

110TH CONGRESS  
1ST SESSION

# H. R. 2503

To amend the Federal Food, Drug, and Cosmetic Act with respect to the Office of Women’s Health and the regulation of breast implants, and to provide for a scientific workshop on the use of emergency contraception by women under age 18.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 24, 2007

Ms. DELAURO (for herself, Ms. SOLIS, Mr. FARR, Ms. WOOLSEY, Mr. GRIJALVA, Mr. WEXLER, Mrs. NAPOLITANO, Ms. SCHAKOWSKY, Ms. SUTTON, and Mr. RUSH) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the Office of Women’s Health and the regulation of breast implants, and to provide for a scientific workshop on the use of emergency contraception by women under age 18.

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 “FDA Scientific Fair-  
5 ness for Women Act”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds as follows:

3 (1) With respect to the Office of Women's  
4 Health within the Food and Drug Administration:

5 (A) When first established, the Office re-  
6 ported directly to the Commissioner of Food  
7 and Drugs.

8 (B) In the current organization of the  
9 Food and Drug Administration ("FDA"), the  
10 Office of Women's Health is located at the sec-  
11 ond level reporting within the Office of the  
12 Commissioner and is within the Office of  
13 Science and Health Coordination.

14 (2) With respect to the regulation by the FDA  
15 of silicone breast implants:

16 (A) In a draft guidance issued in January  
17 2004, the FDA asked manufacturers of such  
18 implants—

19 (i) to describe the rates of implant  
20 rupture over the lifetime of the product;

21 (ii) to describe the incidence of gel mi-  
22 gration resulting from ruptures; and

23 (iii) to characterize the health con-  
24 sequences of ruptures and associated mi-  
25 gration.

1           (B) The FDA approved silicone gel breast  
2 implants in November 2006 despite the lack of  
3 data responding to those three essential ques-  
4 tions.

5           (C) A study published by FDA researchers  
6 in 2001, using magnetic resonance imaging  
7 (MRI) to analyze women whose silicone gel  
8 breast implants were an average of 17 years old  
9 found that 69 percent of the women had rup-  
10 tures in one or both silicone breast implants,  
11 and 21 percent experienced gel migration out-  
12 side the scar capsule surrounding the implant.  
13 Implant manufacturers have not established  
14 whether the implants in their premarket-ap-  
15 proval applications would have similar or dif-  
16 ferent failure rates and leakage.

17           (D) In April 2005, a study published in  
18 the American Journal of Surgical Pathology fo-  
19 cusing on gel migration found that 90 percent  
20 of the women studied who had silicone implants  
21 showed silicone in their lymph nodes. The study  
22 also showed that 95 percent of these women  
23 had abnormal cells in their lymph nodes, com-  
24 pared with only 33 percent of women who had  
25 breast cancer surgery but did not have silicone

1 implants. The Secretary of Health and Human  
2 Services has not provided enforceable conditions  
3 to ensure that women are not harmed by leak-  
4 ing silicone from their breast implants.

5 (E) In 2003, the United States Govern-  
6 ment entered into a settlement with breast im-  
7 plant manufacturers for reimbursement for  
8 medical expenses paid by the Government for  
9 women harmed by silicone gel breast implants.  
10 No information has been made public about the  
11 use of those funds to provide health care or dis-  
12 ability benefits for women harmed by breast im-  
13 plants.

14 (3) With respect to the applications submitted  
15 to the FDA by Barr Laboratories for approval of  
16 the contraceptive drug marketed as Plan B:

17 (A) The FDA rejected the first Plan B ap-  
18 plication in May 2004 because of concerns that  
19 easier access to Plan B might result in in-  
20 creased promiscuity among women under 16,  
21 despite studies disproving this contention.

22 (B) The FDA said it would not approve  
23 the Plan B application unless it included an  
24 age-based sales distinction. In response, Barr  
25 Laboratories submitted a new application to

1 provide over-the-counter sales of plan B to  
2 women 16 years and older. More than one year  
3 later, FDA expressed concern that the age-  
4 based sales distinction would present regulatory  
5 concerns, even though the amended application  
6 was the result of FDA's recommendations.

