August 3, 2022

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health & Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Dear Mr. Secretary:

We write in support of the Biden-Harris Administration’s announcement prioritizing the protection and expansion of access to medication abortion in the wake of the Supreme Court’s devastating decision in Dobbs v. Jackson Women’s Health Organization,¹ and to urge you to consider several actions that the Administration can take to support that goal.

For more than two decades, people have been using Mifepristone and misoprostol for medication abortion.² Years of research have affirmed that medication abortion is safe and effective,³ and medication abortion now accounts for more than half of all abortions nationwide.⁴ Following the Supreme Court’s reckless decision to overturn Roe v. Wade, we agree with the Administration that it is more important than ever to defend and expand access to abortion for the 34 million women and girls of reproductive age who are at risk of losing access to this right.⁵ We were encouraged by President Biden’s executive order last month, which directed the Department of Health and Human Services (HHS) to take action to protect access to medication abortion and to submit a report on those efforts by August 7, 2022.⁶ We are writing to share a set of recommendations that we believe will most effectively help the Administration reach this goal, and we respectfully urge you, in coordination with other federal agencies, to consider the following options as you develop plans to ensure that women have access to medication abortion:

³ Id.
1. **Enforce Federal Preemption of State Laws That Ban Medication Abortion.** A number of states have total abortion bans in place that prohibit the use of medications approved by the Food and Drug Administration (FDA) for abortion. Anti-abortion state lawmakers’ decisions to deny women access to these medications undermine FDA’s authority to protect the nation’s public health. Attorney General Merrick Garland has affirmed that: “States may not ban mifepristone based on disagreement with the FDA’s expert judgment about its safety and efficacy” and that the Department of Justice (DOJ) “stand[s] ready to work with other arms of the federal government…to protect and preserve access to reproductive care.” To that end, DOJ, with HHS support, could intervene in lawsuits or bring their own suits to challenge state laws that deny patients access to FDA-approved medications.

2. **Urgently Finalize Updated Risk Evaluation and Mitigation Strategy (REMS) for Mifepristone and Consider Lifting Remaining Medically Unnecessary REMS Restrictions.** In December 2021, after undertaking a science and evidence-based review of the Mifepristone REMS program, FDA announced that it was modifying the existing REMS for Mifepristone, including the elimination of the medically unnecessary in-person dispensing requirement. This modification expands access to medication abortion by allowing clinicians to dispense Mifepristone by mail. FDA further updated the REMS to allow certified pharmacies, in addition to certified clinicians, to distribute Mifepristone. But the new changes to the REMS are still going through the FDA process and have not been finalized. Now that manufacturers have submitted an updated REMS to FDA for approval – the first step toward finalizing the REMS – FDA should expedite its review of manufacturers’ plans to certify pharmacies and finalize the updated REMS well before its 180-day statutory deadline. In this moment of crisis, doing so will help make medication abortion more accessible sooner by allowing patients to access Mifepristone at certified pharmacies.

In addition, as FDA prepares to finalize the updated REMS for Mifepristone as announced in December 2021, we ask that you follow the science and reconsider the remaining REMS and lift any additional medically unnecessary restrictions. FDA

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frequently revisits REMS “at periodic intervals following REMS approval,” and as FDA has acknowledged as recently as December 2021, previously modified REMS “after reviewing the data and information submitted by the applicant … and after taking into consideration the safety data that had become available since the initial approval of Mifeprex in 2000.” Based on evidence, FDA should review the remaining REMS to determine if any restrictions placed on the prescription and distribution of Mifepristone, including patient consent forms, are medically unnecessary.

3. **Declare A Public Health Emergency Under the Public Readiness and Emergency Preparedness (PREP) Act.** A public health emergency declaration, which Secretary Becerra can declare under the PREP Act based on the public health emergency created by the Supreme Court and state abortion bans, may protect those involved in the administration or use of “covered countermeasures”—a term which could encompass medication abortion—from certain state restrictions, claims, and lawsuits, including efforts to sue physicians who prescribe or pharmacists who dispense medication abortion, or people who self-administer. To bolster the likelihood that medication abortion would be protected under the PREP Act, FDA could issue an Emergency Use Authorization (EUA) for misoprostol, which has been approved by FDA to reduce the risk of non-steroidal anti-inflammatory drug-induced gastric ulcers, but has been safely used to induce abortion and treat miscarriages for decades. An EUA would allow misoprostol to be considered a “covered countermeasure” that could be used to address this public health emergency.

