

109TH CONGRESS
1ST SESSION

H. R. 4229

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

NOVEMBER 3, 2005

Mrs. MALONEY (for herself, Mr. SHAYS, Mr. INSLEE, Mr. CROWLEY, Ms. WASSERMAN SCHULTZ, Mr. BISHOP of New York, Mr. FARR, Mrs. CAPPS, Ms. ESHOO, Mr. BERMAN, Ms. LINDA T. SÁNCHEZ of California, Ms. SCHAKOWSKY, Mr. WAXMAN, Ms. BALDWIN, Mr. DEFazio, Mr. ROTHMAN, Mr. HONDA, Mr. FILNER, Ms. SOLIS, Mr. FRANK of Massachusetts, Mr. MORAN of Virginia, Ms. MATSUI, Mr. GRIJALVA, Mr. LARSEN of Washington, Mr. GUTIERREZ, Mr. ENGEL, Ms. MCCOLLUM of Minnesota, Mr. KENNEDY of Rhode Island, Mr. HINCHEY, Mr. MCGOVERN, Mr. ACKERMAN, Mr. SABO, Mrs. MCCARTHY, Ms. DELAURO, Mr. EVANS, Mr. ISRAEL, Ms. WOOLSEY, Mr. KUCINICH, and Mr. WU) introduced the following bill; which was referred to the Committee on Energy and Commerce

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Plan B for Plan B
3 Act of 2005”.

4 **SEC. 2. FINDINGS.**

5 The Congress finds as follows:

6 (1) The Food and Drug Administration has de-
7 clared Plan B to be safe and effective in preventing
8 unintended pregnancy, reducing the risk by as much
9 as 89 percent if taken within days of unprotected
10 intercourse and up to 95 percent if taken in the first
11 24 hours.

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

18 (3) On December 16, 2003, a joint panel of the
19 Food and Drug Administration’s Reproductive
20 Health Drugs Advisory Committee and Non-Pre-
21 scription Drugs Advisory Committee voted 28–0 that
22 Plan B could be used safely in a non-prescription
23 setting.

24 (4) On December 16, 2003, a joint panel of the
25 Food and Drug Administration’s Reproductive
26 Health Drugs Advisory Committee and Non-Pre-

1 scription Drugs Advisory Committee voted 23–4 to
2 recommend that the Food and Drug Administration
3 approve the application to make Plan B available
4 over-the-counter for women of all ages.

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

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

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

20 (8) A letter dated July 13, 2005, from Sec-
21 retary of Health and Human Services Michael O.
22 Leavitt to Chairman Mike Enzi of the Committee on
23 Health, Education, Labor, and Pensions of the Sen-
24 ate stated that the Food and Drug Administration

1 would act on the Plan B application by September
2 1, 2005.

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

11 (10) On August 31, 2005, Susan F. Wood,
12 serving as the Food and Drug Administration’s as-
13 sistant commissioner for women’s health and direc-
14 tor of the Office of Women’s Health, resigned her
15 position because of the Administration’s refusal to
16 issue a final decision on the Plan B application, say-
17 ing that she could not serve at the Administration
18 when “scientific and clinical evidence, fully evaluated
19 and recommended for approval by the professional
20 staff [at the Administration], has been overruled”.

21 (11) On September 1, 2005, the Food and
22 Drug Administration issued an advance notice of
23 proposed rulemaking (70 FR 52050) to request
24 comment by November 1, 2005, on whether to ini-
25 tiate a rulemaking to codify the Administration’s in-

1 terpretation of section 503(b) of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 353(b)) regard-
3 ing when an active ingredient may be simultaneously
4 marketed in both a prescription drug product and an
5 over-the-counter (OTC) drug product, potentially
6 adding years of unnecessary regulatory delays to an
7 already extended process which is keeping Plan B
8 from over-the-counter status.

9 **SEC. 3. DECISION BY FDA ON MARKETING OF EMERGENCY**

10 **CONTRACEPTION.**

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

16 (b) **FAILURE TO APPROVE OR DISAPPROVE.**—If the
17 Commissioner fails to approve or disapprove the applica-
18 tion described in subsection (a) by the deadline described
19 in such subsection—

20 (1) the Commissioner is deemed to have ap-
21 proved the application; and

22 (2) such deemed approval shall continue in ef-
23 fect unless the Commissioner publishes in the Fed-
24 eral Register a determination to approve or dis-
25 approve the application.

1 (c) DEFINITIONS.—In this Act:

2 (1) The term “Commissioner” means the Com-
3 missioner of Food and Drugs.

4 (2) The term “formal response” means the for-
5 mal response, dated July 16, 2003, to the non-ap-
6 provable letter, supporting the marketing of Plan B
7 as a prescription drug for women 15 years of age or
8 younger and a nonprescription drug for women 16
9 years of age or older.

10 (3) The term “Plan B” means 0.75 mg
11 levonorgestrel tablets.

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

15 (5) The term “supplemental new drug applica-
16 tion for Plan B” means the supplemental new drug
17 application submitted under section 505(b) of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 355(b)) on April 21, 2003, by product manufactur-
20 ers Women’s Capital Corporation, controlled by Barr
21 Pharmaceuticals, to the Food and Drug Administra-
22 tion to switch Plan B from prescription-only to non-
23 prescription status for women of all ages.

24 (6) The term “non-approvable letter” means
25 the non-approvable letter dated May 6, 2004, from

- 1 the Food and Drug Administration to Barr Pharma-
- 2 ceuticals.

