Women Senators Urge FDA to Consider Women's Health Safety in Decision on Silicone Breast Implants

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Washington, DC – *U.S. Senators Dianne Feinstein (D-Calif.) and Olympia Snowe (R-Maine) along with seven other women Senators today urged the FDA to carefully consider the safety of American women and the recommendations of FDA's own scientists prior to making a final decision on approval of silicone gel breast implants. They wrote to express concerns about the recent split decision by the General and Plastic Surgery Devices Panel of the Food and Drug Administration (FDA) on the applications of silicone gel implant manufacturers Inamed and Mentor Corporations.*

In 1992, FDA restricted the use of silicone implants amid widespread claims that ruptured implants were causing health problems in women. Since the moratorium was put in place, silicone breast implants have remained available to women who have needed reconstructive surgery.

Later this month, the FDA is expected to rule whether the silicone gel implants made by Mentor and Inamed are safe and should be available to women for both breast reconstruction and augmentation. In April, an FDA advisory panel recommended in favor of Mentor's application but not that of Inamed.

Following is the text of a letter Senators Feinstein, Snowe, Hillary Clinton (D-N.Y.), Kay Bailey Hutchison (R-Texas), Barbara Boxer (D-Calif.), Mary Landrieu (D-La.), Debbie Stabenow (D-Mich.), Blanche Lincoln (D-Ark.), and Barbara Mikulski (D-Md.) sent to FDA Commissioner Lester Crawford:

"We are writing to express our concerns regarding the recent split decision by the FDA's General and Plastic Surgery Devices Panel on the applications of the Inamed and Mentor Corporations for approval of silicone breast implants. The divergent recommendations of the Panel on these two manufacturer's devices appear inconsistent with the very similar findings as described in the Summary Panel Memoranda for these applications.

Reconstruction with implants or autologous tissue procedures can offer significant benefit to women who have undergone a mastectomy. Over 215,000 women will be diagnosed with invasive breast cancer this year, and for many, treatment will include a mastectomy. For such women, the benefits of reconstruction can be substantial. We note that both saline and silicone implants have been available to such patients, and encourage FDA to continue to examine promising new prosthetics for breast cancer patients.

The use of breast implants is not without hazards. Surgical risk must be considered, and each woman must understand that these devices, whether saline or silicone, have a finite life. In 2000, a study by FDA scientists reported a failure rate of 55% per implant in women who had silicone implants for an average of 16 years. Thus women receiving implants, particularly at a young age, may anticipate multiple surgeries with added financial burdens.

Silicone implants, while providing a prosthetic with more natural characteristics, bear greater risks than saline implants. As the FDA has noted, such implants can interfere with mammography. In addition, when failure occurs and an implant ruptures, this usually occurs without symptoms and is detected only via magnetic resonance imaging (MRI) - and even MRI does not detect some ruptures.

FDA noted three critical problems in its 2005 review of the Inamed application: long term failure rates for the device couldn't be accurately projected due to a short duration of study, the reasons implants failed were not determined, and the impact of silicone leakage on a woman's health was unclear. In its most recent application, Inamed included data indicating that symptoms of connective tissue disease were evident as well.

The same basic issues remain unresolved for Mentor's device. Mentor Corporation provided short term failure rates which were encouraging, but this conclusion was based on an unpublished study conducted on a very select group of patients, all of whom were operated on by a single surgeon. FDA noted many other problems with Mentor's data, including a failure to study women over time and the exclusion of women who had implants removed – which could include additional implant failures. As a result of these limitations, FDA does not know the true failure rate for Mentor's device, nor the implications of implant rupture. The FDA memorandum also cited specific signs and symptoms of connective tissue disease in augmentation patients with the implanted Mentor device. We are thus extremely concerned that the risks of this device are far disproportionate to the benefit that a woman undergoing breast augmentation would realize.

For both Inamed and Mentor's devices, the inability to project long term failure rates and the causes of failures is a major concern. Given that there are typically no symptoms when silicone breast implants rupture, the cost in morbidity and expense to a woman may be very substantial, as prudent medical practice could entail routine MRI to detect ruptures, in addition to periodic surgeries to adjust or replace implants.

We urge you to note the distinction between the use of implants for reconstruction and augmentation. The FDA has stated, 'the literature does not provide strong scientific support that breast implants have measurable psychological and psychosocial benefits for women seeking breast augmentation.' Such a conclusion of questionable efficacy calls for the highest level of safety in approval of implants for augmentation. It is our understanding that if not approved, silicone breast implants will remain available for breast cancer patients as they have been since 1992, reflecting the greater benefits for that population.

Though some have argued that the imposition of post-marketing conditions would address safety concerns, such conditions have proven to be ineffective or unenforceable and thus cannot serve as a substitute for long-term clinical data. Consequently we urge your careful review of the Panel's memorandum and consistent application of the highest standards of safety in evaluating these applications, in order to protect the health and well being of American women."

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