

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

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.

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 “Breast Implant Re-
5 search and Information Act”.

1 **SEC. 2. FINDINGS AND PURPOSE.**

2 (a) FINDINGS.—Congress makes the following find-
3 ings:

4 (1) According to the Institute of Medicine, it is
5 estimated that 1,000,000 to 2,000,000 American
6 women have received breast implants over the last
7 35 years. Because there has never been a patient
8 registry for breast implant recipients it is impossible
9 to more accurately determine the number of women
10 who have received breast implants. Yet, the Amer-
11 ican Society of Plastic Surgeons estimates that in
12 1999 alone 82,975 women had breast reconstruction
13 following mastectomies and another 167,318 Amer-
14 ican women received breast implants for cosmetic
15 purposes.

16 (2) From 1985 until January 2000, FDA re-
17 ceived 127,770 adverse reaction reports for silicone
18 gel-filled breast implants and 65,720 adverse reac-
19 tion reports for saline-filled implants.

20 (3) Women need complete and accurate infor-
21 mation about the potential health risks and advan-
22 tages of breast implants so that women can make in-
23 formed decisions.

24 (4) Silicone breast implants have never been ap-
25 proved by the Food and Drug Administration; saline
26 breast implants, which consist of a saline solution

1 injected into a silicone envelope, were approved by
2 the agency in 2000 despite alarmingly high com-
3 plication and reoperation rates. After three years, 43
4 percent of the augmentation patients and 73 percent
5 of the reconstruction patients experienced local com-
6 plications and 40 percent of the reconstruction pa-
7 tients were forced to undergo additional surgery for
8 local complications and device failure.

9 (5) In 1998, the Food and Drug Administra-
10 tion opened a criminal investigation following allega-
11 tions that one of the breast implant manufacturers
12 was manipulating research data in breast implant
13 studies. When the Food and Drug Administration's
14 General and Plastic Surgery Devices Panel convened
15 in March 2000 to consider market approval for sa-
16 line implants, it was not informed of the investiga-
17 tion. Although the manufacturer's saline breast im-
18 plant was approved by the Food and Drug Adminis-
19 tration in May 2000, the investigation remains open.

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

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

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

7 (8) A 1993 study by Dr. Suzanne S. Teuber et
8 al., University of California, published in *The Jour-*
9 *nal of Autoimmunity*, investigated the influence of
10 silicone breast implants on the expression of
11 anticollagen antibodies and found a statistically sig-
12 nificant incidence of anticollagen antibodies in
13 women with implants. The researchers concluded
14 that silicone breast implants should not be consid-
15 ered a benign or immunologically inert material; se-
16 rious implications may result from their use.

17 (9) The Institute of Medicine’s 1999 study of
18 silicone breast implant safety found that local com-
19 plications with silicone breast implants were the pri-
20 mary safety issue, that they have not been well stud-
21 ied, and that information on these complications is
22 crucial for women deciding whether or not they want
23 breast implant surgery. Concern remains that expo-
24 sure to silicone breast implants may result in cur-

1 rently undefined connective tissue or autoimmune
2 diseases.

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

7 (11) A 1999 case report by Dr. Suzanne S.
8 Teuber et al., University of California, published in
9 The Journal of Rheumatology, found evidence of sili-
10 cone migration in women with ruptured or leaking
11 silicone breast implants. These patients experienced
12 severe local inflammation and complications result-
13 ing from silicone migration to the axilla, arm or ab-
14 dominal wall. Researchers concluded that once sili-
15 cone gel leaves the implant, it is not biologically
16 inert and in some persons can elicit profound
17 pathologic responses.

18 (12) According to many reports, including a
19 study published in the Journal of the National Can-
20 cer Institute, the presence of a silicone breast im-
21 plant may create difficulties in obtaining accurate
22 and thorough mammograms because as much as 40
23 percent of the breast tissue can be masked by the
24 implant. This delays the early detection of breast
25 cancer in women.

1 (13) According to a 2000 Food and Drug Ad-
2 ministration publication, women of childbearing age
3 who want to breast feed should be aware of the neg-
4 ative impact of breast implants on breast feeding. It
5 is not known if a small amount of silicone may pass
6 from the silicone shell of an implant into breast
7 milk. If this occurs, it is not known what effect it
8 may have on the nursing infant.

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

17 (c) RULE OF CONSTRUCTION.—Nothing in this Act
18 shall be construed to affect any rule or regulation promul-
19 gated under the authority of the Federal Food, Drug and
20 Cosmetic Act (21 U.S. 301 et seq.) that is in effect on
21 the date of enactment of this Act relating to the avail-
22 ability of silicone breast implant for reconstruction after
23 mastectomy, correction of congenital deformities, or re-
24 placement for ruptured silicone implants for augmenta-
25 tion.

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

4 (a) STATUS OF EXISTING RESEARCH.—The Director
5 of the National Institutes of Health shall report to all ap-
6 propriate committees of Congress on the status of the ex-
7 isting breast implant research funded by such Institutes
8 within 90 days after the date of the enactment of this Act.

