

United States Senate

WASHINGTON, DC 20510

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:

¹ White House, “FACT SHEET: President Biden to Sign Executive Order Protecting Access to Reproductive Health Care Services,” press release, July 8, 2022, <https://www.whitehouse.gov/briefing-room/statements-releases/2022/07/08/fact-sheet-president-biden-to-sign-executive-order-protecting-access-to-reproductive-health-care-services/>.

² Guttmacher Institute, “Medication Abortion,” February 2021, <https://www.guttmacher.org/evidence-you-can-use/medication-abortion>.

³ *Id.*

⁴ Guttmacher Institute, “Medication Abortion Now Accounts for More Than Half of All US Abortions,” Rachel K. Jones, Elizabeth Nash, Lauren Cross, Jesse Philbin, and Marielle Kirstein, February 24, 2022, <https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions>.

⁵ Center for American Progress, “Expanding Access and Protections in States Where Abortion Is Legal,” Kierra B. Jones, July 25, 2022, <https://www.americanprogress.org/article/expanding-access-and-protections-in-states-where-abortion-is-legal/>.

⁶ White House, “FACT SHEET: President Biden to Sign Executive Order Protecting Access to Reproductive Health Care Services,” press release, July 8, 2022, <https://www.whitehouse.gov/briefing-room/statements-releases/2022/07/08/fact-sheet-president-biden-to-sign-executive-order-protecting-access-to-reproductive-health-care-services/>.

- 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)⁷ for abortion.⁸ 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."⁹ 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.¹⁰ This modification expands access to medication abortion by allowing clinicians to dispense Mifepristone by mail.¹¹ 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.¹² In this moment of crisis, doing so will help make medication abortion more accessible sooner by allowing patients to access Mifepristone at certified pharmacies.¹³

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

⁷ Guttmacher Institute, "Medication Abortion Now Accounts for More Than Half of All US Abortions," Rachel K. Jones, Elizabeth Nash, Lauren Cross, Jesse Philbin, and Marielle Kirstein, February 24, 2022, <https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions>.

⁸ Center for Reproductive Rights, "After Roe Fell: Abortion Laws by State," <https://reproductiverights.org/maps/abortion-laws-by-state/>.

⁹ U.S. Department of Justice, "Attorney General Merrick B. Garland Statement on Supreme Court Ruling in Dobbs v. Jackson Women's Health Organization," press release, June 24, 2022, <https://www.justice.gov/opa/pr/attorney-general-merrick-b-garland-statement-supreme-court-ruling-dobbs-v-jackson-women-s>.

¹⁰ Food and Drug Administration, "Mifeprex (mifepristone) Information," www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.

¹¹ The American College of Obstetricians and Gynecologists, "Understanding the Practical Implications of the FDA's December 2021 Mifepristone REMS Decision," March 28, 2022, <https://www.acog.org/news/news-articles/2022/03/understanding-the-practical-implications-of-the-fdas-december-2021-mifepristone-rems-decision>.

¹² Kaiser Family Foundation, "The Availability and Use of Medication Abortion," April 6, 2022, <https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/>.

¹³ Washington Post, "Abortion pills by mail are safe. The FDA finally acknowledged it," Daniel Grossman, December 20, 2021, <https://www.washingtonpost.com/outlook/2021/12/20/telemedicine-abortion-fda-safe/>.

frequently revisits REMS “at periodic intervals following REMS approval,”¹⁴ 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.”¹⁵ 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.¹⁶

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.¹⁷ 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,¹⁸ 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.¹⁹
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.²⁰ We were glad to see that HHS, through the Centers for Medicare and Medicaid Services (CMS), plans to ensure

¹⁴ U.S. Food and Drug Administration, “Frequently Asked Questions (FAQs) about REMS,” January 26, 2018, <https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems>.

¹⁵ Letter from FDA CDER to American Association of Pro-Life Obstetricians and Gynecologists and American College of Pediatricians, December 16, 2021, <https://www.regulations.gov/document/FDA-2019-P-1534-0016>.

