Health
National Asian Pacific American Women’s Forum
Positive Women’s Network - USA
ACT UP New York
Daniel Grossman, MD, Advancing New Standards in Reproductive Health, University of
California San Francisco*

Paul D. Blumenthal, MD, MPH, Stanford University*
Ruth Lesnewski, MD
Susan F. Wood, PhD, Jacobs Institute of Women's Health, George Washington University*

Sheila P. Vakharia, PhD, Drug Policy Alliance*
Paula Tavrow, PhD, Bixby Program in Population & Reproductive Health, Fielding School of
Public Health, University of California Los Angeles*
Mary Pendergast, JD, Former FDA Deputy Commissioner

Cc: Kaveeta Vasisht, M.D., Pharm.D. - Acting Associate Commissioner for Women's Health

*Institutional affiliation listed for identification purposes only.

ⁱ See U.S. Food and Drug Administration, <https://www.fda.gov/about-fda/what-we-do#mission>

ⁱⁱ Murtagh, C., Wells, E., Raymond, E. G., Coeytaux, F., & Winikoff, B. (2018). Exploring the feasibility of obtaining mifepristone and misoprostol from the internet. *Contraception*, 97(4), 287-291.

ⁱⁱⁱ Mifeprex REMS Study Group (2017). "Sixteen Years of Overregulation: Time to Unburden Mifeprex." *N Engl J Med* 376(8): 790-794.

^{iv} World Health Org., *WHO Statement Regarding the Use of Misoprostol for Postpartum Haemorrhage Prevention and Treatment* 2009, <http://bit.ly/2XKbn1X>

^v Tang, J. , Kapp, N. , Dragoman, M. and de Souza, J. P. (2013), WHO recommendations for misoprostol use for obstetric and gynecologic indications. *International Journal of Gynecology & Obstetrics*, 121: 186-189. ("WHO recognizes the crucial role of misoprostol in reproductive health and has incorporated recommendations for its use into 4 reproductive health guidelines focused on induction of labor, prevention and treatment of postpartum hemorrhage, and management of spontaneous and induced abortion.")

^{vi} National Academies of Sciences, Engineering, and Medicine. (2018). *The safety and quality of abortion care in the United States*. National Academies Press.

^{vii} Upadhyay, U. D., Desai, S., Zlidar, V., Weitz, T. A., Grossman, D., Anderson, P., & Taylor, D. (2015). Incidence of emergency department visits and complications after abortion. *Obstetrics & Gynecology*, 125(1), 175-183.

^{viii} Guttmacher Institute, *Fact Sheet: Induced Abortion in the United States*, Jan. 2018, <http://bit.ly/2g9zzqx>.

^{ix} Mifeprex REMS Study Group (2017). "Sixteen Years of Overregulation: Time to Unburden Mifeprex." *N Engl J Med* 376(8): 790-794.

^x Endler, M., Lavelanet, A., Cleeve, A., Ganatra, B., Gomperts, R., & Gemzell-Danielsson, K. (2019). Telemedicine for medical abortion: a systematic review. *BJOG: An International Journal of Obstetrics & Gynaecology*.

^{xi} If/When/How: Lawyering for Reproductive Justice (formerly SIA Legal Team), *Roe's Unfinished Promise: Decriminalizing Abortion Once and For All* (2017); available at <http://bit.ly/2WvuEm2>; If/When/How: Lawyering for Reproductive Justice, *Fulfilling Roe's Promise: 2019 Update* (2019), available at <http://bit.ly/2Wu2F6m>; Paltrow, L. & Flavin, J (2013). Arrests of and Forced Interventions on Pregnant Women in the United States, 1973-2005: Implications for Women's Legal Status and Public Health, 38 *J. Health Pol., Pol'y & L.* 299, available at <http://bit.ly/2q0I3FU>.

^{xii} *Roe v. Wade*, 93 S.Ct. 705, 708 (1973).

^{xiii} UN HR Committee, General comment on article 6 on the right to life, CCPR/C/GC/36 (Oct. 30, 2018).

^{xiv} Cates, W. Jr., *Legal Abortion: The Public Health Record*, 215 *Science* 1586 (1982).

^{xv} Jones, R. K. and Jerman, J. (2017), Abortion Incidence and Service Availability In the United States, 2014. *Perspect Sex Repro H*, 49: 17-27.

^{xvi} Sabrina Tavernise, *'The Time is Now': States are Rushing to Restrict Abortion, or to Protect It*, *NY Times*, May 15, 2019.

^{xvii} Roberts, S. C., Turok, D. K., Belusa, E. , Combellick, S. and Upadhyay, U. D. (2016), Utah's 72-Hour Waiting Period for Abortion: Experiences Among a Clinic-Based Sample of Women. *Perspect Sex Repro H*, 48: 179-187.

^{xviii} Reproductive Health Technologies Project, *Two Sides of the Same Coin: Integrating Economic and Reproductive Justice*, 2015, <http://bit.ly/2I4Lxjr>.

^{xix} Aiken, A., Broussard, K., Johnson, D.M., and Padron, E. Motivations and Experiences of People Seeking Medication Abortion Online in the United States. *Perspectives on Sexual and Reproductive Health*, 2018

^{xx} Bracken, H., Clark, W., Lichtenberg, E. S., Schweikert, S. M., Tanenhaus, J., Barajas, A., Alpert, L., & Winikoff, B. (2011). Alternatives to routine ultrasound for eligibility assessment prior to early termination of pregnancy with mifepristone–misoprostol. *BJOG: An International Journal of Obstetrics & Gynaecology*, 118(1), 17-23.

^{xxi} Aiken, A. R., Digol, I., Trussell, J., & Gomperts, R. (2017). Self reported outcomes and adverse events after medical abortion through online telemedicine: population based study in the Republic of Ireland and Northern Ireland. *BMJ*, 357.

^{xxii} Abortion medications are safer than many common over-the-counter and prescription drugs in the United States, including acetaminophen (Tylenol) or sildenafil (Viagra). *Advancing New Standards in Reproductive Health (ANSIRH), Issue Brief: Analysis of Medication Abortion Risk and the FDA report “Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018”*, April 2019, <http://bit.ly/2ZwZWEd>.

^{xxiii} See note 2 above.

^{xxiv} Christina Caron, *Michigan Pharmacist Refused to Dispense Miscarriage Medication, Citing Religious Beliefs*, *NY Times*, Oct. 18, 2018, <https://nyti.ms/2Wx3SyC>; Erin B. Logan, *Walgreens Pharmacist Denies Woman Miscarriage Medication Because it Goes Against His Ethics*, June 25, 2018, <https://wapo.st/2Iw5leU>.

^{xxv} Robert Reinhold, *Infected But Not Ill, Many Try Unproven Drug to Block AIDS*, *NY Times*, May 20, 1987, <https://nyti.ms/2WAwh6P>.