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119TH CONGRESS
1ST SESSION

H. R. 5646

To require the Secretary of Health and Human Services to approve a risk evaluation and mitigation strategy for mifepristone that is identical to the strategy previously approved, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 30, 2025

Mrs. MILLER of Illinois (for herself, Mr. MOORE of Alabama, Mrs. BIGGS of South Carolina, Mr. WEBER of Texas, Mr. HARRIGAN, Mr. BURCHETT, and Mr. LAMALFA) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To require the Secretary of Health and Human Services to approve a risk evaluation and mitigation strategy for mifepristone that is identical to the strategy previously approved, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Restoring Safeguards for Dangerous Abortion Drugs Act".

SEC. 2. DEFINITION.

In this Act, the term ''covered medication'' means mifepristone, also known by the brand names, Mifeprex and Korlym, and the developmental code name, RU–486.

SEC. 3. MIFEPRISTONE REMS.

(a) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) withdraw approval of the risk evaluation and mitigation strategy pursuant to section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) for the covered medication that is in effect on the date of enactment of this Act; and

(2) approve a risk evaluation and mitigation strategy for the covered medication that is identical to the risk evaluation and mitigation strategy for such covered medication that was approved by such Secretary in June 2011.

(b) RESTRICTION.—Notwithstanding any provision of section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), the Secretary of Health and Human Services—

(1) shall require a risk evaluation and mitigation strategy pursuant to such section 505–1 for the covered medication; and

(2) may not approve a risk evaluation and mitigation strategy pursuant to such section for the covered medication that is different from the strategy described in subsection (a)(2).

SEC. 4. FEDERAL TORT FOR HARM TO WOMEN CAUSED BY ABORTION DRUGS.

(a) DEFINITION.—In this section, the term ''covered entity'' means a telehealth provider, pharmacy, or any other person who knowingly imports or transports a covered medication in interstate or foreign commerce in violation of section 1462 of title 18, United States Code.

(b) LIABILITY.—A covered entity shall be liable in accordance with this section to any individual who suffers bodily injury or harm to mental health (including any physical, psychological, emotional, or physiological harm) that is attributable, in whole or in part, to the individual's use of a covered medication imported or transported as described in subsection (a).

(c) PRIVATE RIGHT OF ACTION.—An individual who suffers bodily injury or harm to mental health that is attributable, in whole or in part, to the individual's use of a covered medication as described in subsection (b) may bring a civil action against the covered entity in an appropriate district court of the United States or a State court of competent jurisdiction for—

(1) compensatory damages;

(2) punitive damages; and

(3) attorney's fees and costs.

(d) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to preempt any State law that makes available any other remedy to an individual described in subsection (b).

(e) EFFECTIVE DATE.—This section shall take effect on the date that is 90 days after the date of enactment of this Act.

SEC. 5. BAN ON IMPORTATION.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

(1) in the third sentence of subsection (a), by inserting ''or is mifepristone,'' after ''under section 569D,''; and

(2) in subsection (d)(1), by adding at the end the following:

''(C) Notwithstanding any other provision of law, no person may import the drug mifepristone into the United States, including by mailing such drug to individuals.''.

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