



## Senators Feinstein, Snowe Urge FDA to Investigate Whistleblower Claims of Safety Risks in Mentor Corp. Silicone Breast Implants

December 7, 2005

**Washington, DC** – U.S. Senators Dianne Feinstein (D-Calif.) and Olympia Snowe (R-Maine) are urging the Federal Drug Administration (FDA) to rigorously investigate safety concerns raised by a whistleblower about Mentor’s silicone breast implants.

**“The FDA is responsible for ensuring the very highest standards of safety for devices and drugs used by women,”** Senator Feinstein said. **“The recent allegations raised by a former Mentor employee about safety risks associated with the company’s silicone breast implants, if true, are very worrisome. And so I urge the FDA to carefully investigate the validity of these claims and make certain that it has all of the facts before moving to a final decision on approval. The protection of women’s health must be our foremost priority.”**

**“The FDA must fully investigate these very serious allegations,”** Senator Snowe said. **“The critical concerns – how many implants rupture, why they do, and what the consequences could be – still remains in doubt. Most troubling now is the prospect that a woman could be being misled about the quality of the implant which they would actually receive. To provide her with an inferior version of the product is unconscionable.”**

### Background

As reported in an article in the *Washington Post* earlier this week, a former employee of Mentor has gone public with two key allegations against the company. The first is that Mentor’s implants used in surgery leak more than the ones used in demonstrations to doctors and patients. The second allegation is that there is a design flaw in Mentor’s implants which has resulted in a higher rupture rate and that the higher rupture rate has not been accurately reported to the FDA.

In April, an FDA advisory panel recommended in favor of Mentor’s application but not that of Inamed. Last summer, both Mentor and Inamed Corporations received approvable letters from the FDA. Their devices will not be generally available until the FDA completes the conditional requirements that both manufacturers must meet.

In 1992, the FDA restricted the use of silicone implants amid widespread claims that ruptured implants were causing health problems in women.

Following is the text of a letter sent by Senators Feinstein and Snowe to FDA Acting Commissioner Andrew von Eschenbach:

**December 7, 2005**

**Andrew C. von Eschenbach, M.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
Parklawn Bldg.  
5600 Fisher Lane  
Rockville, MD 20857-0001**

**Dear Dr. von Eschenbach:**

**We are writing to express our concern about allegations made by a former Mentor Corporation employee about the safety of Mentor's silicone gel breast implants as reported in the *Washington Post* earlier this week. These allegations are serious and, if true, they put women's health and safety at risk. We ask that you and your staff meet with this individual and fully investigate the claims and inform us of what steps the FDA is taking in light of these new allegations.**

**Silicone gel breast implants were removed from the market for general use in 1992 because the FDA did not find them to be safe and effective. Today, as in 1992, it is equally important that the FDA has all clinical trial data on silicone gel breast implants and that sufficient testing of the short and long term safety and efficacy of these devices has been conducted and made available to the FDA.**

**We understand that the FDA is in discussions with Mentor and Inamed Corporations regarding conditional availability of their products to women nationwide, and we ask that the FDA take its time to properly address and respond to these new allegations before making a final decision.**

**We have previously written expressing our concerns about the safety of these devices. Most recently, on July 28, we joined with seven other women Senators in writing then-Commissioner Lester Crawford to raise questions about the split decision of the FDA's advisory panel which was considering Mentor and Inamed Corporations applications for approval. We have enclosed a copy of that letter for your reference.**

**The whistleblower has made two key allegations against Mentor. The first is that Mentor's implants used in surgery leak more than the ones used in demonstrations to doctors and patients. If this allegation proves true, women and their doctors will have been intentionally misled.**

**The second allegation is that there is a design flaw in Mentor's implants which has resulted in a higher rupture rate and that the higher rupture rate has not been accurately**

**reported to the FDA. This allegation, if true, is particularly disturbing. As we pointed out in our letter on July 28 to the FDA Commissioner, we shared serious concerns about whether silicone gel implant manufacturers had presented all available studies on the long and short term safety and efficacy of their devices to the FDA and whether the FDA knew the true failure rate for silicone gel breast implants or what the implications of implant leakage or rupture were to women.**

**The health and safety of American women is paramount. The FDA exists to safeguard women from drugs and devices that may do them harm. These allegations should be rigorously investigated and addressed by the FDA before it proceeds with the approval process. American women must be assured of the safety of these products, which have a troubled history, before approval is granted.**

**Thank you for your consideration. We look forward to your response.**

**Sincerely,**

**Dianne Feinstein  
United States Senator**

**Olympia Snowe  
United States Senator**

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