April 6, 2020

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

Dear Commissioner Hahn,

We, the undersigned XX health advocacy 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.

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.[i]

Now, these requirements are endangering patients and further 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 sharply 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."[ii]

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."[iii] Some pregnant people will use alternative, non-medical methods of home 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 women 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 with your response.

Sincerely,

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[i] "The Safety and Quality of Abortion Care in the United States: Consensus Study Report," National Academies of Sciences, Engineering, and Medicine, The National Academies Press, 2018. https://www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states

[ii] "Policy for Certain REMS Requirements During the COVID19 Public Health Emergency: Guidance for Industry and Health Care Professionals," U.S. Food and Drug Administration, March 2020. https://www.fda.gov/media/136317/download

[iii] "WARNING LETTER to Aidaccess.org," U.S. Food and Drug Administration, 8 March 2019. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019