

TESTIMONY OF PAMELA BRIDGEWATER ON BEHALF OF OUR BODIES OURSELVES

August 31, 2011

Submitted to members of the FDA General and Plastic Surgery Devices Panel (regarding post-approval studies for silicone gel-filled breast implants)

My name is Pam Bridgewater. I am a faculty member at the American University Washington College of Law and am writing on behalf of Our Bodies Ourselves (OBOS), a nonprofit, public interest organization on whose board of directors I served for three years. (I was unable to attend the hearing on August 31 as planned.) I have no conflicts of interest.

OBOS is best known for the landmark book about women and health entitled *Our Bodies, Ourselves* – just named by TIME MAGAZINE as one of the 100 best nonfiction books written since 1923. The totally revised ninth edition of this classic will be released in early October, at the same time that the organization is celebrating the 40th anniversary of this book. It includes important information about breast implants that was vetted by multiple experts. In addition, there are now 31 foreign editions of this classic text in such languages as Chinese, Russian, Spanish, Nepali, Tibetan, German, French, Italian, Bangla, Armenian, Polish, Romanian, and Thai, with new updated editions in Turkish, Arabic, Hebrew, and Kiswahili due out soon.

OBOS is very concerned about the lack of long term safety data on breast implants. We are especially concerned that FDA-approved breast implants contingent on the companies conducting long term safety studies that they have failed to do.

If the FDA fails to enforce those post-market research requirements, making new study requirements in the future will be equally unsuccessful.

This would be dangerous for women considering breast implants and for all of us, because it sets such a dangerous precedent.

By losing more than three quarters of their patients, Mentor should lose FDA approval for their implants. By losing half their augmentation patients, Allergan has also raised questions about the integrity of their data.

Unfortunately, we can't trust the complication rates reported in such poorly implemented studies.

This isn't the first time. Both companies lost most of their adjunct study patients in those previously required studies. Yesterday, several panel members suggested that the doctors and companies need stronger incentives to do good studies. I agree.

OBOS has talked to hundreds college students about breast implants, usually after screenings of the excellent documentary film, "Absolutely Safe." Most know almost nothing about the potential risks but have been given many unrealistic ideas about the benefits.

Plastic surgeons tell patients that silicone bleed and leakage is an old story about “old” implants. That's not true. Today's implants are better than the implants of the 1970s, but they still break in women's bodies, where they can do harm and where the silicone can be impossible to remove. And that's why we still need well conducted scientific research to find out how long they last and especially what damage is done by leaking silicone in terms of health and medical expenses.

OBOS is also concerned about the many women with implants who report autoimmune symptoms. We want to make sure that everyone working on this issue understands that an autoimmune reaction can cause a very diverse range of symptoms – including joint pain, hair loss, memory problems, chronic fatigue, fibromyalgia, dry eye, and sensitivity to sunlight.

Basically, the body is turning its immune response onto itself. What seems like a ridiculous laundry list of symptoms are actually all related. Those are the kinds of symptoms that many of the implanted women have reported at this FDA meeting. And the symptoms tend to decrease dramatically when the implants are removed because the implants had set that autoimmune reaction in motion.

Our Bodies Ourselves urges the panel members and the FDA to listen to the patients and make sure that future studies reflect what they are telling you. Patients cannot make safe choices about breast implants if there are no studies of long-term risks that include the kinds of symptoms that the women have reported anecdotally.