4. **Strengthen Enforcement of Existing Abortion Requirements and Enhance State Medicaid Programs.** In 2019, the Government Accountability Office found that several states were out of compliance with federal Medicaid requirements to cover eligible abortions in the case of rape, incest, and life endangerment. We were glad to see that HHS, through the Centers for Medicare and Medicaid Services (CMS), plans to ensure

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that all states meet these minimum requirements, including by ensuring access to
medication abortion. Additionally, we were pleased to see President Biden’s
announcement directing HHS to explore the use of Medicaid funds to allow patients to
travel across state lines for medical care. This is a strong step, and the administration
could go even further. State Medicaid programs could more easily accept out-of-state
patients seeking reproductive care. Disaster-Relief State Plan Amendments, which could
be put in place after the declaration of a public health emergency through 1135 waivers,
could enable states to expand the pool of people covered by their Medicaid programs,
including out-of-state residents who leave their home states for medical reasons such as
to seek medication abortion.

5. **Ask FDA to Work with Drug Sponsors to Add a Miscarriage Indication for Mifepristone with misoprostol.** In coordination with drug sponsors, FDA can add a
second indication to the Mifepristone with misoprostol label for the use of miscarriage
management. As many as 26 percent of all pregnancies result in miscarriage, and
evidence shows that Mifepristone significantly improves the management of early
pregnancy loss, resulting in fewer complications, when taken with misoprostol. Yet,
many patients in states that have restricted access to medication abortion have reported
being denied these medications to treat their miscarriages – to devastating effect.
Updating the Mifepristone with misoprostol label will help ensure that patients
experiencing miscarriages are not unnecessarily denied access to this medication.

6. **Eliminate Barriers to Importation.** Given the expected uptick in demand for
medication abortion, which could potentially result in shortages, HHS should consider

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28 Fortune, “Abortion pill distributor sees no surge or shortages after Roe v. Wade overturned: ‘We are very confident in our position,’” Christine Mui, June 28, 2022, [https://fortune.com/2022/06/28/abortion-pill-no-shortages-mifeprex/](https://fortune.com/2022/06/28/abortion-pill-no-shortages-mifeprex/).
issuing clarifying guidance related to the personal importation of medication abortion, including by creating a carve-out from existing importation restrictions for medication abortion. HHS should also work with the Department of Homeland Security to ensure that there are no unnecessary legal obstacles preventing Americans from obtaining abortion services abroad or from bringing medication abortion prescribed by foreign health care professionals into the country, such as existing importation restrictions.

7. **Expand Access to Medication Abortion for Veterans.** The Department of Veterans Affairs (VA) should immediately take action to ensure that all service members can access abortions and other critical reproductive health care. The VA should begin rulemaking to allow veterans and eligible dependents to receive abortions and all abortion-related services, allowing providers to offer medication abortion to the approximately 550,000 women veterans accessing care through the VA. HHS must also work with the VA to ensure that veterans who must travel out of state or outside the VA health system to receive reproductive health care including abortion have access to quality and comprehensive sexual and reproductive health services. Providers employed by the VA are eligible to provide telehealth services to any VA patient, even across state lines.

As states escalate bans and restrictions on abortion, there is more urgency than ever to take immediate steps to expand access to medication abortion. We support your efforts to take all possible actions to protect abortion access, and as you work to meet this goal, we urge you to consider these options, which we believe will have the greatest impact on expanding access to medication abortion across the nation.

Thank you for your attention to this important matter.

Sincerely,

Elizabeth Warren  
United States Senator

Mazie K. Hirono  
United States Senator

Tammy Baldwin  
United States Senator

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CC:

Secretary McDonough
U.S. Department of Veterans Affairs

Attorney General Merrick Garland
U.S. Department of Justice

Secretary Alejandro Mayorkas
U.S. Department of Homeland Security