9 (b) AMENDMENT TO PUBLIC HEALTH SERVICE
10 ACT.—Part H of title IV of the Public Health Service Act
11 (42 U.S.C. 289 et seq.) is amended by adding at the end
12 of the following:

13 **“SEC. 498C. BREAST IMPLANT RESEARCH.**

14 “(a) INSTITUTE-WIDE COORDINATOR.—The Director
15 of NIH shall appoint an appropriate official of the Depart-
16 ment of Health and Human Services to serve as the Na-
17 tional Institutes of Health coordinator regarding breast
18 implant research. Such coordinator shall encourage and
19 coordinate the participation of all appropriate Institutes
20 research including—

21 “(1) the Office of Research on Women’s
22 Health;

23 “(2) the National Institute of Allergy and In-
24 fectious Diseases;

25 “(3) the National Institute of Arthritis and
26 Musculoskeletal and Skin diseases;

1 “(4) the National Institute of Child Health and
2 Human Development;

3 “(5) the National Institute of Environmental
4 Health Sciences;

5 “(6) the National Institute of Neurological Dis-
6 orders and Stroke; and

7 “(7) the National Cancer Institute.

8 “(b) STUDY SECTIONS.—The Director of NIH shall
9 establish a study section or special emphasis panel if de-
10 termined to be appropriate, for the National Institutes of
11 Health to review extramural research grant applications
12 regarding breast implants to ensure the appropriate de-
13 sign and high quality of such research and shall take ap-
14 propriate action to ensure the quality of intramural re-
15 search activities.

16 “(c) CLINICAL STUDY.—

17 “(1) IN GENERAL.—The Director of NIH shall
18 conduct or support research to expand the under-
19 standing of the health implications of both saline
20 and silicone breast implants. Such research should,
21 if determined to be scientifically appropriate, include
22 multidisciplinary, clinical, case-controlled study of
23 women with breast implants for at least eight years
24 whether it be one prosthesis or multiple, and dif-
25 ferentiate between women receiving implants for

1 mastectomy, reconstructive or cosmetic purposes and
2 include subsets of women with saline implants and
3 silicone implants. Such a study should focus on the
4 rate of local complications which includes capsular
5 contracture, leakage, loss of nipple sensation, defla-
6 tion and rupture as well the presentation of atypical
7 symptoms, silicone migration, neurological dysfunc-
8 tion, and immune system irregularities, and evaluate
9 to what extent if any, their health differs from that
10 of suitable controls.

11 “(2) ANNUAL REPORT.—The Director of NIH
12 shall annually prepare and submit to the appropriate
13 Committees of Congress a report concerning the re-
14 sults of the study conducted under paragraph (1).”.

15 **SEC. 4. INTENSIFICATION OF ACTIVITIES REGARDING**
16 **POSTMARKET RESEARCH OF SALINE BREAST**
17 **IMPLANTS AT THE FOOD AND DRUG ADMINIS-**
18 **TRATION.**

19 To ensure that the Food and Drug Administration
20 conducts postmarket evaluations of saline implant manu-
21 facturers’ data based on the postmarket recommendations
22 made by the Food and Drug Administration’s General and
23 Plastic Surgery Devices Panel, the Commissioner of Food
24 and Drugs shall report to Congress on the implementation
25 status of the postmarket recommendations at 6, 12, and

1 18 month intervals after the date of the enactment of this
2 Act and annually thereafter.

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

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

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

15 (2) ensure that the toll-free consumer informa-
16 tion line and materials concerning breast implants
17 provided by the Food and Drug Administration are
18 available, up to date, and responsive to reports of
19 problems with breast implants, and that timely ag-
20 gregate data concerning such reports shall be made
21 available to the public upon request and consistent
22 with existing confidentiality standards;

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

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

4 (4) require that any manufacturers of such im-
5 plants that are conducting clinical studies on silicone
6 breast implants—

7 (A) require its clinical investigators to pro-
8 vide prospective patients with the Food and
9 Drug Administration’s breast implant booklet;

10 (B) amend such study protocol and in-
11 formed consent document to reflect that pa-
12 tients must be provided with a copy of informed
13 consent documents at the initial, or earliest pos-
14 sible, consultation regarding breast prosthesis;

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

21 (D) amend the informed consent document
22 to provide potential participants with the inclu-
23 sion criteria for the clinical trial and the toll-
24 free Consumer Information number; and

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

3 (A) convenes annually for the sole purpose
4 of reviewing breast implant information and ad-
5 vertisements provided by the manufacturers and
6 the Food and Drug Administration to ensure
7 consumer information is thorough and accurate;
8 and

9 (B) includes in its membership (but is not
10 limited to) saline and silicone breast implant re-
11 cipients, bioethicists, rheumatologists, and
12 oncologists with experience in both clinical care
13 and research regarding breast implants.

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