II

107TH CONGRESS
1ST SESSION

S. 961

To promote research to identify and evaluate the health effects of breast implants; to ensure that women receive accurate information about such implants and to encourage the Food and Drug Administration to thoroughly review the implant manufacturers' standing with the agency.

IN THE SENATE OF THE UNITED STATES

MAY 24, 2001

Mrs. BOXER introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To promote research to identify and evaluate the health effects of breast implants; to ensure that women receive accurate information about such implants and to encourage the Food and Drug Administration to thoroughly review the implant manufacturers' standing with the agency.

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 "Breast Implant Research and Information Act".

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress makes the following findings:

(1) According to the Institute of Medicine, it is estimated that 1,000,000 to 2,000,000 American women have received breast implants over the last 35 years. Because there has never been a patient registry for breast implant recipients it is impossible to more accurately determine the number of women who have received breast implants. Yet, the American Society of Plastic Surgeons estimates that in 1999 alone 82,975 women had breast reconstruction following mastectomies and another 167,318 American women received breast implants for cosmetic purposes.

(2) From 1985 until January 2000, FDA received 127,770 adverse reaction reports for silicone gel-filled breast implants and 65,720 adverse reaction reports for saline-filled implants.

(3) Women need complete and accurate information about the potential health risks and advantages of breast implants so that women can make informed decisions.

(4) Silicone breast implants have never been approved by the Food and Drug Administration; saline breast implants, which consist of a saline solution

injected into a silicone envelope, were approved by the agency in 2000 despite alarmingly high complication and reoperation rates. After three years, 43 percent of the augmentation patients and 73 percent of the reconstruction patients experienced local complications and 40 percent of the reconstruction patients were forced to undergo additional surgery for local complications and device failure.

(5) In 1998, the Food and Drug Administration opened a criminal investigation following allegations that one of the breast implant manufacturers was manipulating research data in breast implant studies. When the Food and Drug Administration's General and Plastic Surgery Devices Panel convened in March 2000 to consider market approval for saline implants, it was not informed of the investigation. Although the manufacturer's saline breast implant was approved by the Food and Drug Administration in May 2000, the investigation remains open.

(6) According to a 1997 Mayo Clinic study, within 5 years of receiving such implants, 1 in 4 women required additional surgery.

(7) In 2000, research sponsored by the Food and Drug Administration found that even among women who had not sought medical treatment for

implant problems, almost 70 percent had at least one ruptured implant after 10 to 15 years. Silicone was found to be migrating away from the implants in 21 percent of those women. The FDA researchers concluded that ''the relationship of free silicone to development or progression of disease is unknown''.

(8) A 1993 study by Dr. Suzanne S. Teuber et al., University of California, published in The Journal of Autoimmunity, investigated the influence of silicone breast implants on the expression of anticollagen antibodies and found a statistically significant incidence of anticollagen antibodies in women with implants. The researchers concluded that silicone breast implants should not be considered a benign or immunologically inert material; serious implications may result from their use.

(9) The Institute of Medicine's 1999 study of silicone breast implant safety found that local complications with silicone breast implants were the primary safety issue, that they have not been well studied, and that information on these complications is crucial for women deciding whether or not they want breast implant surgery. Concern remains that exposure to silicone breast implants may result in cur-

rently undefined connective tissue or autoimmune diseases.

(10) A 2001 National Cancer Institute study found breast implant recipients suffer from higher rates of lung and brain cancer than other plastic surgery patients.

(11) A 1999 case report by Dr. Suzanne S. Teuber et al., University of California, published in The Journal of Rheumatology, found evidence of silicone migration in women with ruptured or leaking silicone breast implants. These patients experienced severe local inflammation and complications resulting from silicone migration to the axilla, arm or abdominal wall. Researchers concluded that once silicone gel leaves the implant, it is not biologically inert and in some persons can elicit profound pathologic responses.

(12) According to many reports, including a study published in the Journal of the National Cancer Institute, the presence of a silicone breast implant may create difficulties in obtaining accurate and thorough mammograms because as much as 40 percent of the breast tissue can be masked by the implant. This delays the early detection of breast cancer in women.

(13) According to a 2000 Food and Drug Administration publication, women of childbearing age who want to breast feed should be aware of the negative impact of breast implants on breast feeding. It is not known if a small amount of silicone may pass from the silicone shell of an implant into breast milk. If this occurs, it is not known what effect it may have on the nursing infant.

(b) PURPOSE.—It is the purpose of this Act to promote research to identify and evaluate the health effects of breast implants, to ensure that women receive accurate information about such implants and to encourage the Food and Drug Administration to conclude its criminal investigation based on the allegations of wrong-doing by one of the implant manufacturers which ultimately may affect their products and the health of American women.

(c) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to affect any rule or regulation promulgated under the authority of the Federal Food, Drug and Cosmetic Act (21 U.S. 301 et seq.) that is in effect on the date of enactment of this Act relating to the availability of silicone breast implant for reconstruction after mastectomy, correction of congenital deformities, or replacement for ruptured silicone implants for augmentation.

