

119TH CONGRESS
2^D SESSION

S. RES. _____

Expressing the sense of the Senate that over 25 years of real-world evidence and hundreds of peer-reviewed studies proving that mifepristone is safe and effective should be respected, and law and policy governing access to lifesaving, time-sensitive medication abortion care in the United States should be equitable, transparent, and based on the best available peer-reviewed evidence-based science.

IN THE SENATE OF THE UNITED STATES

Ms. WARREN submitted the following resolution; which was referred to the Committee on _____

RESOLUTION

Expressing the sense of the Senate that over 25 years of real-world evidence and hundreds of peer-reviewed studies proving that mifepristone is safe and effective should be respected, and law and policy governing access to lifesaving, time-sensitive medication abortion care in the United States should be equitable, transparent, and based on the best available peer-reviewed evidence-based science.

Whereas Congress, by enacting the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), authorized the Food and Drug Administration (FDA) to determine, based on the scientific evidence, whether a drug is safe and effective for the intended use of the drug;

Whereas Congress authorized the FDA to impose or maintain a Risk Evaluation and Mitigation Strategy (REMS) for a drug only where “necessary to ensure that the benefits of the drug outweigh the risks of the drug” considering certain statutorily enumerated factors;

Whereas Congress prohibited the FDA from imposing or maintaining an Element to Assure Safe Use (ETASU) within a REMS program if, inter alia, the ETASU is “unduly burdensome on patient access,” considering in particular “patients who have difficulty accessing health care”;

Whereas mifepristone is a medication recommended by leading medical authorities for its FDA-approved use to terminate a pregnancy and for its off-label use to manage miscarriage;

Whereas mifepristone received approval from the FDA more than 25 years ago, and according to the FDA, the “efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare”;

Whereas the FDA approved mifepristone following a rigorous 54-month review period that included the review of 3 complete phases of clinical trials that involved thousands of participants and that showed mifepristone was safe and effective for termination of an early pregnancy;

Whereas, despite mifepristone’s exceptional safety record, the FDA still regulates this medication more heavily than 99 percent of prescription drugs;

Whereas, in December 2021, after an extensive review of high-quality research and years of real-world data confirming that mifepristone remains just as safe when pa-

tients can fill their prescription by mail or at a pharmacy, the FDA concluded that the Mifepristone REMS should be modified to lessen the burdens on patient access and the health care system and, in January 2023, approved this modification to the REMS that removed the in-person dispensing ETASU and added a pharmacy certification ETASU , allowing Mifeprex and its approved generics to be dispensed by certified pharmacies, both in-person and by mail, as well as by or under the supervision of certified prescribers;

Whereas numerous peer-reviewed studies since January 2023 have further established that mifepristone remains highly safe and effective;

Whereas mifepristone is more accessible when dispensed to eligible patients by mail or at a pharmacy after clinical evaluation and counseling through telemedicine;

Whereas few drugs have been studied so extensively after their FDA approval and few hold such an explicit and convincing safety record as mifepristone;

Whereas leading medical and scientific organizations, including the World Health Organization, the American Medical Association, the American College of Obstetricians & Gynecologists, the American Academy of Family Physicians, the Society of Family Planning, and the Society for Maternal-Fetal Medicine, recognize that mifepristone is safe and effective, including when prescribed through telemedicine and dispensed to eligible patients by mail or at a pharmacy, and continue to recommend the use of mifepristone as part of an evidence-based regimen to safely end a pregnancy;

Whereas the importance of medication abortion is recognized globally, and the World Health Organization has included mifepristone on its list of essential medicines since 2005;

Whereas the safety record of mifepristone is demonstrated by its availability in more than 90 countries, including countries without restrictions like the mifepristone REMS;

Whereas medication abortion accounted for 63 percent of all abortions in the United States in 2023;

Whereas, following the decision of the Supreme Court of the United States in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), to overturn decades of precedent in *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), as of May 2026, bans have eliminated all or some abortions in 20 States, compounding an already complex landscape and exacerbating the existing abortion-access crisis;

Whereas, in the years since the decision of the Supreme Court of the United States to overturn *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), anti-abortion politicians and groups have filed multiple baseless lawsuits against the FDA over its approval and regulation of mifepristone, attempting to use misinformation about mifepristone to justify restricting access to this essential medication nationwide, despite its longstanding safety record;

Whereas the impact to the health and well-being of patients across the country would be devastating if any action reduced patient access to medication abortion or increased

barriers to prescribing and dispensing medication abortion;

Whereas abortion bans and restrictions force patients to travel greater distances for care and face longer wait times, and force some patients who are unable to access care to remain pregnant against their will;

Whereas scientific research has demonstrated that restricting access to abortion increases the risk of domestic violence for pregnant people and data suggests that the privacy of a telehealth consultation may increase a patient's willingness to disclose abuse or coercion; and

Whereas, due to discrimination, unnecessary restrictions on abortion, including medication abortion, disproportionately push care out of reach for—

- (1) Black and Indigenous people;
- (2) people of color;
- (3) immigrants;
- (4) people with lower incomes;
- (5) people in rural communities;
- (6) LGBTQ+ people;
- (7) people living with disabilities;
- (8) people experiencing intimate partner violence;

and

(9) other pregnant people who have been disproportionately harmed by systemic inequities in health care:
Now, therefore, be it

1 *Resolved*, That it is the sense of the Senate that—

- 2 (1) FDA policies affecting access to medication
- 3 abortion care in the United States must be based on
- 4 transparent scientific review of the full body of gold-
- 5 standard medical evidence, as well as considerations

1 of potential burdens on patient access and the health
2 care delivery system, as required by the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
4 seq.);

5 (2) Congress has granted the FDA the author-
6 ity to regulate prescription drug medications and
7 medical devices based on scientific determinations of
8 their safety and efficacy grounded in the best avail-
9 able peer-reviewed evidence-based science, and with-
10 out political interference;

11 (3) the FDA has performed multiple scientific
12 reviews of mifepristone over 25 years, each time
13 finding mifepristone to be safe and effective for
14 pregnancy termination, including when mifepristone
15 is prescribed through telemedicine and dispensed to
16 eligible patients by mail or at a pharmacy, based on
17 high-quality clinical research and real-world-safety
18 data; and

19 (4) preserving and expanding access to medica-
20 tion abortion care, including preserving the ability to
21 prescribe mifepristone through telemedicine and dis-
22 pense to eligible patients by mail or at a pharmacy,
23 is important to ensure equitable access to abortion
24 for patients harmed by statutory, regulatory, finan-

- 1 cial, and circumstantial restrictions that worsen re-
- 2 productive health disparities for—
- 3 (A) Black and Indigenous people;
- 4 (B) people of color;
- 5 (C) immigrants;
- 6 (D) people with lower incomes;
- 7 (E) people in rural communities;
- 8 (F) LGBTQ+ people;
- 9 (G) people living with disabilities;
- 10 (H) people experiencing intimate partner
- 11 violence; and
- 12 (I) people in other marginalized commu-
- 13 nities.