

106TH CONGRESS
1ST SESSION

H. R. 1323

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 HOUSE OF REPRESENTATIVES

MARCH 25, 1999

Mr. GREEN of Texas (for himself, Mr. SHERMAN, Mr. SANDERS, Mr. DEFAZIO, Mr. FROST, Mr. LAFALCE, Mr. BENTSEN, Mr. SANDLIN, Mr. BALDACCI, Ms. STABENOW, Mr. FILNER, Mr. BROWN of Ohio, Mrs. MALONEY of New York, Mr. UNDERWOOD, Ms. PELOSI, Mr. WAXMAN, Mr. SHOWS, Mr. JEFFERSON, Mr. LAMPSON, Mr. MCNULTY, Ms. DEGETTE, Mr. HORN, Ms. JACKSON-LEE of Texas, Mrs. THURMAN, Mr. FORD, Ms. CARSON, Mr. GILMAN, Mr. MALONEY of Connecticut, Mr. RANGEL, Mr. ENGEL, Ms. NORTON, Ms. RIVERS, Mrs. EMERSON, Ms. KAPTUR, Mr. PAYNE, Mr. WYNN, Mr. PALLONE, Mr. GONZALEZ, Mrs. WILSON, Mr. WHITFIELD, Mr. HULSHOF, and Mr. KIND) introduced the following bill; which was referred to the Committee on Commerce

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Silicone Breast Im-
3 plant Research and Information Act”.

4 **SEC. 2. FINDINGS AND PURPOSE.**

5 (a) FINDINGS.—Congress makes the following find-
6 ings:

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

11 (2) Silicone breast implants have been used pri-
12 marily for breast augmentation, but also as an im-
13 portant part of reconstruction surgery for breast
14 cancer or other conditions.

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

18 (4) Women need complete and accurate infor-
19 mation about the potential health risks and advan-
20 tages of silicone breast implants so that women can
21 make informed decisions.

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

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

4 (7) In addition to potential systemic complica-
5 tions, local changes in breast tissue such as hard-
6 ening, contraction of scar tissue surrounding im-
7 plants, blood clots, severe pain, burning rashes, seri-
8 ous inflammation, or other complications requiring
9 surgical intervention following implantation have
10 been reported.

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

20 (9) According to the Institute of Medicine, con-
21 cern remains that exposure to silicone or other com-
22 ponents in silicone breast implants may result in
23 currently undefined connective tissue or autoimmune
24 diseases.

1 (10) A group of independent scientists and cli-
2 nicians convened by the National Institute of Arthri-
3 tis and Musculoskeletal and Skin Diseases in April
4 of 1997 addressed concerns that an association may
5 exist between atypical connective tissue disease and
6 silicone breast implants, and called for additional
7 basic research on the components of silicone as well
8 as biological responses to silicone.

9 (11) According to many reports, including a
10 study published in the Journal of the National Can-
11 cer Institute, the presence of silicone breast implants
12 may create difficulties in obtaining complete mam-
13 mograms.

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

21 (b) PURPOSE.—It is the purpose of this Act to pro-
22 mote research to identify and evaluate the health effects
23 of silicone breast implants, and to ensure that women and
24 their doctors receive accurate information about such im-
25 plants.

1 (c) **RULE OF CONSTRUCTION.**—Nothing in this Act
2 shall be construed to affect any rule or regulation promul-
3 gated under the authority of the Federal Food, Drug and
4 Cosmetic Act that is in effect on the date of enactment
5 of this Act relating to the availability of silicone breast
6 implants for reconstruction after mastectomy, correction
7 of congenital deformities, or replacement for ruptured sili-
8 cone implants for augmentation.

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

12 Part H of title IV of the Public Health Service Act
13 (42 U.S.C. 289 et seq.) is amended by adding at the end
14 the following:

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

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

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

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

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

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

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

9 “(6) the National Cancer Institute.

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

18 “(c) CLINICAL STUDY.—

19 “(1) IN GENERAL.—The Director of NIH shall
20 conduct or support research to expand the under-
21 standing of the health implications of silicone breast
22 implants. Such research should, if determined to be
23 scientifically appropriate, include a multidisciplinary,
24 clinical, case-controlled study of women with silicone
25 breast implants. Such a study should involve women

1 who have had such implants in place for at least 8
2 years, focus on atypical disease presentation, neuro-
3 logical dysfunction, and immune system irregular-
4 ities, and evaluate to what extent if any, their health
5 differs from that of suitable controls, including
6 women with saline implants as a subset.

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

11 **SEC. 4. EXPANSION AND INTENSIFICATION OF ACTIVITIES**
12 **REGARDING SILICONE BREAST IMPLANTS AT**
13 **THE FOOD AND DRUG ADMINISTRATION.**

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

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

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

6 (3) require that manufacturers of silicone
7 breast implants update implant package inserts and
8 informed consent documents regularly to reflect ac-
9 curate information about such implants, particularly
10 the rupture rate of such implants; and

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

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

19 (B) amend the informed consent to inform
20 women about how to obtain a Medwatch form
21 and encourage any woman who withdraws from
22 the study, or who would like to report a prob-
23 lem, to submit a Medwatch form to report such
24 problem or concerns with the study and reasons
25 for withdrawing; and

1 (C) amend the informed consent document
2 to provide potential participants with the inclu-
3 sion criteria for the clinical trial and the toll-
4 free Consumer Information number.

5 **SEC. 5. PRESIDENT'S INTERAGENCY COMMITTEE ON SILI-**
6 **CONE BREAST IMPLANTS.**

7 (a) ESTABLISHMENT.—There is established an inter-
8 agency committee, to be known as the President's Inter-
9 agency Committee on Silicone Breast Implants (referred
10 to in this Act as the "Committee"), to ensure the strategic
11 management, communication, and oversight of the policy
12 formation, research, and activities of the Federal Govern-
13 ment regarding silicone breast implants.

14 (b) COMPOSITION.—The Committee shall be com-
15 posed of—

16 (1) an individual to be appointed by the Presi-
17 dent who represents the White House domestic pol-
18 icy staff;

19 (2) a representative, to be appointed by the
20 Secretary of Health and Human Services, from—

21 (A) the Office of Women's Health at the
22 Department of Health and Human Services;

23 (B) the National Institutes of Health;

24 (C) the Food and Drug Administration;

25 and

1 (D) the Centers for Disease Control and
2 Prevention;

3 (3) a representative of the Department of De-
4 fense with experience in the Department's breast
5 cancer research program;

6 (4) representatives of any other agencies
7 deemed necessary to accomplish the mission of the
8 Committee, including the Social Security Adminis-
9 tration if appropriate;

10 (5) up to 4 individuals to be appointed by the
11 President from scientists with established credentials
12 and publications in the area of silicone breast im-
13 plants; and

14 (6) 2 women who have or have had silicone
15 breast implants to be appointed by the President.

16 (c) CHAIRPERSON.—

17 (1) IN GENERAL.—The individual appointed
18 under subsection (b)(2)(A), or other official if the
19 President determines that such other official is more
20 appropriate, shall service as the chairperson of the
21 Committee.

22 (2) DUTIES.—The chairperson of the Com-
23 mittee shall—

24 (A) not less than twice each year, convene
25 meetings of the Committee; and

1 (B) compile information for the consider-
2 ation of the full Committee at such meetings.

3 (d) MEETINGS.—The meetings of the Committee
4 shall be open to the public and public witnesses shall be
5 given the opportunity to speak and make presentations at
6 such meetings. Each member of the Committee shall make
7 a presentation to the full Committee at each such meeting
8 concerning the activities conducted by such member or by
9 the entity that such member is representing related to sili-
10 cone breast implants.

11 (e) ADMINISTRATIVE PROVISIONS.—

12 (1) TERMS AND VACANCIES.—A member of the
13 Committee shall serve for a term of 2 or 4 years (ro-
14 tating terms). A member may be reappointed 2
15 times, but shall not exceed 8 years of service. Any
16 vacancy in the membership of the Committee shall
17 be filled in the manner in which the original appoint-
18 ment was made and shall not affect the power of the
19 remaining members to carry out the duties of the
20 Committee.

21 (2) COMPENSATION; REIMBURSEMENT OF EX-
22 PENSES.—Members of the Committee may not re-
23 ceive compensation for service on the Committee.
24 Such members may, in accordance with chapter 57
25 of title 5, United States Code, be reimbursed for

1 travel, subsistence, and other necessary expenses in-
2 curred in carrying out the duties of the Committee.

3 (3) STAFF; ADMINISTRATIVE SUPPORT.—The
4 Secretary of Health and Human Services shall, on
5 a reimbursable basis, provide to the Committee such
6 staff, administrative support, and other assistance
7 as may be necessary for the Committee to effectively
8 carry out the duties under this section.

9 (4) CONFLICT OF INTEREST.—The members of
10 the Committee shall not be in violation of any Fed-
11 eral conflict of interest laws.

12 (f) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated such sums as may be
14 necessary to carry out this section.

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