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108TH CONGRESS
1ST SESSION

H. R. 3453

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under the Federal Food, Drug, and Cosmetic Act for the drug commonly known as RU–486 is deemed to have been withdrawn, to provide for the review by the Comptroller General of the United States of the process by which the Food and Drug Administration approved such drug, and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

NOVEMBER 6, 2003

Mr. DEMINT (for himself, Mr. BARTLETT of Maryland, Mr. DELAY, Mr. BLUNT, Mr. ADERHOLT, Mr. AKIN, Mr. BARRETT of South Carolina, Mr. BEAUPREZ, Mr. BISHOP of Utah, Mr. BOOZMAN, Mr. BRADY of Texas, Mr. BROWN of South Carolina, Mr. CANTOR, Mr. CARTER, Mr. COLE, Mr. CRANE, Mrs. JO ANN DAVIS of Virginia, Mr. DOOLITTLE, Mr. EVERETT, Mr. FEENEY, Mr. FORBES, Mr. FRANKS of Arizona, Mr. GARRETT of New Jersey, Mr. GUTKNECHT, Ms. HART, Mr. HAYES, Mr. HOEKSTRA, Mr. HOSTETTLER, Mr. HUNTER, Mr. ISTOOK, Mr. SAM JOHNSON of Texas, Mr. JONES of North Carolina, Mr. KELLER, Mr. KENNEDY of Minnesota, Mr. KING of Iowa, Mr. MANZULLO, Mr. MCCOTTER, Mr. MILLER of Florida, Mrs. MUSGRAVE, Mrs. MYRICK, Mr. PENCE, Mr. PICKERING, Mr. PITTS, Mr. RENZI, Mr. RYAN of Wisconsin, Mr. RYUN of Kansas, Mr. SCHROCK, Mr. SHADEGG, Mr. SHIMKUS, Mr. SMITH of New Jersey, Mr. SOUDER, Mr. STEARNS, Mr. STUPAK, Mr. SULLIVAN, Mr. TANCREDO, Mr. TERRY, Mr. TIAHRT, Mr. TOOMEY, Mr. VITTER, and Mr. WILSON of South Carolina) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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application under the Federal Food, Drug, and Cosmetic Act for the drug commonly known as RU–486 is deemed to have been withdrawn, to provide for the review by the Comptroller General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.

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 ''RU–486 Suspension and Review Act of 2003''.

SEC. 2. FINDING.

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

SEC. 3. SUSPENSION OF APPROVAL OF DRUG COMMONLY KNOWN AS RU–486; REVIEW AND REPORT BY GENERAL ACCOUNTING OFFICE.

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

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

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

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

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

(1) IN GENERAL.—The Comptroller General of the United States shall review the process by which the Food and Drug Administration approved mifepristone under section 505 of the Federal Food, Drug, and Cosmetic Act and shall determine whether such approval was provided in accordance with such section. The Secretary of Health and Human Services shall ensure that the Comptroller General has full access to all information possessed by the Department of Human Services that relates to such process.

(2) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Comptroller General shall complete the review under paragraph (1) and submit to the Congress and the Secretary of Health and Human Services a report that provides the findings of the review.

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

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