7 (C) According to court documents released  
8 on August 3, 2006, the director of FDA's Of-  
9 fice of New Drugs learned early in 2004 that  
10 the then-FDA Commissioner had decided  
11 against approval of Plan B before FDA staff  
12 could complete their analysis.

13 (D) In another sworn deposition contained  
14 in the same court documents, one FDA official  
15 was told in January 2004 by the FDA Deputy  
16 Commissioner that Plan B needed to be re-  
17 jected to "appease the administration's con-  
18 stituents".

19 (E) In a letter and congressional testimony  
20 on August 1, the FDA Commissioner rec-  
21 ommended that the appropriate age range for  
22 over-the-counter Plan B is 18 and older. This  
23 recommendation was established arbitrarily and  
24 acknowledged by FDA as not supported by sci-  
25 entific data.

1 (F) A former FDA Commissioner testified  
2 in a sworn statement that he delayed approving  
3 over-the-counter sales of Plan B to determine  
4 how to restrict sales to young teens.

5 (G) A study in the Journal of Obstetrics &  
6 Gynecology concluded that young women are  
7 able to use Plan B “effectively and safely with-  
8 out health care provider intervention”.

9 (H) In November 2005, the Government  
10 Accountability Office found that the May 2004  
11 decision to deny OTC status to Plan B emer-  
12 gency contraception “was unusual” in that the  
13 decision was made at a much higher level with-  
14 in FDA than is usual practice, that the decision  
15 overruled recommendations by several levels of  
16 professional staff, and that the decision to limit  
17 OTC access to only those over a certain age  
18 was made prior to the completion of the regular  
19 review process.

20 **SEC. 3. OFFICE OF WOMEN’S HEALTH WITHIN FOOD AND**  
21 **DRUG ADMINISTRATION.**

22 (a) ESTABLISHMENT.—Section 903 of the Federal  
23 Food, Drug, and Cosmetic Act (21 U.S.C. 392) is amend-  
24 ed—

1           (1) by redesignating subsections (f) and (g) as  
2 subsections (g) and (h), respectively;

3           (2) in subsection (h) (as so redesignated), in  
4 paragraph (1), by striking “subsection (f)” and in-  
5 serting “subsection (g)”; and

6           (3) by inserting after subsection (e) the fol-  
7 lowing subsection:

8           “(f) OFFICE OF WOMEN’S HEALTH.—

9           “(1) IN GENERAL.—There is established within  
10 the Office of the Commissioner an office to be  
11 known as the Office of Women’s Health (referred to  
12 in this subsection as the ‘Office’). The Office shall  
13 be headed by a director, who shall report directly to  
14 the Commissioner.

15           “(2) DUTIES.—With respect to activities of the  
16 Food and Drug Administration that relate to wom-  
17 en’s health, the Director of the Office shall—

18                   “(A) assess the level of agency activity;

19                   “(B) set short-range and long-range goals;

20                   and

21                   “(C) be responsible for activities related to  
22 prevention, research, education and training,  
23 service delivery, and policy development.”.

24           (b) PROHIBITION AGAINST TRANSFER OF FUNDS.—

25 Notwithstanding any other provision of law authorizing

1 the transfer of funds within the Department of Health and  
2 Human Services or within the Food and Drug Administra-  
3 tion, any funds appropriated for the Office of Women’s  
4 Health within the Food and Drug Administration shall not  
5 be transferred to any other agency or office.

6 **SEC. 4. SCIENCE ON BREAST IMPLANTS.**

7 (a) CLASSIFICATION OF BREAST IMPLANTS.—Section  
8 513(f) of the Federal Food, Drug, and Cosmetic Act (21  
9 U.S.C. 360c(f)) is amended by adding at the end the fol-  
10 lowing:

11 “(6) A breast implant (as such term is defined in sec-  
12 tion 515A(f)) is deemed to be a class III device and shall  
13 be required to have an approval under section 515 of an  
14 application for premarket approval. This paragraph ap-  
15 plies to a breast implant irrespective of whether the im-  
16 plant has been cleared under section 510(k) before the  
17 date of the enactment of this paragraph.”.

