Congress of the United States

Washington D.C. 20515

June 16, 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 write to you as Members of Congress deeply committed to the safety of our constituents seeking essential, constitutionally-protected reproductive health care during the COVID-19 pandemic. We urge you to lift the Risk Evaluation and Mitigation Strategies (REMS) imposed by the U.S. Food and Drug Administration (FDA) on mifepristone — the first of two medications used in combination to safely and effectively induce an early abortion or treat an early miscarriage— to ensure safe access to this drug during the pandemic and beyond. At a minimum, we request that you immediately use your enforcement discretion to allow certified prescribers to mail mifepristone to patients at their homes.

As you know, the FDA-approved medication abortion regimen is highly effective,[i] and 14 times safer than carrying a pregnancy to term.[ii] Yet the REMS imposed on mifepristone includes highly restrictive Elements to Assure Safe Use (ETASU) that unnecessarily block patients' access to this essential health care even at the best of times. Now, during the midst of a global pandemic, these restrictions are putting patients and providers at risk of contracting the novel coronavirus.

Despite medication abortion's strong safety profile, the REMS reduces the number of health care providers who can prescribe mifepristone by requiring them to pre-order and stock pills themselves instead of sending prescriptions to retail pharmacies, as they do for virtually every other drug. The REMS requirement that clinicians register with the drug maker also deters some clinicians who fear that their information could become public, exposing them to the violence and harassment to which abortion providers have long been subjected.[iii] Registration itself is a bureaucratic process that creates delays even under normal circumstances. Now, these restrictions limit the ability of new providers to respond to the demand for abortion care during the pandemic.

Most relevant to the accessibility of mifepristone during the COVID-19 pandemic, the REMS requirement that mifepristone must be dispensed from a registered facility or under the supervision of certified provider means that patients must travel unnecessarily during a global

health crisis, risking their safety. This requirement is particularly burdensome in the context of FDA's other rules for mifepristone.

While state laws vary, FDA does not require pregnant people seeking medication abortion care to receive in-person consultations with a clinician, undergo physical exam or laboratory testing, or take the pills in the provider's office, deferring instead to the clinician's medical judgment and the patient's needs and preferences.[iv] The abortion itself always takes place outside of a clinic setting, regardless of where the pills are taken. In fact, a protocol developed by providers and researchers during the pandemic makes clear that, for those patients eligible for a medication abortion through telehealth, the REMS is the only reason they must leave their homes:

> Although FDA-imposed restrictions on mifepristone dispensing may require patients to present to the abortion provider or facility to obtain the drug, this protocol would enable every other part of the [medication abortion] process to be implemented without any in-person encounter.[v]

Thus, the REMS in its current form creates an illogical situation in which a patient can meet with her doctor by telehealth from the safety of her home, take the pills at home, safely have her abortion at home, and follow up with her doctor after the abortion by telehealth again, but must first travel in the midst of a global pandemic just to pick up the pills from a registered facility or provider.

For many patients, this requirement can mean taking public transportation, riding in someone else's car, or traveling hundreds of miles away from home to another county or state — significantly increasing their risk of exposure to the virus. It also means that some providers and clinic staff are forced to have unnecessary in-person interactions that increase their own exposure risks.

Sensibly, the United Kingdom has already issued guidance authorizing physicians to mail mifepristone to pregnant women during the pandemic following a telephone or video consultation,[vi] and FDA itself has already suspended enforcement of other types of REMS restrictions necessitating in-person visits, noting that "patients may need to avoid public places and patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine."[vii]

The medical community has long called for the removal of the REMS on mifepristone.[viii,ix] We urge you to lift the REMS at this time, which would ensure that more providers could safely meet the need for abortion care during the pandemic, would permit mifepristone prescriptions to be mailed directly to patients' homes in accordance with CDC guidance specifically encouraging patients to fill prescriptions via mail-order delivery during the pandemic,[x] and would allow patients to pick up their medication through retail pharmacies that may be much closer to home or have their own delivery services.

At a minimum, we ask that you take immediate action to allow certified prescribers to mail mifepristone to patients during the pandemic. This could be achieved simply by updating the FDA's March 2020 guidance on "REMS Requirements During the COVID19 Public Health

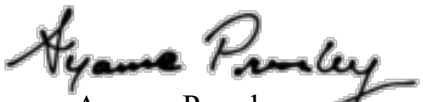
Emergency" to include explicit permission for certified providers to dispense mifepristone by mail.

Thank you for your prompt attention to this urgent public health matter. We request a staff-level briefing or written response by no later than June 30, 2020.

Sincerely,

Diana DeGette
Member of Congress

Barbara Lee
Member of Congress



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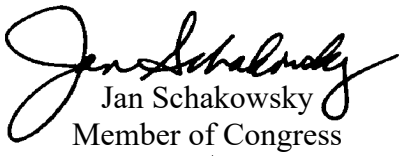

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