¹⁶ American Medical Association, “Doctors back continued nationwide access to medication abortion,” Kevin B. O’Reilly, June 28, 2022, <https://www.ama-assn.org/delivering-care/population-care/doctors-back-continued-nationwide-access-medication-abortion>; American Academy of Family Physicians, “FPs Tackle Primary Care Spending, Other Weighty Topics,” Sheri Porter, October 12, 2018, <https://www.aafp.org/news/2018-congress-fmx/20181012cod-advocacy.html>; American Congress of Obstetricians and Gynecologists (ACOG), “ACOG Statement on Medication Abortion,” press release, March 30, 2016, <https://www.acog.org/news/news-releases/2016/03/acog-statement-on-medication-abortion>.

¹⁷ U.S. Department of Health & Human Services, Federal Register Notice, “Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19,” March 17, 2020, <https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>.

¹⁸ National Institutes of Health, “Misoprostol,” Marissa Krugh and Christopher V. Maani, July 11, 2022, <https://www.ncbi.nlm.nih.gov/books/NBK539873/#:~:text=Currently%2C%20misoprostol%20is%20FDA%20approved.gastric%20ulcers%20with%20other%20etiologies>.

¹⁹ FDA, “Emergency Use Authorization,” July 26, 2022, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

that all states meet these minimum requirements, including by ensuring access to medication abortion.²¹ 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.²² 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,²³ 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.²⁴

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,²⁵ and evidence shows that Mifepristone significantly improves the management of early pregnancy loss, resulting in fewer complications, when taken with misoprostol.²⁶ 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.²⁷ 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,²⁸ which could potentially result in shortages, HHS should consider

²⁰ Government Accountability Office, “CMS Action Needed to Ensure Compliance with Abortion Coverage Requirements,” January 2019, <https://www.gao.gov/assets/gao-19-159.pdf>.

²¹ Centers for Medicare and Medicaid Services, “Following President Biden’s Executive Order to Protect Access to Reproductive Health Care, HHS Announces Guidance to Clarify that Emergency Medical Care Includes Abortion Services,” press release, July 11, 2022, <https://www.cms.gov/newsroom/press-releases/following-president-bidens-executive-order-protect-access-reproductive-health-care-hhs-announces>.

²² The White House, “Executive Order on Securing Access to Reproductive and Other Healthcare Services,” press release, August 3, 2022, <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/08/03/executive-order-on-securing-access-to-reproductive-and-other-healthcare-services/>.

²³ Centers for Medicare and Medicaid Services, “1135 Waivers,” <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>.

²⁴ Medicaid, “Medicaid Disaster Relief for the COVID-19 National Emergency State Plan Amendment Instructions,” <https://www.medicaid.gov/state-resource-center/downloads/medicaid-disaster-relief-spa-instructions.pdf>.

²⁵ National Library of Medicine, “Miscarriage,” June 27, 2022, <https://www.ncbi.nlm.nih.gov/books/NBK532992/>.

²⁶ American College of Obstetricians and Gynecologists, “Early Pregnancy Loss,” November 2018, <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss>; New England Journal of Medicine, “Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss,” Courtney A. Schreiber, Mitchell D. Creinin, Jessica Atrio, Sarita Sonalkar, Sarah J. Ratcliffe, and Kurt T. Barnhart, June 2018, <https://pubmed.ncbi.nlm.nih.gov/29874535/>.

²⁷ Business Insider, “It may soon be harder to access medications used in miscarriages and ectopic pregnancies because they're also used to treat abortions,” Rebecca Cohen, June 24, 2022, <https://www.businessinsider.com/miscarriage-medications-could-be-restricted-abortion-bans-2022-5>.

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/>.


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.²⁹ 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.³⁰


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

²⁹ U.S. Department of Veterans Affairs, “Congressionally Mandated Report: Report on Locations Where Women Veterans are Using Health Care from Department of Veterans Affairs,” February 2022, p. 5, [on file with the Office of Senator Elizabeth Warren]; Congressional Research Service, “Health Care for Dependents and Survivors of Veterans,” April 21, 2021, <https://crsreports.congress.gov/product/pdf/RS/RS22483>.

³⁰ U.S. Department of Veterans Affairs, “VA Expands Telehealth by Allowing Health Care Providers to Treat Patients Across State Lines,” press release, May 11, 2018, <https://www.va.gov/opa/pressrel/pressrelease.cfm?id=4054>.

CC:

Secretary McDonough
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