18 (b) DEMONSTRATION OF SAFETY.—Subchapter A of  
19 chapter V of the Federal Food, Drug, and Cosmetic Act  
20 (21 U.S.C. 351 et seq.) is amended by inserting after sec-  
21 tion 515 the following section:

22 **“SEC. 515A. BREAST IMPLANTS.**

23 “(a) DEMONSTRATION OF SAFETY FOR LIFE OF THE  
24 DEVICE.—

1           “(1) IN GENERAL.—In the case of an applica-  
2           tion for a breast implant filed under section 515, the  
3           Secretary shall not find that a reasonable assurance  
4           of safety has been shown under section 515(d)(2)  
5           unless, prior to the approval of the application, the  
6           applicant involved has established—

7                     “(A) the life of the implant; and

8                     “(B) that safety has been demonstrated  
9                     for the life of the implant.

10           “(2) PREVIOUSLY APPROVED APPLICATIONS.—

11           In the case of an application for a breast implant  
12           approved under section 515 before the date of the  
13           enactment of this section, the breast implant is  
14           deemed to be unsafe for purposes of section  
15           515(e)(1)(A), and the Secretary shall withdraw ap-  
16           proval of the application for such breast implant  
17           under section 515(e), unless the holder of the appli-  
18           cation establishes the life of the implant and dem-  
19           onstrates that safety has been demonstrated for the  
20           life of the implant.

21           “(b) GUIDANCE FOR CLINICAL CARE, REMOVAL AND  
22           REPLACEMENT.—

23                     “(1) IN GENERAL.—In approving an application  
24                     for a breast implant under section 515, the Sec-  
25                     retary shall—

1           “(A) issue appropriate, voluntary guidance  
2           for clinical care, removal, and replacement for  
3           the implant, including appropriate coverage by  
4           government health care systems; and

5           “(B) require such guidance to be clearly  
6           expressed in the labeling and all marketing ma-  
7           terials for such implant.

8           “(2) PREVIOUSLY APPROVED APPLICATIONS.—  
9           In the case of each application for a breast implant  
10          approved under section 515 before the date of the  
11          enactment of this section, the Secretary shall—

12          “(A) not later than 90 days after such  
13          date of enactment, issue guidance for the im-  
14          plant in accordance with paragraph (1)(A);

15          “(B) require such guidance to be clearly  
16          expressed in the labeling and all marketing ma-  
17          terials for the implant; and

18          “(C) require dissemination of such guid-  
19          ance to patients who received the implant be-  
20          fore the inclusion of such guidance into the la-  
21          beling for the implant.

22          “(c) REPORTS TO CONGRESS.—

23          “(1) REQUIREMENT.—On an annual basis, the  
24          Secretary shall submit to the Congress a report that  
25          summarizes the progress of postmarket studies and

1 findings with respect to the safety and effectiveness  
2 of each breast implant approved under section 515,  
3 including the findings on safety for the life of the  
4 implant under subsection (a).

5 “(2) FIRST REPORT.—The Secretary shall sub-  
6 mit the first report under this subsection for a  
7 breast implant not later than—

8 “(A) 120 days after approving an applica-  
9 tion for the implant under section 515; or

10 “(B) if an application for the implant was  
11 approved under section 515 before the date of  
12 the enactment of this section, 120 days after  
13 such date of enactment.

