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(Original Signature of Member)

108TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

To provide for the review by the Commissioner of Food and Drugs of the process by which the Food and Drug Administration made the decision not to approve the commercial distribution of the emergency-contraceptive drug Plan B as an over-the-counter drug, and for other purposes.

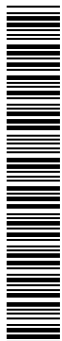
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**IN THE HOUSE OF REPRESENTATIVES**

Mrs. MALONEY (for herself [see attached list of cosponsors]) introduced the following bill; which was referred to the Committee on

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**A BILL**

To provide for the review by the Commissioner of Food and Drugs of the process by which the Food and Drug Administration made the decision not to approve the commercial distribution of the emergency-contraceptive drug Plan B as an over-the-counter 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,*



1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Science Over Politics  
3 Act”.

4 **SEC. 2. FINDINGS.**

5 The Congress finds as follows:

6 (1) Emergency contraceptive pills (“ECPs”) are  
7 approved for use by the Food and Drug Administra-  
8 tion (“FDA”).

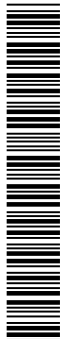
9 (2) Emergency contraceptive pills are a con-  
10 centrated dosage of ordinary birth control pills that  
11 can dramatically reduce a woman’s chance of becom-  
12 ing pregnant.

13 (3) If ECPs are taken within 72 hours of con-  
14 traceptive failure or unprotected sex, ECPs can re-  
15 duce a woman’s risk of pregnancy by up to 89 per-  
16 cent.

17 (4) Emergency contraceptive pills do not cause  
18 abortion but rather prevent pregnancy by inhibiting  
19 ovulation, fertilization, or implantation before a  
20 pregnancy occurs.

21 (5) Emergency contraception cannot interrupt  
22 or disrupt an established pregnancy.

23 (6) Increased use of ECPs could reduce the  
24 number of unintended pregnancies and abortions by  
25 half.

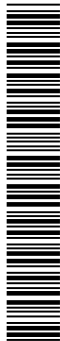


1           (7) A 2002 study revealed that ECP use was  
2 likely responsible for up to 43 percent of the decline  
3 in abortions between 1994 and 2000, with ECP use  
4 preventing over 50,000 abortions in 2000 alone.

5           (8) Over-the-counter sales of ECPs would be  
6 particularly beneficial for sexual assault victims as  
7 approximately 25,000 women per year in the United  
8 States become pregnant as a result of rape. An esti-  
9 mated 22,000 of these pregnancies, 88 percent,  
10 could be prevented if sexual assault victims had  
11 timely access to emergency contraception.

12           (9) More than 70 organizations, including the  
13 American Nurses Association, the American College  
14 of Obstetricians and Gynecologists, the American  
15 Academy of Pediatrics, the American Medical Asso-  
16 ciation, the American Public Health Association, and  
17 the Association of Reproductive Health Profes-  
18 sionals, support over-the-counter access to ECPs.

19           (10) On April 21, 2003, product manufacturers  
20 Women's Capital Corporation submitted an applica-  
21 tion to the Food and Drug Administration request-  
22 ing to switch the emergency contraceptive Plan B  
23 from prescription-only to over-the-counter ("OTC")  
24 status.



1           (11) ECPs meet all the customary FDA criteria  
2           for over-the-counter status in that they are safe and  
3           effective, are not associated with any serious or  
4           harmful side-effects, are easily self-administered,  
5           and require no need for medical supervision. More-  
6           over, ECPs are not harmful to an existing preg-  
7           nancy and their use does not lead to riskier behavior  
8           or less frequent use of other forms of contraception,  
9           has no potential for overdose or addiction, is not  
10          harmful to an existing pregnancy, is easily self-ad-  
11          ministered, and requires no need for medical screen-  
12          ing.

13          (12) FDA staff and experts appointed to the  
14          advisory committees considered volumes of evidence  
15          showing that making Plan B available over-the-  
16          counter was safe and effective for women of all re-  
17          productive age.

18          (13) On December 16, 2003, a joint panel of  
19          the FDA's Reproductive Health Drugs Advisory  
20          Committee and Non-Prescription Drugs Advisory  
21          Committee voted 28-0 that Plan B could be safely  
22          sold as an over-the-counter medication.

23          (14) On December 16, 2003, a joint panel of  
24          the FDA's Reproductive Health Drugs Advisory  
25          Committee and Non-prescription Drugs Advisory



1 Committee voted 23–4 to recommend that the FDA  
2 approve the application to make Plan B available  
3 over-the-counter for women of all ages.

4 (15) The FDA’s rejection of over-the-counter  
5 status for Plan B on May 6, 2004, directly contra-  
6 dicted the overwhelming weight of scientific evi-  
7 dence.

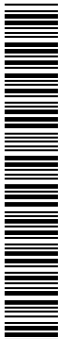
8 (16) The limited options offered by the FDA  
9 for future consideration of over-the-counter sale of  
10 Plan B are not warranted by the volumes of existing  
11 evidence and run counter to the advice of the FDA’s  
12 independent experts, staff, and precedent.

13 (17) Evidence suggests that the FDA’s decision  
14 resulted from an unprecedented political takeover of  
15 what is supposed to be an independent scientific re-  
16 view.

17 **SEC. 3. FDA DENIAL OF OTC STATUS FOR EMERGENCY-**  
18 **CONTRACEPTIVE DRUG PLAN B; REVIEW BY**  
19 **COMMISSIONER OF FOOD AND DRUGS.**

20 (a) IN GENERAL.—Not later than 30 days after the  
21 date of the enactment of this Act, the Commissioner of  
22 Food and Drugs shall—

23 (1) review the decision of the Food and Drug  
24 Administration not to approve the supplemental ap-  
25 plication submitted under section 505(b) of the Fed-



1       eral Food, Drug, and Cosmetic Act to obtain ap-  
2       proval for the commercial distribution of the drug  
3       Plan B (levonorgestrel in 0.75 mg. tablet form) as  
4       a drug that is not subject to the requirements of sec-  
5       tion 503(b)(1) of such Act (commonly known as an  
6       over-the-counter, or OTC, drug); and

7               (2) affirm, under penalty of law, that such  
8       decision—

9                       (A) was not politically influenced;

10                      (B) was based on sound science; and

11                      (C) conformed to precedents and proce-  
12                      dures of the Food and Drug Administration.

13       (b) PUBLICATION IN FEDERAL REGISTER.—The af-  
14       firmation under subsection (a) shall be made through a  
15       statement published in the Federal Register.

