



## Senators Feinstein and Snowe Call for Safety Review of Mentor Corporation's Silicone Gel Breast Implant

October 20, 2006

**Washington, DC** – U.S. Senators Dianne Feinstein (D-Calif.) and Olympia Snowe (R-Maine) today voiced concern about the safety of silicone gel breast implants produced by Mentor Corporation and called for a full review of product testing data by the U.S. Food and Drug Administration before final approval is granted.

*In a joint letter to FDA Acting Commissioner Andrew von Eschenbach, Senators Feinstein and Snowe cited recent reports that reveal Mentor may have unreported data and inaccuracies regarding dangerous leakage from the company's silicone gel breast implants.*

*"The FDA must not allow these products on the market while so many unanswered questions remain. Women deserve full and accurate information about the potential risks of these implants," Senator Feinstein said.*

*"Americans expect the FDA to approve a drug or device based on complete and accurate information," said Senator Snowe. "If critical data is distorted or not even submitted to the FDA, the health of Americans can be jeopardized. It is imperative that the FDA consider all relevant research in evaluating the Mentor product to ensure that women's health is protected."*

*The following is the text of the Senators' letter:*

October 20, 2006

**Andrew von Eschenbach, M.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
15B-31 Parklawn Building  
5600 Fishers Lane  
Rockville, MD 20857**

**Dear Dr. von Eschenbach:**

**We are writing to express our concern about new allegations made by a former Mentor scientist regarding data on the company's silicone gel breast implants. If true, it raises serious concerns about the accuracy of the data your agency is using to consider final approval for these implants.**

**We have written previously to express our concerns about allegations from another former Mentor employee. A copy of that letter is enclosed for your reference. Our underlying concern remains the same: that the Food and Drug Administration collect and review all applicable data on the short and long term efficacy and safety of silicone gel breast implants before granting final approval.**

**The most recent allegations, as reported by the *Washington Post* on October 13, 2006, suggest that Mentor has collected data that has not been reported to your agency. It is our understanding that Mentor may have also submitted inaccurate results from gel bleed chemical tests, which underestimate the amount of low molecular weight siloxanes that leak from an implant. The former Mentor employee has also alleged that upon contacting your agency with information about unreported data and potential inaccuracies, he was told that because the data in question was not a required submission, your agency would not review it.**

**We request that you will fully review all data collected by Mentor, whether or not it was originally required. If the FDA has already investigated these allegations, we request that you share with us the nature and results of this investigation.**

**No medical device should be granted final approval if data that could reveal potential dangers has not been fully investigated and analyzed. The health and safety of American women should be the top concern of your agency as the approval process moves forward.**

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

**Best personal regards,**

**Dianne Feinstein  
United States Senator**

**Olympia Snowe  
United States Senator**

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