

106TH CONGRESS
1ST SESSION

S. 1075

To promote research to identify and evaluate the health effects of silicone breast implants, and to ensure that women and their doctors receive accurate information about such implants.

IN THE SENATE OF THE UNITED STATES

MAY 19, 1999

Mrs. BOXER (for herself, Mrs. HUTCHISON, and Ms. LANDRIEU) 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 silicone breast implants, and to ensure that women and their doctors receive accurate information about such implants.

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 “Silicone Breast Im-
5 plant Research and Information Act”.

6 **SEC. 2. FINDINGS AND PURPOSE.**

7 (a) FINDINGS.—Congress makes the following find-
8 ings:

1 (1) According to the Institute of Medicine, it is
2 estimated that 1,000,000 to 2,000,000 American
3 women have received silicone breast implants over
4 the last 35 years.

5 (2) Silicone breast implants have been used pri-
6 marily for breast augmentation, but also as an im-
7 portant part of reconstruction surgery for breast
8 cancer or other conditions.

9 (3) Women with breast cancer or other medical
10 conditions seek access to the broadest possible treat-
11 ment options, including silicone breast implants.

12 (4) Women need complete and accurate infor-
13 mation about the potential health risks and advan-
14 tages of silicone breast implants so that women can
15 make informed decisions.

16 (5) Although the rate of implant rupture and
17 silicone leakage has not been definitively established,
18 estimates are as high as 70 percent.

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

23 (7) In addition to potential systemic complica-
24 tions, local changes in breast tissue such as hard-
25 ening, contraction of scar tissue surrounding im-

1 plants, blood clots, severe pain, burning rashes, seri-
2 ous inflammation, or other complications requiring
3 surgical intervention following implantation have
4 been reported.

5 (8) According to the National Science Panel
6 Report released in December 1998, the current body
7 of research on silicone breast implants in immu-
8 nology, rheumatology, toxicology, and epidemiology
9 is inadequate to conclusively determine the effects of
10 silicone. The National Science Panel pointed to
11 many limitations in research methodology and data
12 analysis used in past studies clearly demonstrating
13 the need for future independent clinical research.

14 (9) According to the Institute of Medicine, con-
15 cern remains that exposure to silicone or other com-
16 ponents in silicone breast implants may result in
17 currently undefined connective tissue or autoimmune
18 diseases.

19 (10) A group of independent scientists and cli-
20 nicians convened by the National Institute of Arthri-
21 tis and Musculoskeletal and Skin Diseases in April
22 of 1997 addressed concerns that an association may
23 exist between atypical connective tissue disease and
24 silicone breast implants, and called for additional

1 basic research on the components of silicone as well
2 as biological responses to silicone.

3 (11) According to many reports, including a
4 study published in the Journal of the National Cancer
5 Institute, the presence of silicone breast implants
6 may create difficulties in obtaining complete mam-
7 mograms.

8 (12) According to a 1998 Food and Drug Ad-
9 ministration publication, although silicone breast im-
10 plants usually do not interfere with a woman's abil-
11 ity to nurse, if the implants leak, there is some con-
12 cern that the silicone may harm the baby. Some
13 studies suggest a link between breast feeding with
14 implants and problems with the child's esophagus.

15 (b) PURPOSE.—It is the purpose of this Act to pro-
16 mote research to identify and evaluate the health effects
17 of silicone breast implants, and to ensure that women and
18 their doctors receive accurate information about such im-
19 plants.

20 (c) RULE OF CONSTRUCTION.—Nothing in this Act
21 shall be construed to affect any rule or regulation promul-
22 gated under the authority of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 321 et seq.) that is in effect on
24 the date of enactment of this Act relating to the avail-
25 ability of silicone breast implants for reconstruction after

1 mastectomy, correction of congenital deformities, or re-
2 placement for ruptured silicone implants for augmenta-
3 tion.

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

7 Part H of title IV of the Public Health Service Act
8 (42 U.S.C. 289 et seq.) is amended by adding at the end
9 the following:

10 **“SEC. 498C. SILICONE BREAST IMPLANT RESEARCH.**

11 “(a) INSTITUTE-WIDE COORDINATOR.—The Director
12 of NIH shall appoint an appropriate official of the Depart-
13 ment of Health and Human Services to serve as the Na-
14 tional Institutes of Health coordinator regarding silicone
15 breast implant research. Such coordinator shall encourage
16 and coordinate the participation of all appropriate Insti-
17 tutes in research on silicone breast implants, including—

18 “(1) the National Institute of Allergy and In-
19 fectious Diseases;

20 “(2) the National Institute of Arthritis and
21 Musculoskeletal and Skin Diseases;

22 “(3) the National Institute of Child Health and
23 Human Development;

24 “(4) the National Institute of Environmental
25 Health Sciences;

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

3 “(6) the National Cancer Institute.

4 “(b) STUDY SECTIONS.—The Director of NIH shall
5 establish a study section or special emphasis panel if de-
6 termined to be appropriate, for the National Institutes of
7 Health to review extramural research grant applications
8 regarding silicone breast implants to ensure the appro-
9 priate design and high quality of such research and shall
10 take appropriate action to ensure the quality of intramural
11 research activities.

12 “(c) CLINICAL STUDY.—

13 “(1) IN GENERAL.—The Director of NIH shall
14 conduct or support research to expand the under-
15 standing of the health implications of silicone breast
16 implants. Such research should, if determined to be
17 scientifically appropriate, include a multidisciplinary,
18 clinical, case-controlled study of women with silicone
19 breast implants. Such a study should involve women
20 who have had such implants in place for at least 8
21 years, focus on atypical disease presentation, neuro-
22 logical dysfunction, and immune system irregular-
23 ities, and evaluate to what extent if any, their health
24 differs from that of suitable controls, including
25 women with saline implants as a subset.

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

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

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

11 (1) ensure that the toll-free Consumer Informa-
12 tion Line and materials concerning breast implants
13 provided by the Food and Drug Administration are
14 available, up to date, and responsive to reports of
15 problems with silicone breast implants, and that
16 timely aggregate data concerning such reports shall
17 be made available to the public upon request and
18 consistent with existing confidentiality standards;

19 (2) revise the Administration’s breast implant
20 information update to clarify the procedure for re-
21 porting problems with silicone implants or with the
22 conduct of adjunct studies, and specifically regard-
23 ing the use of the Medwatch reporting program;

24 (3) require that manufacturers of silicone
25 breast implants update implant package inserts and

1 informed consent documents regularly to reflect ac-
2 curate information about such implants, particularly
3 the rupture rate of such implants; and

4 (4) require that any manufacturer of such im-
5 plants that is conducting an adjunct study on sili-
6 cone breast implants—

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

12 (B) amend the informed consent to inform
13 women about how to obtain a Medwatch form
14 and encourage any woman who withdraws from
15 the study, or who would like to report a prob-
16 lem, to submit a Medwatch form to report such
17 problem or concerns with the study and reasons
18 for withdrawing; and

19 (C) amend the informed consent document
20 to provide potential participants with the inclu-
21 sion criteria for the clinical trial and the toll-
22 free Consumer Information number.

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