SEC. 3. EXPANSION AND INTENSIFICATION OF ACTIVITIES REGARDING SILICONE BREAST IMPLANTS AT THE NATIONAL INSTITUTES OF HEALTH.

(a) STATUS OF EXISTING RESEARCH.—The Director of the National Institutes of Health shall report to all appropriate committees of Congress on the status of the existing breast implant research funded by such Institutes within 90 days after the date of the enactment of this Act.

(b) AMENDMENT TO PUBLIC HEALTH SERVICE ACT.—Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by adding at the end of the following:

"SEC. 498C. BREAST IMPLANT RESEARCH.

''(a) INSTITUTE-WIDE COORDINATOR.—The Director of NIH shall appoint an appropriate official of the Department of Health and Human Services to serve as the National Institutes of Health coordinator regarding breast implant research. Such coordinator shall encourage and coordinate the participation of all appropriate Institutes research including—

''(1) the Office of Research on Women's Health;

''(2) the National Institute of Allergy and Infectious Diseases;

''(3) the National Institute of Arthritis and Musculoskeletal and Skin diseases;

''(4) the National Institute of Child Health and Human Development;

''(5) the National Institute of Environmental Health Sciences;

''(6) the National Institute of Neurological Disorders and Stroke; and

''(7) the National Cancer Institute.

''(b) STUDY SECTIONS.—The Director of NIH shall establish a study section or special emphasis panel if determined to be appropriate, for the National Institutes of Health to review extramural research grant applications regarding breast implants to ensure the appropriate design and high quality of such research and shall take appropriate action to ensure the quality of intramural research activities.

''(c) CLINICAL STUDY.—

''(1) IN GENERAL.—The Director of NIH shall conduct or support research to expand the understanding of the health implications of both saline and silicone breast implants. Such research should, if determined to be scientifically appropriate, include multidisciplinary, clinical, case-controlled study of women with breast implants for at least eight years whether it be one prosthesis or multiple, and differentiate between women receiving implants for

mastectomy, reconstructive or cosmetic purposes and include subsets of women with saline implants and silicone implants. Such a study should focus on the rate of local complications which includes capsular contracture, leakage, loss of nipple sensation, deflation and rupture as well the presentation of atypical symptoms, silicone migration, neurological dysfunction, and immune system irregularities, and evaluate to what extent if any, their health differs from that of suitable controls.

''(2) ANNUAL REPORT.—The Director of NIH shall annually prepare and submit to the appropriate Committees of Congress a report concerning the results of the study conducted under paragraph (1).''.

SEC. 4. INTENSIFICATION OF ACTIVITIES REGARDING POSTMARKET RESEARCH OF SALINE BREAST IMPLANTS AT THE FOOD AND DRUG ADMINISTRATION.

To ensure that the Food and Drug Administration conducts postmarket evaluations of saline implant manufacturers' data based on the postmarket recommendations made by the Food and Drug Administration's General and Plastic Surgery Devices Panel, the Commissioner of Food and Drugs shall report to Congress on the implementation status of the postmarket recommendations at 6, 12, and

18 month intervals after the date of the enactment of this Act and annually thereafter.

SEC. 5. EXPANSION AND INTENSIFICATION OF ACTIVITIES REGARDING SILICONE BREAST IMPLANTS AT THE FOOD AND DRUG ADMINISTRATION.

To assist women in receiving accurate and complete information about the risks of silicone breast implants, the Commissioner of Food and Drugs shall—

(1) expedite the conclusion the agency's criminal investigation into allegations of wrong-doing by one of the implant manufacturers; brief appropriate Committees of Congress on the findings and take appropriate action within 90 days after the date of the enactment of this Act;

(2) ensure that the toll-free consumer information line and materials concerning breast implants provided by the Food and Drug Administration are available, up to date, and responsive to reports of problems with breast implants, and that timely aggregate data concerning such reports shall be made available to the public upon request and consistent with existing confidentiality standards;

(3) require that manufacturers of silicone breast implants update implant package inserts and informed consent documents regularly to reflect ac-

curate information about such implants, particularly the rate of local complications and ruptures of such implants;

(4) require that any manufacturers of such implants that are conducting clinical studies on silicone breast implants—

(A) require its clinical investigators to provide prospective patients with the Food and Drug Administration's breast implant booklet;

(B) amend such study protocol and informed consent document to reflect that patients must be provided with a copy of informed consent documents at the initial, or earliest possible, consultation regarding breast prosthesis;

(C) amend the informed consent protocol to inform women about how to obtain a Medwatch form and encourage any woman who withdraws from the study, or who would like to report such problem or concerns with the study and reason for withdrawing; and

(D) amend the informed consent document to provide potential participants with the inclusion criteria for the clinical trial and the toll-free Consumer Information number; and

(5) appoint a special ad hoc patient information panel that—

(A) convenes annually for the sole purpose of reviewing breast implant information and advertisements provided by the manufacturers and the Food and Drug Administration to ensure consumer information is thorough and accurate; and

(B) includes in its membership (but is not limited to) saline and silicone breast implant recipients, bioethicists, rheumatologists, and oncologists with experience in both clinical care and research regarding breast implants.

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