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SPECIAL JOINT BULLETIN

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FDA approves return of silicone breast implants

The Food and Drug Administration announced today that it has issued approval with conditions to Allergan Corp. and Mentor Corp. to market silicone gel-filled breast implants in the U.S., effective immediately. The decision comes 14 years after the FDA restricted access to the devices due to safety concerns.

ASPS and ASAPS leaders applauded the action, which has been anticipated since the agency sent "approvable with conditions" letters to the manufacturers in the second half of 2005. Those letters followed years of scientific review, clinical trials and public hearings.

"The specialty of plastic surgery has always advocated that science should determine the availability of these devices, not emotion and special interests," said ASPS President Roxanne Guy, MD. "Silicone breast implants have been scrutinized more than any medical device, and we applaud the FDA for making its well thought-out decision and allowing American women to make informed choices about their health care."

Approved with conditions

FDA approved the silicone gel-filled breast implants with a number of conditions, including requiring each company to:

- Conduct a large postapproval study;
- Continue its core study through 10 years;
- Conduct a focus group study of the patient labeling;
- Continue laboratory studies to further characterize types of device failure; and
- Track each implant in the event, for example, that health professionals and patients need to be notified of updated product information.

In the FDA's statement announcing the approval, Daniel Schultz, MD, the FDA Director, Center for Devices and Radiological Health stated that the FDA has, "reviewed an extensive amount of data from clinical trials of women studied for up to four years, as well as a wealth of other information to determine the benefits and risks of these products. The extensive body of scientific evidence provides reasonable assurance of the benefits and risks of these devices. This information is available in the product labeling and will enable women and their physicians to make informed decisions."

The FDA further stated that the "postapproval studies will continue to gather information about the safety and effectiveness of the implants. Information will be collected about rates of local

complications, rates of connective tissue disease and its signs and symptoms, rates of neurological disease and its signs and symptoms, potential effects on offspring of women with breast implants, potential effects on reproduction and lactation, rates of cancer, rates of suicide, potential interference of breast implants with mammography, and MRI compliance and rupture rates."

The end of a 14-year process

Today's FDA decision follows a lengthy review process which culminated last year in "approvable with conditions" letters sent to the two silicone breast implant manufacturers. The approvable letter stipulated a number of conditions that the manufacturers needed to satisfy in order to receive FDA final approval to market and sell silicone breast implants in the United States. These letters came after an FDA advisory panel hearing in April 2005, in which the panel heard more than 20 hours of data presentations from the manufacturers and public comment. The FDA's decision comes just four weeks after the announcement by Health Canada that Canadian plastic surgeons would also once again have access to silicone implants, following a similar period of clinical trials and restricted use and a similar slate of followup study conditions.

"Plastic surgeons are committed to patient safety and education," said James Stuzin, MD, ASAPS president. "It is clear that the agency has carefully evaluated the data presented by the manufacturers, as well as the testimony of physicians, patients and advocacy groups and has made a thoughtful decision to give our patients the access to silicone gel breast implants that women in 60 countries around the world have."

Approximately 300,000 women chose breast augmentation in 2005, according to ASAPS and ASPS statistics. Nearly 58,000 women had breast reconstruction in 2005, according to ASPS. Both breast augmentation and reconstruction have been proven in numerous studies to have psychological and physical benefits for women who choose these procedures.

"This is first and foremost a validation of science," adds ASPS President-elect Richard D'Amico, MD. "This is the most studied device in history, and the science has won out. Patients and their plastic surgeons will now have a choice of whether they use a silicone gel-filled or saline implant. This is a choice that's been available around the world for a long time and it's good to know that American plastic surgeons and their patients again have the same options."

ASPS and ASAPS will continue to offer their assistance to the manufacturers for the conditions set forth by the FDA related to physician and patient education. One comprehensive example of this assistance is a joint Web site, www.breastimplantsafety.org, which offers objective and science based information regarding saline and silicone breast implants.