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Comment on the FDA's Draft Guidance for Industry and FDA Staff on Saline, Silicone Gel, and Alternative Breast Implants

Submitted by Judy Norsigian, Executive Director, Our Bodies Ourselves

We appreciate the opportunity to comment on the FDA's January 2004 Draft Guidance on breast implants. Our Bodies Ourselves (OBOS) is a non-profit educational and advocacy organization that provides information about health, sexuality, and reproduction from feminist and consumer perspectives. We are best known for the landmark book, *Our Bodies, Ourselves*, to be published in 2005 as the eighth revised edition.

OBOS supports the FDA's decision to ask sponsors to more carefully examine the causes and consequences of implant rupture. We support the recommendations that mechanical testing be improved, and that sponsors develop a new gel bleed test. We are concerned, however, that the draft guidance does not emphasize the need for better pre-market clinical trials and epidemiological research.

Breast implants are expected to be as permanent as possible, and therefore should be studied on women who have had them for many years, before they are approved. Well-designed studies by the National Cancer Institute (NCI) and the FDA evaluated the health of women who had implants for a minimum of seven or eight years, respectively. The women with leaking silicone gel breast implants in the FDA study reported more fibromyalgia and several other autoimmune diseases. In the NCI study, women with breast implants were more likely to die from brain cancer, lung diseases, and suicide, compared to other plastic surgery patients.

Autoimmune diseases and cancers develop over a period of many years, and even more years are likely to pass before they are diagnosed. Pre-market research is needed on women who have had breast implants for at least ten years to provide a reasonable measure of risks of systemic diseases.

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Studies of women with ruptured implants are especially important because of testimony about the risks, and research indicating improved health when leaking implants are removed.

Since FDA officials state that they cannot enforce post market requirements for medical devices, persuasive research must be required before an implant is approved. This is not practical for new medical implants, but should be required for devices that have been widely available for 8-10 years or more.

DRAFT GUIDANCE 9. Clinical Studies

Section 9.1

Long-term clinical trials and/or retrospective research are needed, and diagnosis should be determined by medical exams rather than medical records or self-report. If the device has been on the market for more than ten years, the FDA should recommend at least ten years of pre-market patient follow-up. A literature review and post market approval requirements are not sufficient to ensure safety.

Section 9.2

Breast cancer reconstruction patients who have breast implants are more likely to have complications within three years than augmentation patients. Inamed data released in October, 2003 indicate that 46% of reconstruction patients and 20% of augmentation patients needed at least one additional operation within three years of implantation. The FDA should require long-term research to determine why reconstruction patients experience more complications than augmentation patients, and a comprehensive study of the health effects of silicone gel leakage and migration is needed for breast cancer and augmentation patients.

Women with FDA-approved saline breast implants should not be used as the only control groups in clinical trials, since the shell of saline implants contain silicone and other chemicals. Another control group of women with no implant or silicone exposure are also needed.

High loss to follow-up undermines the integrity of safety research for long-term implants, and should not be acceptable to the FDA.

Section 9.3

We support the FDA recommendation that sponsors collect information on incidence, timing, and type of new breast cancer diagnosis after implants, including interference with mammograms.

Research is needed on the impact of implants on breastfeeding, including lactation complications and the testing of chemical contamination in breast milk.

There are insufficient research data on the long-term impact of breast implants on systemic diseases. The Institute of Medicine Report includes few epidemiological studies, and most included women who had implants for only a few months. A comprehensive Core Study is needed to carefully examine a wide range of signs, symptoms, and diagnoses. In addition to those described in the FDA draft guidance, better information is needed on respiratory diseases, autoimmune diseases, and depression.

DRAFT GUIDANCE 10. Clinical Data Presentation

Research conducted by the National Cancer Institute found a increased risk of deaths from suicide and lung diseases among women with breast implants. The FDA should therefore recommend an evaluation of depression as well as respiratory problems and diseases.

DRAFT GUIDANCE 11. Labeling

We are concerned that informed consent materials, including booklets produced by implant manufacturers, are difficult to understand.

Pilot testing is essential to ensure that the final product is an effective source of information for the vast majority of women who undergo breast implant surgery.