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109TH CONGRESS
2D SESSION

H. R. 6235

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.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2006

Ms. DELAURO (for herself, Mr. HINCHEY, Mr. CONYERS, Ms. JACKSON-LEE of Texas, Mrs. DAVIS of California, Ms. SOLIS, Mr. MCDERMOTT, Ms. LINDA T. SÁNCHEZ of California, Mr. STARK, Mr. MORAN of Virginia, Mr. GRIJALVA, and Mrs. CAPPS) 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.

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 ''FDA Scientific Fairness for Women Act''.

SEC. 2. FINDINGS.

The Congress finds as follows:

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

(A) When first established, the Office reported directly to the Commissioner of Food and Drugs.

(B) In the current organization of the Food and Drug Administration (''FDA''), the Office of Women's Health is located at the second level reporting within the Office of the Commissioner and is within the Office of Science and Health Coordination.

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

(A) In a draft guidance issued in January 2004, the FDA asked manufacturers of such implants—

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

(ii) to describe the incidence of gel migration resulting from ruptures; and

(iii) to characterize the health consequences of ruptures and associated migration.

(B) The manufacturers of silicone breast implants have not complied with that draft guidance for the specific implants in their premarket-approval applications.

(C) A study released by FDA researchers in 2000 reviewed silicone breast implants that were an average age of 17 years and concluded that 69 percent of the women had ruptures in one or more silicone breast implants, and 21 percent experienced gel migration outside the implant. Implant manufacturers have not established whether the implants in their premarket-approval applications would have similar or different failure rates and leakage after 17 years.

(D) In April 2005, a study published in the American Journal of Surgical Pathology focusing on gel migration found that 90 percent of the women studied who had silicone implants showed silicone droplets in their lymph nodes. The study also showed that 95 percent of these women had abnormal cells in their lymph nodes, compared with only 33 percent of women who had breast cancer surgery without the addition of silicone implants.

(E) In 2003, the U.S. government entered into a settlement with breast implant manufacturers for reimbursement for medical expenses paid by the Federal Government for women harmed by silicone gel breast implants.

(F) FDA's Office of Criminal Investigations (''OCI'') has investigated whether one manufacturer of breast implants submitted inaccurate data on ruptures in its application. The FDA OCI also is investigating allegations regarding whether that same manufacturer failed to ensure that their implants were used in compliance with FDA restrictions for the Adjunct Study.

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

(A) The FDA rejected the first Plan B application in May 2004 because of concerns that easier access to Plan B might result in increased promiscuity among women under 16, despite studies disproving this contention.

(B) The FDA said it would not approve the Plan B application unless it included an age-based sales distinction. In response, Barr

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

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

(D) In another sworn deposition contained in the same court documents, one FDA official was told in January 2004 by the FDA Deputy Commissioner that Plan B needed to be rejected to ''appease the administration's constituents''.

(E) In a letter and congressional testimony on August 1, the FDA Commissioner recommended that the appropriate age range for over-the-counter Plan B is 18 and older. This recommendation was established arbitrarily and

acknowledged by FDA as not supported by scientific data.

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

(G) A study in the Journal of Obstetrics & Gynecology concluded that young women are able to use Plan B ''effectively and safely without health care provider intervention''.

(H) In November 2005, the Governmental Accountability Office found that the May 2004 decision to deny OTC status to Plan B emergency contraception ''was unusual'' in that the decision was made at a much higher level within FDA than is usual practice, that the decision overruled recommendations by several levels of professional staff, and that the decision to limit OTC access to only those over a certain age was made prior to the completion of the regular review process.

SEC. 3. OFFICE OF WOMEN'S HEALTH WITHIN FOOD AND DRUG ADMINISTRATION.

Section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 392) is amended—

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

(2) in subsection (g) (as so redesignated), in paragraph (1), by striking ''subsection (f)'' and inserting ''subsection (g)''; and

(3) by inserting after subsection (e) the following subsection:

''(f) OFFICE OF WOMEN'S HEALTH.—

''(1) IN GENERAL.—There is established within the Office of the Commissioner an office to be known as the Office of Women's Health (referred to in this subsection as the 'Office'). The Office shall be headed by a director, who shall report directly to the Commissioner.

''(2) DUTIES.—With respect to activities of the Food and Drug Administration that relate to women's health, the Director of the Office shall—

''(A) assess the level of agency activity;

''(B) set short-range and long-range goals; and

''(C) be responsible for activities related to prevention, research, education and training, service delivery, and policy development.''.

SEC. 4. SCIENCE ON BREAST IMPLANTS.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515 the following section:

"SEC. 515A. BREAST IMPLANTS.

"(a) DEMONSTRATION OF SAFETY FOR LIFE OF THE DEVICE.—In the case of an application under section 515 for a breast implant, the Secretary shall not find that a reasonable assurance of safety has been shown under section 515(d)(2) unless the applicant involved has established the lifetime of the implant, and demonstrates, prior to approval of the application, that safety has been demonstrated for the life of the implant.

"(b) CERTAIN PRODUCT REQUIREMENTS.—In approving an application under section 515 for a breast implant, the Secretary shall determine appropriate clinical care and removal and replacement requirements for the implant, including appropriate coverage by government health care systems. In addition, the life of the implant and follow-up care and removal requirements of the implant shall be clearly defined in all materials, including labeling, patient information, and marketing materials.

"(c) REPORT TO CONGRESS REGARDING APPROVAL.—Not later than 30 days after approving an application under section 515 regarding a breast implant, the Secretary shall submit to the Congress a report that

summarizes the findings of the Secretary with respect to the safety and effectiveness of the implant, including the finding under subsection (a).

''(d) BREAST IMPLANT ADVISORY COMMITTEES.—With respect to membership on any advisory committee of the Food and Drug Administration (including any subcommittee or panel thereof) that considers issues concerning breast implants, the following applies:

''(1) The Secretary may not grant any exemptions for conflicts related to personal financial interests.

''(2) Before adding a member to the committee, the Secretary shall post a notice on the Internet site of such Administration that the individual involved will become a member of the committee. The notice shall include a summary of the professional and educational background of the individual.

''(3) The individual may not serve at any meeting of the committee until 30 days after the notice is posted on such site.

''(e) STUDY ON THE IONIZATION OF PLATINUM.—The Secretary shall provide for a study on the ionization and levels of platinum in silicone breast implants, analyzing the platinum found in silicone gel breast implants in vivo as well as levels and ionization found in the wom-

en's tissues, breast milk, and other bodily fluids. The study shall also report the potential short-term and long-term risks of the presence of platinum or platinum salts. The Secretary shall establish a panel of independent scientists, including scientists from the Centers for Disease Control and Prevention and the National Institutes of Health, for the purpose of designing and conducting the study.

''(f) DEFINITION.—For purposes of this section, the term 'breast implant' means a device intended to be implanted to augment or reconstruct the female breast that contains a filler material comprised of a substance or substances other than sterile isotonic saline.''.

SEC. 5. SCIENTIFIC WORKSHOP ON USE OF EMERGENCY CONTRACEPTION BY WOMEN UNDER AGE 18.

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

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

(2) include among the participants in the workshop—

(A) scientific and clinical representatives from the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the Society of Adolescent Medicine, the American Medical Association, the National Institutes of Health, and the Agency for Healthcare Research and Quality;

(B) scientific and clinical researchers who have carried out research on use of contraceptives, including emergency contraceptives, by women under the age of 18; and

(C) the appropriate review divisions of the Food and Drug Administration and the professional scientific and clinical staff within such divisions.

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