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(Original Signature of Member)

109TH CONGRESS
1ST SESSION

H. R. _____

To require the Commissioner of Food and Drugs to determine whether to allow the marketing of Plan B as a prescription drug for women 15 years of age or younger and a nonprescription drug for women 16 years of age or older, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mrs. MALONEY introduced the following bill; which was referred to the Committee on _____

A BILL

To require the Commissioner of Food and Drugs to determine whether to allow the marketing of Plan B as a prescription drug for women 15 years of age or younger and a nonprescription drug for women 16 years of age or older, 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 ''Plan B for Plan B Act of 2005''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) The Food and Drug Administration has declared Plan B to be safe and effective in preventing unintended pregnancy, reducing the risk by as much as 89 percent if taken within days of unprotected intercourse and up to 95 percent if taken in the first 24 hours.

(2) On April 21, 2003, product manufacturers Women's Capital Corporation, controlled by Barr Pharmaceuticals, submitted a supplemental new drug application to the Food and Drug Administration to switch Plan B from prescription-only to over-the-counter status for women of all ages.

(3) On December 16, 2003, a joint panel of the Food and Drug Administration's Reproductive Health Drugs Advisory Committee and Non-Prescription Drugs Advisory Committee voted 28–0 that Plan B could be used safely in a non-prescription setting.

(4) On December 16, 2003, a joint panel of the Food and Drug Administration's Reproductive Health Drugs Advisory Committee and Non-Prescription Drugs Advisory Committee voted 23–4 to recommend that the Food and Drug Administration

approve the application to make Plan B available over-the-counter for women of all ages.

(5) On May 6, 2004, the Food and Drug Administration deemed the application not approvable, directly contradicting the overwhelming weight of their own scientific evidence.

(6) At the suggestion of the Food and Drug Administration, Barr Pharmaceutical submitted a formal response, dated July 16, 2003, to the Administration's non-approvable determination, supporting the marketing of Plan B as a prescription drug for women 15 years of age or younger and a non-prescription drug for women 16 years of age or older.

(7) On January 21, 2005, the Food and Drug Administration delayed issuing a decision on the Plan B application.

(8) A letter dated July 13, 2005, from Secretary of Health and Human Services Michael O. Leavitt to Chairman Mike Enzi of the Committee on Health, Education, Labor, and Pensions of the Senate stated that the Food and Drug Administration would act on the Plan B application by September 1, 2005.

(9) On August 26, 2005, the Food and Drug Administration did not approve or disapprove the Plan B application, and instead decided to publish an advance notice of proposed rulemaking in the Federal Register, even while concluding that ''the available scientific data are sufficient to support the safe use of Plan B as an OTC product... for women who are 17 years of age or older''.

(10) On August 31, 2005, Susan F. Wood, serving as the Food and Drug Administration's assistant commissioner for women's health and director of the Office of Women's Health, resigned her position because of the Administration's refusal to issue a final decision on the Plan B application, saying that she could not serve at the Administration when ''scientific and clinical evidence, fully evaluated and recommended for approval by the professional staff [at the Administration], has been overruled''.

(11) On September 1, 2005, the Food and Drug Administration issued an advance notice of proposed rulemaking (70 FR 52050) to request comment by November 1, 2005, on whether to initiate a rulemaking to codify the Administration's interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) regard-

ing when an active ingredient may be simultaneously marketed in both a prescription drug product and an over-the-counter (OTC) drug product, potentially adding years of unnecessary regulatory delays to an already extended process which is keeping Plan B from over-the-counter status.

SEC. 3. DECISION BY FDA ON MARKETING OF EMERGENCY CONTRACEPTION.

(a) IN GENERAL.—Not later than 30 days after the date of the enactment of this Act, the Commissioner of Food and Drugs shall approve or disapprove the supplemental new drug application for Plan B, as amended by the formal response to the non-approvable letter.

(b) FAILURE TO APPROVE OR DISAPPROVE.—If the Commissioner fails to approve or disapprove the application described in subsection (a) by the deadline described in such subsection—

(1) the Commissioner is deemed to have approved the application; and

(2) such deemed approval shall continue in effect unless the Commissioner publishes in the Federal Register a determination to approve or disapprove the application.

(c) DEFINITIONS.—In this Act:

(1) The term ''Commissioner'' means the Commissioner of Food and Drugs.

(2) The term ''formal response'' means the formal response, dated July 16, 2003, to the non-approvable letter, supporting the marketing of Plan B as a prescription drug for women 15 years of age or younger and a nonprescription drug for women 16 years of age or older.

(3) The term ''Plan B'' means 0.75 mg levonorgestrel tablets.

(4) The term ''prescription drug'' means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(5) The term ''supplemental new drug application for Plan B'' means the supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) on April 21, 2003, by product manufacturers Women's Capital Corporation, controlled by Barr Pharmaceuticals, to the Food and Drug Administration to switch Plan B from prescription-only to nonprescription status for women of all ages.

(6) The term ''non-approvable letter'' means the non-approvable letter dated May 6, 2004, from

the Food and Drug Administration to Barr Pharmaceuticals.