

April 6, 2020

Dr. Stephen Hahn  
Commissioner  
Office of the Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002

Dear Commissioner Hahn,

We, the undersigned 80 organizations, urge you to immediately lift the medically unnecessary restrictions on medication abortion that further endanger pregnant people and strain the health care system during the global COVID-19 outbreak. As you may be aware, the United Kingdom Department of Health recently approved home use of both stages of medication abortion to limit the spread of COVID-19<sup>i</sup>. The U.S. FDA should similarly act quickly to protect the health of pregnant people and health care professionals.

Due to the pandemic, one in four Americans are currently under strict shelter-at-home orders to slow the virus's spread, with more closures expected as the health system copes with a growing caseload. We know that hundreds of thousands of pregnant people will need an abortion during this crisis. For many of these people, access to safe and effective mifepristone could be a lifeline, ensuring they receive prompt abortion care without having to visit a clinic, or even leave their homes.

Yet the FDA mandates that providers must be certified and registered with the drug sponsor to prescribe the drug, and pregnant people must go to a clinic, medical office or hospital to obtain it, rather than through a retail pharmacy — even though the FDA permits patients to wait until they get home to swallow the pill. Solid research and nearly 20 years of clinical experience have demonstrated that these requirements are medically unnecessary.<sup>ii</sup>

These requirements have long harmed patients' health by delaying or blocking access to medication abortion with no countervailing medical benefit. Now, in the midst of a public health emergency, these requirements are further endangering patients and straining the health system. Under the Risk Evaluation and Mitigation Strategies (REMS) and Elements to Assure Safe Use (ETASU) imposed by the FDA on mifepristone, both patients and clinic staff are forced to travel during a pandemic, don protective gear, and increase their exposure to potentially sick individuals — with no corresponding health benefit to justify these serious risks.

Some states have attempted to prohibit clinic-based abortion services altogether by falsely declaring that abortions are “nonessential” procedures and can be delayed during the outbreak. But even in states with robust support for abortion access, clinic services may be curtailed

by nationwide shortages of basic medical supplies and personal protective equipment, such as gloves and masks.

In every case, requiring pregnant people to travel to providers for services that could be performed remotely through telehealth consultations in order to receive FDA-approved medication that could be available at retail pharmacies through pickup or delivery, threatens both patient and provider.

Sensibly, the FDA has explicitly recognized that enforcement of REMS and ETASU restrictions during a pandemic “put[s] patients and others at risk for transmission of the coronavirus” and has suspended its enforcement of critical restrictions imposed on other drugs — even when they have a far riskier safety profile.

In guidance issued in March, the FDA noted its “critical role in protecting the United States from threats including emerging infectious diseases” and its commitment “to providing timely guidance to support response efforts to this pandemic.”<sup>iii</sup>

The guidance states:

FDA recognizes that during the COVID-19 PHE [public health emergency], completion of REMS-required laboratory testing or imaging studies may be difficult *because patients may need to avoid public places and patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine*. Under these circumstances, undergoing laboratory testing or imaging studies *in order to obtain a drug subject to a REMS can put patients and others at risk for transmission of the coronavirus* [emphasis ours].

In light of the FDA’s March guidance and explicit recognition of the dire risks, we urge you to lift the REMS and ETASU restrictions on mifepristone to ensure that pregnant people have access to this safe and effective drug even during this national public health crisis. If everyone who needs a medication abortion can safely access mifepristone through telehealth appointments and have it shipped to them, then that action alone would alleviate strain on the health system while protecting patients.

In the absence of this action, the FDA will force pregnant people to pursue alternatives. Some will turn to overseas pharmacies. While many of us believe that this can be a safe method for procuring medication abortion, *the FDA* has argued that doing so “poses an inherent risk to consumers who purchase those products.”<sup>iv</sup> Some pregnant people will use alternative, non-medical methods of self-managed abortion — as long practiced by women — that can be safe and effective. But many others will turn to dangerous or unproven methods. Some people who travel (often over long distances) to pick up mifepristone in a clinic will be exposed to COVID-19. And, of course, many people will be forced to carry an unwanted pregnancy to term during a pandemic — with unknown but likely significant risks. **In making a risk-benefit analysis around the REMS and ETASU for mifepristone, the FDA must weigh all of these real-world considerations.**

The FDA is putting the lives of pregnant people at risk. We urge you to take steps now to ensure that mifepristone remains a safe and effective form of abortion care during the crisis.

Thank you for your prompt attention to this urgent public health matter. Please contact Cynthia A. Pearson, Executive Director at the National Women's Health Network at [cpearson@nwhn.org](mailto:cpearson@nwhn.org) with your response.

Sincerely,

500 Women Scientists  
Abortion Care Network  
Access Reproductive Care-Southeast  
Advocates for Youth  
All-Options  
American Humanist Association  
American Medical Student Association (AMSA)  
AMPLIFY GA  
Asian & Pacific Islander American Health Forum  
Black Women's Health Imperative  
California Latinas for Reproductive Justice  
Catholics for Choice  
Center for American Progress  
CHOICES. Memphis Center for Reproductive Health  
Civil Liberties and Public Policy  
Clearinghouse on Women's Issues  
Cobalt  
Consumers for Affordable Health Care  
Creating a Clinician Corps  
DuPont Clinic  
Equality California  
Equity Forward  
EverThrive Illinois  
Feminist Majority Foundation  
Feminist Women's Health Center  
Florida Access Network  
Forward Together Action  
Gender Justice  
Gender Justice League Seattle  
GLMA: Health Professionals Advancing LGBTQ Equality  
If/When/How: Lawyering for Reproductive Justice  
In Our Own Voice: National Black Women's Reproductive Justice Agenda  
Indiana Religious Coalition for Reproductive Choice  
International Campaign for Women's Safe Right to Abortion  
International Women's Health Coalition

Ipas  
Jacobs Institute of Women's Health  
Jane's Due Process  
Legal Voice  
Medical Students for Choice  
NARAL Pro-Choice America  
NARAL Pro-Choice Texas  
National Abortion Federation  
National Advocates for Pregnant Women  
National Asian Pacific American Women's Forum  
National Center for Lesbian Rights  
National Council of Jewish Women  
National Health Law Program  
National Hispanic Medical Association  
National Latina Institute for Reproductive Justice  
National Minority Quality Forum  
National Network of Abortion Funds  
National Organization for Women  
National Women's Health Network  
National Working Positive Coalition  
New Era Colorado  
Our Bodies Ourselves  
PAI  
Pendergast Consulting  
Physicians for Reproductive Health  
Population Connection Action Fund  
Power to Decide  
Progress Florida Education Institute  
Public Citizen  
Religious Coalition for Reproductive Choice  
Reproaction  
Reproductive Health Access Project  
SIECUS: Sex Ed for Social Change  
SisterSong Women of Color Reproductive Justice Collective  
Southwest Women's Law Center in Albuquerque, New Mexico  
SPARK Reproductive Justice NOW!  
Students for Choice  
The Women's Centers  
Union of Concerned Scientists  
URGE: Unite for Reproductive & Gender Equity  
Women First Digital  
Women's Health Specialists  
Women Have Options/Ohio  
Women's Law Project, Pennsylvania  
WVFREE

CC:  
Dr. Janet Woodcock  
Director  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration