

105TH CONGRESS
2^D SESSION

H. R. 4028

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

JUNE 10, 1998

Mr. GREEN 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,*

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 them.

22 (7) In addition to potential systemic complica-
23 tions, local changes in breast tissue such as harden-
24 ing, contraction of scar tissue surrounding implants,
25 blood clots, severe pain, burning rashes, serious in-

1 inflammation, or other complications requiring sur-
2 gical intervention following implantation have been
3 reported.

4 (8) According to the Institute of Medicine, con-
5 cern remains that exposure to silicone or other com-
6 ponents in silicone breast implants may result in
7 currently undefined connective tissue or autoimmune
8 diseases.

9 (9) A group of independent scientists and clini-
10 cians convened by the National Institute of Arthritis
11 and Musculoskeletal and Skin Diseases in April of
12 1997 addressed concerns that an association may
13 exist between atypical connective tissue disease and
14 silicone breast implants, and called for additional
15 basic research on the components of silicone as well
16 as biological responses to silicone.

17 (10) According to many reports, including a
18 study published in the Journal of the National Can-
19 cer Institute, the presence of silicone breast implants
20 may create difficulties in obtaining complete mam-
21 mograms.

22 (11) According to a 1995 Food and Drug Ad-
23 ministration publication, although silicone breast im-
24 plants usually do not interfere with a woman's abil-
25 ity to nurse, if the implants leak, there is some con-

1 cern that the silicone may harm the baby. Some
2 studies suggest a link between breast feeding with
3 implants and problems with the child’s esophagus.

4 (b) PURPOSE.—It is the purpose of this Act to pro-
5 mote research to identify and evaluate the health effects
6 of silicone breast implants, and to ensure that women and
7 their doctors receive accurate information about such im-
8 plants.

9 (c) RULE OF CONSTRUCTION.—Nothing in this Act
10 shall be construed to affect any rule or regulation promul-
11 gated under the authority of the Food, Drug and Cosmetic
12 Act that is in effect on the date of enactment of this Act
13 relating to the availability of silicone breast implants for
14 reconstruction after mastectomy, correction of congenital
15 deformities, or replacement for ruptured silicone implants
16 for augmentation.

17 **SEC. 3. EXPANSION AND INTENSIFICATION OF ACTIVITIES**

18 **REGARDING SILICONE BREAST IMPLANTS AT**

19 **THE NATIONAL INSTITUTES OF HEALTH.**

20 Part H of title IV of the Public Health Service Act
21 (42 U.S.C. 289 et seq.) is amended by adding at the end
22 the following:

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

24 “(a) INSTITUTE-WIDE COORDINATOR.—The Director
25 of NIH shall appoint an appropriate official of the Depart-

1 ment of Health and Human Services to serve as the Na-
2 tional Institutes of Health coordinator regarding silicone
3 breast implant research. Such coordinator shall encourage
4 and coordinate the participation of all appropriate Insti-
5 tutes in research on silicone breast implants, including—

6 “(1) the National Institute of Allergy and In-
7 fectious Diseases;

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

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

12 “(4) the National Institute of Environmental
13 Health Sciences;

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

16 “(6) the National Cancer Institute.

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

25 “(c) CLINICAL STUDY.—

1 “(1) IN GENERAL.—The Director of NIH shall
2 conduct or support research to expand the under-
3 standing of the health implications of silicone breast
4 implants. Such research should, if determined to be
5 scientifically appropriate, include a multidisciplinary,
6 clinical, case-controlled study of women with silicone
7 breast implants. Such a study should involve women
8 who have had such implants in place for at least 8
9 years, focus on atypical disease presentation, neuro-
10 logical dysfunction, and immune system irregular-
11 ities, and evaluate to what extent if any, their health
12 differs from that of suitable controls, including
13 women with saline implants as a subset.

