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

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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.

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 ''Silicone 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 silicone breast implants over the last 35 years.

(2) Silicone breast implants have been used primarily for breast augmentation, but also as an important part of reconstruction surgery for breast cancer or other conditions.

(3) Women with breast cancer or other medical conditions seek access to the broadest possible treatment options, including silicone breast implants.

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

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

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

(7) In addition to potential systemic complications, local changes in breast tissue such as hardening, contraction of scar tissue surrounding im-

plants, blood clots, severe pain, burning rashes, serious inflammation, or other complications requiring surgical intervention following implantation have been reported.

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

(9) According to the Institute of Medicine, concern remains that exposure to silicone or other components in silicone breast implants may result in currently undefined connective tissue or autoimmune diseases.

(10) A group of independent scientists and clinicians convened by the National Institute of Arthritis and Musculoskeletal and Skin Diseases in April of 1997 addressed concerns that an association may exist between atypical connective tissue disease and silicone breast implants, and called for additional

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

(11) According to many reports, including a study published in the Journal of the National Cancer Institute, the presence of silicone breast implants may create difficulties in obtaining complete mammograms.

(12) According to a 1998 Food and Drug Administration publication, although silicone breast implants usually do not interfere with a woman's ability to nurse, if the implants leak, there is some concern that the silicone may harm the baby. Some studies suggest a link between breast feeding with implants and problems with the child's esophagus.

(b) PURPOSE.—It is the purpose of this Act 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.

(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.C. 321 et seq.) that is in effect on the date of enactment of this Act relating to the availability of silicone breast implants 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.

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 the following:

''SEC. 498C. SILICONE 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 silicone breast implant research. Such coordinator shall encourage and coordinate the participation of all appropriate Institutes in research on silicone breast implants, including—

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

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

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

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

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

''(6) 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 silicone 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 silicone breast implants. Such research should, if determined to be scientifically appropriate, include a multidisciplinary, clinical, case-controlled study of women with silicone breast implants. Such a study should involve women who have had such implants in place for at least 8 years, focus on atypical disease presentation, neurological dysfunction, and immune system irregularities, and evaluate to what extent if any, their health differs from that of suitable controls, including women with saline implants as a subset.

''(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. EXPANSION AND INTENSIFICATION OF ACTIVITIES REGARDING SILICONE BREAST IMPLANTS AT THE FOOD AND DRUG ADMINISTRATION.

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

(1) 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 silicone 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;

(2) revise the Administration's breast implant information update to clarify the procedure for reporting problems with silicone implants or with the conduct of adjunct studies, and specifically regarding the use of the Medwatch reporting program;

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

informed consent documents regularly to reflect accurate information about such implants, particularly the rupture rate of such implants; and

(4) require that any manufacturer of such implants that is conducting an adjunct study on silicone breast implants—

(A) 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;

(B) amend the informed consent 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 a problem, to submit a Medwatch form to report such problem or concerns with the study and reasons for withdrawing; and

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

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