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**To: Food and Drug Administration
Division of Dockets Management Branch
5630 Fishers Lane Room 1061
Rockville, MD 20852**

Docket Number: 2004D-0002

**Fr: Sybil N. Goldich
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Re: Addendum to comments filed on March 12, 2004

Mammography

For clarification, my original comments discussed the importance of including MRI evaluation for all patients in clinical trials. MRIs have demonstrated utility in determining silent (asymptomatic) rupture and gel migration. If we are to ascertain realistic risk of these phenomena then we must use the best methods available to study the function of the device in vivo.

We are additionally concerned with reduced sensitivity of mammography and how this might impact the long-term "risk" associated with the use of silicone breast implants. According to the FDA, silicone gel-filled breast implants decrease mammographic detection of potentially curable breast cancer. According to FDA's summary panel memorandum from the October 2003 advisory panel meeting, from 22% to 83% of breast tissue may be obscured by silicone gel-filled breast implants.

The Journal of the American Medical Association published a report in January 2004 demonstrating that breast implants decrease the sensitivity of screening mammography among asymptomatic women. The authors found that mammograms missed 55% of breast cancers in women with implants compared to 33% among women without implants.

FDA has acknowledged that silicone gel is radiodense and obscures part of the breast tissue. Silicone breast implants also decrease compressibility of the breast, compress adjacent soft tissue resulting in increased density and poorer radiographic images and decrease the measurable area for mammography.

Also, capsular contracture may distort the breast making compression difficult and painful. It is reported that up to 70% of women with breast implants experience capsular

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contracture. In fact, for some women with severe capsular contracture mammographic imaging may not be possible.

The decreased sensitivity of mammography is not only a risk to breast cancer survivors but also to the generations of young women who may develop breast cancer in their lifetime. Clinical trials should track women with breast implants for periods of time long enough to evaluate mammographic interference, complications in the diagnosis, treatment and survival of breast cancer. For women at appropriate ages, baseline mammograms should be taken prior to implantation. Subsequent follow-up should include secondary mammographic imaging to determine interference with imaging.

Risks following Explantation of Silicone Breast Implants

In the presence of silicone gel or oil migration, women will continue to be exposed to components of the silicone gel-filled breast implants over time, perhaps for their lifetime. In the unique case of silicone gel-filled breast implants, a component of the device (silicone gel or oil) may persist in the body long after the shell has been removed.

The FDA acknowledged in its testimony before the October 2003 advisory panel that *“when breast implants rupture, silicone gel may migrate out of the scar capsule and through tissues. Across a series of studies, gel migration was observed for 11 to 23 percent of ruptured implants. There have also been cases of gel migration from intact implants. These may be cases of silicone oil migration from intact implants or possibly gel migration from minimally ruptured implants. The frequency and severity of distant gel migration are unknown.”*

Evaluation of continued exposure to components of silicone breast implants is a critical element in determining long-term risks and consequences to health. Therefore, clinical trials should continue to follow women who have had their devices removed. These women should be strongly encouraged to continue annual follow-up examinations. If silicone gel migration is confirmed through MRI or subsequent surgery, these women should continue to receive lifelong follow-up and referrals to appropriate physicians should symptoms or health complications occur as part of the clinical trial and under the direct guidance and support of the sponsoring manufacturer.

As a breast cancer survivor and former recipient of silicone breast implants, I can attest to the real and serious long-term harm these devices can cause. The decision by the Food and Drug Administration in early 2004 to delay approval of silicone breast implants until additional safety questions are addressed was an important first step in ensuring that women have access to devices that do not contribute to serious, long-term health risks.