

109TH CONGRESS
1ST SESSION

H. R. 1079

To provide that the approved application under the Federal Food, Drug, and Cosmetic Act for the drug commonly known as RU-486 is deemed to have been withdrawn, to provide for the review by the Comptroller General of the United States of the process by which the Food and Drug Administration approved such drug, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 3, 2005

Mr. BARTLETT of Maryland (for himself, Mr. HALL, Mr. WICKER, Mr. MILLER of Florida, Mr. NORWOOD, Mr. SMITH of New Jersey, Mr. WAMP, Mr. PITTS, Mr. CHABOT, Mrs. BLACKBURN, Mr. BAKER, Mr. FORBES, Mr. WELDON of Florida, Mr. ROGERS of Alabama, Mr. SHIMKUS, Mrs. JO ANN DAVIS of Virginia, Mr. DAVIS of Kentucky, Mr. AKIN, Ms. HART, Mr. GINGREY, Mr. PICKERING, Mr. KING of Iowa, Mr. RYUN of Kansas, Mrs. MUSGRAVE, Mr. ADERHOLT, Mr. INGLIS of South Carolina, Mr. DAVIS of Tennessee, Mr. RENZI, Mr. JONES of North Carolina, Mr. STEARNS, Mr. CANTOR, Mr. MCCOTTER, Mrs. MYRICK, Mr. BEAUPREZ, Mr. FRANKS of Arizona, Mr. PENCE, Mr. SAM JOHNSON of Texas, Mr. TERRY, Mr. TIBERI, Mr. DOOLITTLE, Mr. ROGERS of Kentucky, Mr. SOUDER, Mr. BROWN of South Carolina, Mr. KENNEDY of Minnesota, Mr. BOOZMAN, Mr. WHITFIELD, Ms. FOXX, and Mrs. EMERSON) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide that the approved application under the Federal Food, Drug, and Cosmetic Act for the drug commonly known as RU-486 is deemed to have been withdrawn, to provide for the review by the Comptroller General of the United States of the process by which the Food

and Drug Administration approved such drug, 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 “RU–486 Suspension
5 and Review Act of 2005”.

6 **SEC. 2. FINDING.**

7 The Congress finds that the use of the drug
8 mifepristone (marketed as Mifeprex, and commonly known
9 as RU–486) in conjunction with the off-label use of
10 misoprostol to chemically induce abortion has caused a
11 significant number of deaths, near deaths, and adverse re-
12 actions.

13 **SEC. 3. SUSPENSION OF APPROVAL OF DRUG COMMONLY**
14 **KNOWN AS RU–486; REVIEW AND REPORT BY**
15 **GOVERNMENT ACCOUNTABILITY OFFICE.**

16 (a) IN GENERAL.—Effective upon the expiration of
17 14 days after the date of the enactment of this Act:

18 (1) The approved application under section
19 505(b) of the Federal Food, Drug, and Cosmetic Act
20 for the drug mifepristone (marketed as Mifeprex,
21 and commonly known as RU–486) is deemed to have
22 been withdrawn under section 505(e) of such Act.

23 (2) For purposes of sections 301(d) and 304 of
24 such Act, the introduction or delivery for introduc-

1 tion of such drug into interstate commerce shall be
2 considered a violation of section 505 of such Act.

3 (3) The drug misoprostol shall be considered
4 misbranded for purposes of sections 301 and 304 of
5 such Act if the drug bears labeling providing that
6 the drug may be used for the medical termination of
7 intrauterine pregnancy or that the drug may be used
8 in conjunction with another drug for the medical ter-
9 mination of intrauterine pregnancy.

10 (b) REVIEW AND REPORT BY GENERAL ACCOUNTING
11 OFFICE.—

12 (1) IN GENERAL.—The Comptroller General of
13 the United States shall review the process by which
14 the Food and Drug Administration approved
15 mifepristone under section 505 of the Federal Food,
16 Drug, and Cosmetic Act and shall determine wheth-
17 er such approval was provided in accordance with
18 such section. The Secretary of Health and Human
19 Services shall ensure that the Comptroller General
20 has full access to all information possessed by the
21 Department of Human Services that relates to such
22 process.

23 (2) REPORT.—Not later than 180 days after
24 the date of the enactment of this Act, the Comp-
25 troller General shall complete the review under para-

1 graph (1) and submit to the Congress and the Sec-
2 retary of Health and Human Services a report that
3 provides the findings of the review.

4 (c) CONTINGENT REINSTATEMENT OF APPROVAL OF
5 DRUG.—If the report under subsection (b) includes a de-
6 termination by the Comptroller General that the approval
7 by the Food and Drug Administration of mifepristone was
8 provided in accordance with section 505 of the Federal
9 Food, Drug, and Cosmetic Act, the Secretary of Health
10 and Human Services shall publish such statement in the
11 Federal Register. Effective upon the expiration of 30 days
12 after such publication, subsection (a) ceases to have any
13 legal effect.

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