National Organization for Women Foundation

Testimony of Terry O'Neill, President,
National Organization for Women (NOW) Foundation
Presented by Jan Erickson, Director, NOW Foundation Programs
to the U.S. Food and Drug Administration,
General and Plastic Surgery Devices Panel Review of
Post-Approval Studies for Silicone Gel-Filled Breast Implants

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Thank you for the opportunity to comment on the post-approval studies of women who have silicone gel-filled breast implants. My name is Jan Erickson and as director of the National Organization for Women Foundation programs, I am speaking on behalf of our president, Terry O'Neill, who is unable to be here today.

The National Organization for Women (NOW) Foundation advocates for women's equal rights, women's economic and social well-being, and women's health. The National Organization for Women Foundation and myself represent only our own 501(c) 3 non-profit corporation and no other party. My appearance today is underwritten by many contributing supporters across the country. NOW Foundation is affiliated with National Organization for Women, the grassroots arm of the women's movement with hundreds of chapters and hundreds of thousands of members, supporters and activists in all 50 states and the District of Columbia.

Over the years we have heard from countless women who are saline and silicone breast implant patients and who have suffered from complications, involving both short- and long-term health conditions believed to be related to their implants. Implants rupture and leak. Implants sometimes migrate. Implants often harden and cause capsular contracture. Nearly all will need to be replaced at some point. Reported conditions involve local infections, necrosis, hematoma, connective tissue disorders and immune disorders like fibromyalgia, rheumatoid arthritis, chronic fatigue syndrome, multiple sclerosis, lupus, Sjogren's syndrome and others. National Cancer Institute studies indicate that women who have breast implants are at increased risk of brain cancer, lung cancer, emphysema, pneumonia and suicide. Although research paid for by implant companies disagrees, those findings need to be evaluated by independent researchers. And now we learn that a rare type of immune system cancer, anaplastic large-cell lymphoma (ALCL), is found

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growing near the capsule of scar tissue around the breast implant. The risk of developing ALCL for women with implants was significantly higher than that found in women without breast implants.

NOW opposed FDA approval of silicone gel-filled implants, convinced that risks clearly out-weighed benefits. A number of FDA staff and advisory committee members agreed with us then. We have testified numerous times before FDA advisory committees on the need for well-controlled *independent* long-range studies that closely track a significant number of patients. NOW was then and remains of the opinion that the companies have little motivation to carry out rigorous long-term evaluations of implant patients -- and the experience since the 2006 approval of silicone gel-filled implants confirms our view. In January 2004, the FDA found that Inamed (Allergan) had failed to provide long-term safety data on silicone gel-filled breast implants. Implant companies have now had 18 years to collect long-term data on implant patients. The problem is always the same: too many implant patients dropped out of the studies or, more accurately in our view, the companies failed to carry out an effective surveillance of implant patients. We know that many women who had complications attempted to report these to their doctors and to the companies and were not taken seriously. Records became "lost."

It is unacceptable that again a substantial number of the 40,000 patients that Mentor and Allergan were required to track were "lost" in just a very short time frame. Mentor had lost track of 79 percent of all patients within three years of their enrollment and Allergan lost track of almost half of their augmentation patients within their first two years, along with 25-31 percent of their reconstruction patients in that same length of time. Such a high loss to follow-up completely undermines the value of any findings. Patients who have dropped out are not likely to participate later, yet we know from patient testimony at past FDA meetings that symptoms often develop 10 or more years after implantation. In the "connected" information universe we live in with the Internet, email and Facebook, it is hard to believe that the companies were not able to maintain contact over time with a larger number of implant patients. They could have, for example, provided an incentive to stay in the studies, as is done in other research.

The Core studies also lost many of their patients. Again, Mentor's track record was worse, and augmentation studies were worse. Also regrettable is the fact that the largest studies relied primarily on information derived from questionnaires filled out by the patients, rather than information from medical records or medical examinations. The Adjunct studies lost track of so many patients that they do not offer any useful information.

There are apparent errors in the reporting of complications in the Core studies, including cumulative percentages that are smaller after 8 or 10 years than they were at 3 years. And rupture rates were apparently calculated per implant rather than per patient, thus understating the actual incidence of rupture.

After reviewing the FDA and company documents released for this meeting and learning of the companies' failure to conduct effective post-approval studies due to a significant loss of patients, we conclude that approval to market silicone gel-filled implants for one company -- Mentor -- should be rescinded. With regard to Allergan, a moratorium should be placed on further marketing of implants, and the company should be required to

continue research with an improved study design and heightened FDA oversight. If Allergan is not able to improve its patient follow-up within two years, then approval to market their silicone gel-filled implant should also be rescinded.

There remains a continuing need to conduct clinical and laboratory studies on the immunological and toxicological effects of silicone gel on human physiology. We need properly designed studies that measure the effect of the chemical constituents of silicone gel in pregnant women and on their developing fetuses. We need information about the transmission of potentially harmful chemicals to breastfeeding infants. Clinical trials should follow children born to mothers with silicone gel-filled breast implants to evaluate any health or developmental problems.

All of these recommendations were previously made by the National Organization for Women to the FDA. In addition, a series of research recommendations were made at a Symposium on the Safety and Effectiveness of Silicone Gel-Filled Breast Implants in July 2003, (http://www.now.org/issues/health/symposium.html) which are summarized in the attached document. Most of these research needs are, to our knowledge, unmet.

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