United States Senate

WASHINGTON, DC 20510

November 18, 2022

Dr. Robert M Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf:

In the wake of the Supreme Court's devastating decision in *Dobbs v. Jackson Women's Health Organization* to eliminate the right to an abortion,[1] we urge you to immediately act to defend Americans' fundamental reproductive rights. We respectfully request that you consider the following three actions to protect and expand access to medication abortion: (1) finalize the updated Risk Evaluation and Mitigation Strategy (REMS) for Mifepristone, (2) lift remaining medically unnecessary REMS restrictions, and (3) work with drug sponsors to add a miscarriage management indication for Mifepristone taken with misoprostol.

For over two decades, women have been safely and effectively using medication abortion – Mifepristone and misoprostol – to terminate a pregnancy.[2] But the Supreme Court's reckless decision to overturn *Roe v. Wade* now endangers millions of women in this country who are facing restrictions to lifesaving care and rights.[3]

Soon after the Supreme Court's *Dobbs* decision, in July 2022, President Biden released an Executive Order to protect access to reproductive health care services.[4] In August 2022, the Department of Health and Human Services (HHS) responded by publishing a report that provided an "action plan to protect and strengthen reproductive care."[5] The HHS report included a recommendation to expand access to medication abortion through FDA finalization of updated REMS for Mifepristone "that have been found to be safe and effective."[6] We are writing to ask you to consider the following recommendations, specifically, that you:

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[1] Dobbs v. Jackson Women's Health Organization, 597 U.S. _ (2022).
[2] Guttmacher Institute, "Medication Abortion," February 2021, https://www.guttmacher.org/evidence-you-can-use/medication-abortion.
[3] New York Times, "Medical Impact of Roe Reversal Goes Well Beyond Abortion Clinics, Doctors Say," Kate Zernike, September 10, 2022, https://www.nytimes.com/2022/09/10/us/abortion-bans-medical-care-women.html.
[4] 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/.
[5] Department of Health and Human Services, "Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care," August 2022, p. 1, https://www.hhs.gov/sites/default/files/hhs-report-reproductive-health.pdf.
[6] Department of Health and Human Services, "Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care," August 2022, p. 6, https://www.hhs.gov/sites/default/files/hhs-report-reproductive-health.pdf.

1. **Finalize the Updated Risk Evaluation and Mitigation Strategy (REMS) for Mifepristone.** In December 2021, FDA conducted a scientific and evidence-based review of the Mifepristone REMS program and announced it would modify the existing REMS for Mifepristone, including eliminating the medically unnecessary in-person dispensing requirement.[7] This modification would expand access to medication abortion by allowing clinicians to dispense Mifepristone by mail order and/or for patients to obtain access to Mifepristone at retail pharmacies.[8] However, FDA is still processing the changes to the REMS and has not finalized them yet, despite the fact that manufacturers have already made their required submissions to FDA for approval.[9] We encourage you to finalize your review of manufacturers' plans to certify pharmacies and the updated REMS, especially as we advance closer to the 180-day deadline that FDA has to review or modify submissions.[10] It is crucial that you act as soon as possible to allow patients to access Mifepristone via certified mail delivery and at retail pharmacies. Until you finalize the updated REMS, we ask FDA to continue its policy of exercising enforcement discretion (put in place at the beginning of the COVID-19 pandemic) to protect access to medication abortion, regardless of when the COVID-19 public health emergency ends.[11]

2. **Consider Lifting Remaining Medically Unnecessary REMS Restrictions.** Distributing Mifepristone as a normal prescription, without REMS, is safe and effective.[12] As you prepare to finalize the updated REMS for Mifepristone that you announced almost a year ago, we ask that you continue to follow the science and reconsider the remaining REMS, lifting any remaining medically unnecessary restrictions.[13] FDA frequently reviews REMS "at periodic intervals following REMS approval."[14] You acknowledged in December 2021 that FDA modified the REMS for Mifepristone "after reviewing the data and information submitted by the applicant … and after taking into consideration the

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

[8] The American College of Obstetricians and Gynecologists, "Understanding the Practical Implications of the FDA's December 2021 Mifepristone REMS Decision," news release, March 28, 2022, https://www.acog.org/news/news-articles/2022/03/understanding-the-practical-implications-of-the-fdas-december-2021-mifepristone-rems-decision; Congressional Research Service, "Medication Abortion: A Changing Legal Landscape," Jennifer A. Staman and John O. Shimabukuro, October 5, 2022, https://crsreports.congress.gov/product/pdf/LSB/LSB10706.

[9] Inside Health Policy, "Abortion Pill Makers Send FDA Detailed Proposal To Expand Access," Beth Wang, July 12, 2022, https://insidehealthpolicy.com/inside-telehealth-daily-news/abortion-pill-makers-send-fda-detailed-proposal-expand-access.

[10] New England Journal of Medicine, "Sixteen Years of Overregulation: Time to Unburden Mifeprex," Mifeprex REMS Study Group, February 23, 2017, https://www.nejm.org/doi/10.1056/NEJMsb1612526.

[11] Letter from Food and Drug Administration to American College of Obstetricians and Gynecologists, April 12, 2021, https://www.aclu.org/letter/fda-response-acog-april-2021; 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/.