14 “(d) BREAST IMPLANT ADVISORY PANELS.—

15 “(1) REVIEW OF 10-YEAR LONGITUDINAL STUD-  
16 IES.—The Breast Implant Advisory Panel of the  
17 General and Plastic Surgery Advisory Committee of  
18 the Food and Drug Administration shall meet—

19 “(A) in 2007 to review the results and  
20 quality of the research under the 10-year longi-  
21 tudinal studies required by the Food and Drug  
22 Administration for saline breast implants ap-  
23 proved under section 515; and

24 “(B) in each of 2008 and 2009 to review  
25 the progress of the 10-year longitudinal studies

1 required by the Food and Drug Administration  
2 for silicone gel breast implants approved under  
3 section 515.

4 “(2) MEMBERSHIP.—With respect to member-  
5 ship on any advisory committee of the Food and  
6 Drug Administration (including any subcommittee  
7 or panel thereof) that considers issues concerning  
8 breast implants, the following applies:

9 “(A) The Secretary may not grant any ex-  
10 emptions for conflicts related to personal finan-  
11 cial interests.

12 “(B) Before adding a member to the com-  
13 mittee, the Secretary shall post a notice on the  
14 Internet site of such Administration that the in-  
15 dividual involved will become a member of the  
16 committee. The notice shall include a summary  
17 of the professional and educational background  
18 of the individual.

19 “(C) The individual may not serve at any  
20 meeting of the committee until 30 days after  
21 the notice is posted on such site.

22 “(e) STUDY ON THE IONIZATION OF PLATINUM.—

23 “(1) IN GENERAL.—Not later than 365 days  
24 after the date of the enactment of this section, the

1 Secretary shall complete a study and submit a re-  
2 port to the Congress on—

3 “(A) the ionization and levels of platinum  
4 in silicone breast implants, analyzing the plat-  
5 inum found in silicone gel breast implants in  
6 vivo as well as levels and ionization found in  
7 women’s tissues, breast milk, and other bodily  
8 fluids; and

9 “(B) the potential short-term and long-  
10 term risks of the presence of platinum or plat-  
11 inum salts.

12 “(2) PANEL OF INDEPENDENT SCIENTISTS.—  
13 The Secretary shall establish a panel of independent  
14 scientists, including scientists from the Centers for  
15 Disease Control and Prevention and the National In-  
16 stitutes of Health, for the purpose of designing and  
17 conducting the study under this subsection. No sci-  
18 entist with financial ties to a breast implant com-  
19 pany, silicone company, or plastic surgeon shall  
20 serve on such panel or participate in the design or  
21 conduct of such studies.

22 “(f) DEFINITION.—For purposes of this section, the  
23 term ‘breast implant’ means a device intended to be im-  
24 planted to augment or reconstruct the female breast that,  
25 except as provided in subsection (d)(1)(A), contains a filler

1 material comprised of a substance or substances other  
2 than sterile isotonic saline.”.

3 **SEC. 5. SCIENTIFIC WORKSHOP ON USE OF EMERGENCY**

4 **CONTRACEPTION BY WOMEN UNDER AGE 18.**

5 The Secretary of Health and Human Services, acting  
6 through the Commissioner of Food and Drugs, shall con-  
7 vene a scientific workshop within six months after the date  
8 of the enactment of this Act to review and evaluate current  
9 scientific data on the use of emergency contraception by  
10 females of childbearing potential under the age of 18. The  
11 scientific workshop shall—

12 (1) address the scientific questions identified in  
13 the recent limited approval of Plan B emergency  
14 contraception; and

15 (2) include among the participants in the work-  
16 shop—

17 (A) scientific and clinical representatives  
18 from the American Academy of Pediatrics, the  
19 American College of Obstetricians and Gyne-  
20 cologists, the Society of Adolescent Medicine,  
21 the American Medical Association, the National  
22 Institutes of Health, and the Agency for  
23 Healthcare Research and Quality;

24 (B) scientific and clinical researchers who  
25 have carried out research on use of contracep-

1           tives, including emergency contraceptives, by  
2           women under the age of 18; and

3                   (C) the appropriate review divisions of the  
4           Food and Drug Administration and the profes-  
5           sional scientific and clinical staff within such  
6           divisions.

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