

119TH CONGRESS
1ST SESSION

S. _____

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 SENATE OF THE UNITED STATES

Mr. HAWLEY introduced the following bill; which was read twice and referred to the Committee on _____

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Restoring Safeguards
5 for Dangerous Abortion Drugs Act”.

1 **SEC. 2. DEFINITION.**

2 In this Act, the term “covered medication” means
3 mifepristone, also known by the brand names, Mifeprex
4 and Korlym, and the developmental code name, RU-486.

5 **SEC. 3. MIFEPRISTONE REMS.**

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

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

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

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

23 (1) shall require a risk evaluation and mitiga-
24 tion strategy pursuant to such section 505-1 for the
25 covered medication; and

1 (2) may not approve a risk evaluation and miti-
2 gation strategy pursuant to such section for the cov-
3 ered medication that is different from the strategy
4 described in subsection (a)(2).

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

7 (a) DEFINITION.—In this section, the term “covered
8 entity” means a telehealth provider, pharmacy, or any
9 other person who knowingly imports or transports a cov-
10 ered medication in interstate or foreign commerce in viola-
11 tion of section 1462 of title 18, United States Code.

12 (b) LIABILITY.—A covered entity shall be liable in ac-
13 cordance with this section to any individual who suffers
14 bodily injury or harm to mental health (including any
15 physical, psychological, emotional, or physiological harm)
16 that is attributable, in whole or in part, to the individual’s
17 use of a covered medication imported or transported as
18 described in subsection (a).

19 (c) PRIVATE RIGHT OF ACTION.—An individual who
20 suffers bodily injury or harm to mental health that is at-
21 tributable, in whole or in part, to the individual’s use of
22 a covered medication as described in subsection (b) may
23 bring a civil action against the covered entity in an appro-
24 priate district court of the United States or a State court
25 of competent jurisdiction for—

- 1 (1) compensatory damages;
- 2 (2) punitive damages; and
- 3 (3) attorney's fees and costs.

4 (d) RULES OF CONSTRUCTION.—Nothing in this sec-
5 tion shall be construed to preempt any State law that
6 makes available any other remedy to an individual de-
7 scribed in subsection (b).

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

11 **SEC. 5. BAN ON IMPORTATION.**

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

14 (1) in the third sentence of subsection (a), by
15 inserting “or is mifepristone,” after “under section
16 569D,”; and

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

19 “(C) Notwithstanding any other provision of
20 law, no person may import the drug mifepristone
21 into the United States, including by mailing such
22 drug to individuals.”.