

110TH CONGRESS
1ST SESSION

H. R. 63

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under the Federal Food, Drug, and Cosmetic Act for the drug commonly known as RU-486 is deemed to have been withdrawn, to provide for the review by the Comptroller General of the United States of the process by which the Food and Drug Administration approved such drug, and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

JANUARY 4, 2007

Mr. BARTLETT of Maryland 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application under the Federal Food, Drug, and Cosmetic Act for the drug commonly known as RU-486 is deemed to have been withdrawn, to provide for the review by the Comptroller General of the United States of the process by which the Food and Drug Administration approved such drug, and for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 2007”.

1 **SEC. 2. FINDING.**

2 The Congress finds that the use of the drug
3 mifepristone (marketed as Mifeprex, and commonly known
4 as RU-486) in conjunction with the off-label use of
5 misoprostol to chemically induce abortion has caused a
6 significant number of deaths, near deaths, and adverse re-
7 actions.

8 **SEC. 3. SUSPENSION OF APPROVAL OF DRUG COMMONLY**
9 **KNOWN AS RU-486; REVIEW AND REPORT BY**
10 **GOVERNMENT ACCOUNTABILITY OFFICE.**

11 (a) IN GENERAL.—Effective upon the expiration of
12 14 days after the date of the enactment of this Act:

13 (1) The approved application under section
14 505(b) of the Federal Food, Drug, and Cosmetic Act
15 for the drug mifepristone (marketed as Mifeprex,
16 and commonly known as RU-486) is deemed to have
17 been withdrawn under section 505(e) of such Act.

18 (2) For purposes of sections 301(d) and 304 of
19 such Act, the introduction or delivery for introduc-
20 tion of such drug into interstate commerce shall be
21 considered a violation of section 505 of such Act.

22 (3) The drug misoprostol shall be considered
23 misbranded for purposes of sections 301 and 304 of
24 such Act if the drug bears labeling providing that
25 the drug may be used for the medical termination of
26 intrauterine pregnancy or that the drug may be used

1 in conjunction with another drug for the medical ter-
2 mination of intrauterine pregnancy.

3 (b) REVIEW AND REPORT BY GOVERNMENT AC-
4 COUNTABILITY OFFICE.—

5 (1) IN GENERAL.—The Comptroller General of
6 the United States shall review the process by which
7 the Food and Drug Administration approved
8 mifepristone under section 505 of the Federal Food,
9 Drug, and Cosmetic Act and shall determine wheth-
10 er such approval was provided in accordance with
11 such section. The Secretary of Health and Human
12 Services shall ensure that the Comptroller General
13 has full access to all information possessed by the
14 Department of Health and Human Services that re-
15 lates to such process.

16 (2) REPORT.—Not later than 180 days after
17 the date of the enactment of this Act, the Comp-
18 troller General shall complete the review under para-
19 graph (1) and submit to the Congress and the Sec-
20 retary of Health and Human Services a report that
21 provides the findings of the review.

22 (c) CONTINGENT REINSTATEMENT OF APPROVAL OF
23 DRUG.—If the report under subsection (b) includes a de-
24 termination by the Comptroller General that the approval
25 by the Food and Drug Administration of mifepristone was

1 provided in accordance with section 505 of the Federal
2 Food, Drug, and Cosmetic Act, the Secretary of Health
3 and Human Services shall publish such statement in the
4 Federal Register. Effective upon the expiration of 30 days
5 after such publication, subsection (a) ceases to have any
6 legal effect.

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