

National Organization for Women

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Dear Representative:

We have received word that the Food and Drug Administration (FDA) is poised to grant final approval to silicone-gel breast implants in the days ahead. If the rumor is true, we find it shocking that the FDA would make such a move at this time, as more and more evidence has accumulated that critical information has been withheld by the manufacturers that would clearly demonstrate that *these implants are not safe*.

We hope that you will call FDA acting Commissioner Andrew von Eschenbach (301-827-2410) immediately and urge him to delay issuing final marketing approval until the new Congress has an opportunity to provide oversight of the FDA's review of these safety issues involving potentially fraudulent or misleading data. A call to the Secretary of Health and Human Services, Mike Leavitt, at 202-960-7000 with this information would also be helpful.

Silicone Effects in Children: A peer-reviewed published study has recently shown that women with implants and their children who are ill with autoimmune diseases and other health problems have high levels of a toxic form of platinum found in samples of their blood, tissue, hair, nail, urine and breast milk.ⁱ Rather than attempting to replicate the study, FDA officials responded by dismissing it, following the lead of scientists who are paid consultants to implant makers.

FDA scientists have also expressed their strong concerns about the potential impact of silicone breast implants on offspring. They just published a peer-reviewed article in a medical journal, describing 339 reports sent to the FDA's post market surveillance system.ⁱⁱ Many serious gastro-intestinal disorders were reported, and other health problems include skeletal abnormalities, cardiac problems, immune deficiency, brain malformations, central nervous system disorders, connective tissue diseases/symptoms, pulmonary/respiratory difficulties, allergies, and leaning disabilities. In addition, many of the women were unable to breastfeed because of their implants or were afraid to breastfeed; as a result, these babies will not have the superior nutrition and health benefits that breast milk provides.

At NOW, we have heard from many women who believe that their silicone breast implants have adversely affected their children's health. Many of these women have *healthy* children who were born *before* they received silicone-gel implants. In the coming weeks, we will be reviewing more than 1,000 questionnaires filled out by mothers with implants who detail the deformities and illnesses found in their children. What we need is solid research on this issue.

Unfortunately, the FDA has not required implant manufacturers to study the impact of silicone implants on breast milk, breastfeeding, or the health of offspring born to women with implants.

Falsified or Misleading Safety Data on Implants: In October, a senior scientist formerly with an implant manufacturer, Mentor Corporation, reported that company studies "showed that in the silicone rubber envelope of the implant, Platinum existed in the +2 oxidation state (Pt II). This previously unknown finding is of potential importance since this oxidation state is thought to be more toxic than the Pt (0) oxidation state of the metal. Again, this information was not sent to the FDA."ⁱⁱⁱ

This scientist also charged that company data suggesting a continual leakage of dangerous low-molecular-weight siloxanes into women's bodies was not provided to the FDA, and that important safety data that the company provided to the FDA was misrepresented. He urged Mentor to disclose the information, but instead they terminated his employment after 15 years with the company. These allegations are strikingly similar to those previously made by an engineer who formerly worked for Mentor. In both cases, the company cast aspersions on the allegations rather than scientifically refuting them, and the FDA did not require new studies to determine if the allegations were correct.

Instead of conducting new research, implant manufacturers have spent millions of dollars in public relations and lobbying for approval. And, so far their strategy has worked.

Despite the pressure that the FDA is under to improve its review of medical products, the FDA has shown little interest in carefully examining the concerns expressed by their own scientists or the allegations of industry whistleblowers. Rather than conduct new research examining the potential risks of platinum from silicone gel breast implants, the FDA relied on a research review published by a paid consultant to an implant manufacturer. This is yet another indication that the FDA scientific review and approval process is broken.

It is impossible for women to give informed consent for implants if the information they are receiving is inaccurate or incomplete. The very real possibility that their children will be exposed to grave health risks is an even more serious matter.

The FDA should not approve silicone-gel breast implants at this time and Congress should examine these and other instances where FDA is not requiring sound science before making approval decisions. Please contact Dr. von Eschenbach before it is too late; the FDA has never rescinded approval for a medical device after it has been approved.

Sincerely,



Kim Gandy
NOW President

ⁱ Lykissa, ED and Maharaj, SVM. Total Platinum Concentration and Platinum Oxidation States in Body Fluids, Tissue, and Explants from Women Exposed to Silicone and Saline Breast Implants by IC-ICPMS, *Analytical Chemistry*, 2006, 78(9):2925-2933.

ⁱⁱ Brown, SL, Todd, JF, Cope, JU and Sachs, HC, Breast Implant Surveillance Reports to the U.S.

Food and Drug Administration: Maternal Child Health Problems, *Journal of Long-Term Effects of Medical Implants*, 2006, 16 (4): 281-290.

ⁱⁱⁱ Public Citizen Calls for Criminal Investigation of Breast Implant Manufacturer for Withholding Safety Data from FDA (HRG Publications #1790), Letter from Sidney Wolfe, MD to the FDA, <http://www.citizen.org/publications/release.cfm?ID=7476>