[12] New England Journal of Medicine, "Abortion Safety and Use with Normally Prescribed Mifepristone in Canada," Laura Schummers, Elizabeth K. Darling, Sheila Dunn, Kimberlyn McGrail, Anastasia Gayowsky, Michael R. Law, Tracey-Lea Laba, Janusz Kaczorowski, and Wendy V. Norman, January 6, 2022, https://www.nejm.org/doi/full/10.1056/NEJMsa2109779.

[13] *Id.*

[14] Food and Drug Administration, "Frequently Asked Questions," https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems.

safety data that had become available since the initial approval of Mifeprex in 2000."[15] Given this example, we urge you to proactively review the remaining REMS to determine if any restrictions placed on the prescription and distribution of Mifepristone, including patient consent forms, are also medically unnecessary.[16]

3. **Work with Drug Sponsors to Add a Miscarriage Indication for Mifepristone with Misoprostol.** To further protect reproductive health and rights, we urge you to work with drug sponsors to add an additional indication to the Mifepristone with misoprostol label: use for miscarriage management.[17] As many as 26 percent of all pregnancies end in miscarriage,[18] and Mifepristone, when taken with misoprostol, significantly improves the management of early pregnancy loss and results in fewer complications.[19] 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.[20] Coordinating with drug sponsors to update the Mifepristone with misoprostol label will help ensure that patients experiencing miscarriages are not denied access to this medication.[21] Until you update the label, we ask FDA to exercise enforcement discretion regarding the use and distribution of Mifepristone under its current REMS and indication.

Since the Supreme Court overturned *Roe v. Wade,* states have continued to place radical bans and restrictions on abortion.[22] As states implement new restrictions, it is more important than ever that you take immediate steps to expand access to medication abortion. We encourage and support your efforts to protect access to abortion and reproductive rights across the nation. To continue coordinating our efforts, we request a staff-level briefing or written response by December 1, 2022 that provides a detailed update on FDA's actions regarding the REMS for Mifepristone and the Mifepristone with misoprostol label.

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[15] Letter Food and Drug Administration Center for Drug Evaluation and Research 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] New England Journal of Medicine, "Sixteen Years of Overregulation: Time to Unburden Mifeprex," Mifeprex REMS Study Group, February 23, 2017, p. 793, https://www.nejm.org/doi/10.1056/NEJMsb1612526.

[17] Citizen Petition from American College of Obstetrician and Gynecologists to Food and Drug Administration, October 4, 2022, https://emaaproject.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-American-College-of-Obstetrician-and-Gynecologists-et-al-10.3.22-EMAA-website.pdf.

[18] National Library of Medicine, "Miscarriage," Carla Dugas and Valori H. Slane, June 27, 2022, https://www.ncbi.nlm.nih.gov/books/NBK532992/.

[19] American College of Obstetricians and Gynecologists, "Early Pregnancy Loss," practice bulletin, 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 7, 2018, https://pubmed.ncbi.nlm.nih.gov/29874535/.

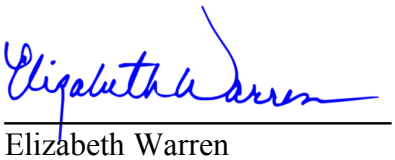
[20] Politico, "Patients face barriers to routine care as doctors warn of ripple effects from broad abortion bans," Alice Miranda Ollstein and Daniel Payne, September 28, 2022, https://www.politico.com/news/2022/09/28/abortion-bans-medication-pharmacy-prescriptions-00059228.

[21] The 19th, "Label change for mifepristone could reduce barriers to care for miscarriages, advocates say in petition to FDA," Jennifer Gerson, October 4, 2022, https://19thnews.org/2022/10/mifepristone-miscarriage-label-change-fda-petition/.

[22] Axios, "Where abortion has been banned now that Roe v. Wade is overturned," Oriana Gonzalez and Jacob Knutson, October 11, 2022, https://www.axios.com/2022/06/25/abortion-illegal-7-states-more-bans-coming.

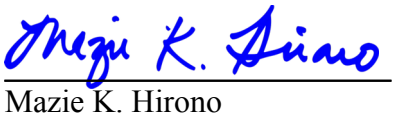
Thank you for your prompt attention to this urgent matter.

Sincerely,



Elizabeth Warren
United States Senator

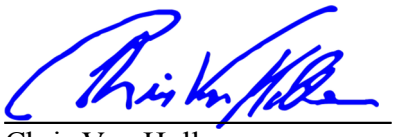
Bernard Sanders
United States Senator



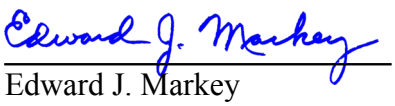
Mazie K. Hirono
United States Senator

Kirsten Gillibrand
United States Senator

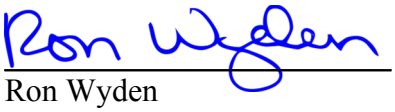
Angus S. King, Jr.
United States Senator



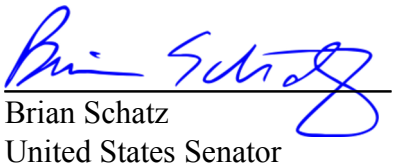
Chris Van Hollen
United States Senator



Edward J. Markey
United States Senator



Ron Wyden
United States Senator



Brian Schatz
United States Senator