

119TH CONGRESS
2D SESSION

S. _____

To provide that the approved application under the Federal Food, Drug, and Cosmetic Act for the drug mifepristone for the purpose of the termination of intrauterine pregnancy is deemed to have been withdrawn, to establish a Federal tort for harm to women caused by chemical abortion drugs, and for other purposes.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 provide that the approved application under the Federal Food, Drug, and Cosmetic Act for the drug mifepristone for the purpose of the termination of intrauterine pregnancy is deemed to have been withdrawn, to establish a Federal tort for harm to women caused by chemical abortion drugs, and for other purposes.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 “Safeguarding Women
5 from Chemical Abortion Act”.

1 **SEC. 2. WITHDRAWAL OF APPROVAL OF THE DRUG**
2 **MIFEPRISTONE FOR TERMINATION OF PREG-**
3 **NANCY.**

4 Effective upon the expiration of 14 days after the
5 date of the enactment of this Act:

6 (1) Approval of an application submitted under
7 subsection (b) of section 505 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 355) for the
9 drug mifepristone (marketed as Mifeprex, and also
10 known as RU-486) with an indication for the termi-
11 nation of intrauterine pregnancy, and of any applica-
12 tion submitted under subsection (j) of such section
13 for a drug with the same indication and for which
14 mifepristone is the reference drug, is deemed to have
15 been withdrawn under subsection (e) of such section.

16 (2) For purposes of sections 301(d) and 304 of
17 the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 331(d); 334), the introduction or delivery for
19 introduction of a drug, the approval of which has
20 been withdrawn as described in paragraph (1), into
21 interstate commerce shall be considered a violation
22 of section 505 of such Act (21 U.S.C. 355).

23 (3) The drug mifepristone shall be considered
24 misbranded for purposes of sections 301 and 304 of
25 the Federal Food, Drug, and Cosmetic Act (21
26 U.S.C. 331; 334) if the drug bears labeling pro-

1 use of a covered medication manufactured by a covered
2 entity.

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

- 10 (1) compensatory damages;
11 (2) punitive damages; and
12 (3) attorney’s fees and costs.

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

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

20 **SEC. 4. RULE OF CONSTRUCTION.**

21 Nothing in this Act shall be construed to affect any
22 provision of section 1461 of title 18, United States Code.