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

18 **SEC. 4. EXPANSION AND INTENSIFICATION OF ACTIVITIES**
19 **REGARDING SILICONE BREAST IMPLANTS AT**
20 **THE FOOD AND DRUG ADMINISTRATION.**

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

24 (1) ensure that the toll-free Consumer Informa-
25 tion Line and materials concerning breast implants

1 provided by the Food and Drug Administration are
2 available, up to date, and responsive to reports of
3 problems with silicone breast implants, and that
4 timely aggregate data concerning such reports shall
5 be made available to the public upon request and
6 consistent with existing confidentiality standards;

7 (2) revise the Administration's breast implant
8 information update to clarify the procedure for re-
9 porting problems with silicone implants or with the
10 conduct of adjunct studies, and specifically regard-
11 ing the use of the Medwatch reporting program;

12 (3) require that manufacturers of silicone
13 breast implants update implant package inserts and
14 informed consent documents regularly to reflect ac-
15 curate information about such implants, particularly
16 the rupture rate of such implants; and

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

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

1 (B) amend the informed consent to inform
2 women about how to obtain a Medwatch form
3 and encourage any woman who withdraws from
4 the study, or who would like to report a prob-
5 lem, to submit a Medwatch form to report such
6 problem or concerns with the study and reasons
7 for withdrawing; and

8 (C) amend the informed consent document
9 to provide potential participants with the inclu-
10 sion criteria for the clinical trial and the toll-
11 free Consumer Information number.

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

14 (a) ESTABLISHMENT.—There is established an inter-
15 agency committee, to be known as the President's Inter-
16 agency Committee on Silicone Breast Implants (referred
17 to in this Act as the "Committee"), to ensure the strategic
18 management, communication, and oversight of the policy
19 formation, research, and activities of the Federal Govern-
20 ment regarding silicone breast implants.

21 (b) COMPOSITION.—The Committee shall be com-
22 posed of—

23 (1) an individual to be appointed by the Presi-
24 dent who represents the White House domestic pol-
25 icy staff;

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

3 (A) the Office of Women’s Health at the
4 Department of Health and Human Services;

5 (B) the National Institutes of Health;

6 (C) the Food and Drug Administration;

7 and

8 (D) the Centers for Disease Control and
9 Prevention;

10 (3) a representative of the Department of De-
11 fense with experience in the Department’s breast
12 cancer research program;

13 (4) representatives of any other agencies
14 deemed necessary to accomplish the mission of the
15 Committee, including the Social Security Adminis-
16 tration if appropriate;

17 (5) up to 4 individuals to be appointed by the
18 President from scientists with established credentials
19 and publications in the area of silicone breast im-
20 plants; and

21 (6) 2 women who have or have had silicone
22 breast implants to be appointed by the President.

23 (c) CHAIRPERSON.—

24 (1) IN GENERAL.—The individual appointed
25 under subsection (b)(2)(A), or other official if the

1 President determines that such other official is more
2 appropriate, shall service as the chairperson of the
3 Committee.

4 (2) DUTIES.—The chairperson of the Commit-
5 tee shall—

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

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

10 (d) MEETINGS.—The meetings of the Committee
11 shall be open to the public and public witnesses shall be
12 given the opportunity to speak and make presentations at
13 such meetings. Each member of the Committee shall make
14 a presentation to the full Committee at each such meeting
15 concerning the activities conducted by such member or by
16 the entity that such member is representing related to sili-
17 cone breast implants.

18 (e) ADMINISTRATIVE PROVISIONS.—

19 (1) TERMS AND VACANCIES.—A member of the
20 Committee shall serve for a term of 2 or 4 years (ro-
21 tating terms). A member may be reappointed 2
22 times, but shall not exceed 8 years of service. Any
23 vacancy in the membership of the Committee shall
24 be filled in the manner in which the original appoint-
25 ment was made and shall not affect the power of the

1 remaining members to carry out the duties of the
2 Committee.

3 (2) COMPENSATION; REIMBURSEMENT OF EX-
4 PENSES.—Members of the Committee may not re-
5 ceive compensation for service on the Committee.
6 Such members may, in accordance with chapter 57
7 of title 5, United States Code, be reimbursed for
8 travel, subsistence, and other necessary expenses in-
9 curred in carrying out the duties of the Committee.

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

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

19 (f) AUTHORIZATION OF APPROPRIATIONS.—There
20 are authorized to be appropriated such sums as may be
21 necessary to carry out this section.

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