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FDA Approves Silicone Gel-Filled Breast Implants After In-Depth Evaluation

Agency Requiring 10 Years of Patient Follow-Up

After rigorous scientific review, the U.S. Food and Drug Administration (FDA) today approved the marketing of silicone gel-filled breast implants made by two companies for breast reconstruction in women of all ages and breast augmentation in women ages 22 and older. The products are manufactured by Allergan Corp. (formerly Inamed Corp.), Irvine, Calif., and Mentor Corp., Santa Barbara, Calif.

“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,” said Daniel Schultz, M.D., Director, Center for Devices and Radiological Health, FDA. “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.”

Now that the products have been determined to be safe and effective, FDA will continue to monitor them by requiring each company to conduct a large postapproval study following about 40,000 women for 10 years after receiving breast implants. FDA often requires postmarket studies to answer important questions that can only be answered once a product is in broader use, such as the incidence of rare adverse events.

FDA’s decision to approve these implants was based on a thorough review of each company’s clinical (core) and preclinical studies, a review of studies by independent scientific bodies and deliberations of advisory panels of outside experts that heard public comment from hundreds of stakeholders. In addition, FDA conducted inspections of each company’s manufacturing facilities to determine that they comply with FDA’s Good Manufacturing Practices. Some of the complications reported in the core studies included hardening of the area around the implant, breast pain, change in nipple sensation, implant rupture and the need for additional surgery. However, the majority of women in these studies reported being satisfied with their implants.

In the past decade, a number of independent studies have examined whether silicone gel-

filled breast implants are associated with connective tissue disease or cancer. The studies, including a report by the Institute of Medicine, have concluded there is no convincing evidence that breast implants are associated with either of these diseases. However, these issues will be addressed further in the postapproval studies conducted by the companies.

“The silicone breast implant is one of the most extensively studied medical devices,” said Schultz. “We now have a good understanding of what complications can occur and at what rates. We also know that women who get these devices will probably need to have additional breast implant surgery at least once. This is valuable information for women who may be considering these products.”

Full information about the risks and benefits of the devices can be found in the package and patient labeling mandated by FDA. The patient labeling outlines some of the important factors women should consider when deciding whether to get silicone gel-filled breast implants. Some of these factors are: breast implants are not lifetime devices and a woman will likely need additional surgeries on her breast at least once over her lifetime; many of the changes to a woman’s breast following implantation are irreversible; rupture of a silicone gel-filled breast implant is most often silent, which means that usually neither the woman nor her surgeon will know that her implants have ruptured; and a woman will need regular screening MRI examinations over her lifetime to determine if silent rupture has occurred. The device labeling states that a woman should have her first MRI three years after her initial implant surgery and then every two years thereafter. The cost of MRI screening over a woman’s lifetime may exceed the cost of her initial surgery and may not be covered by medical insurance. The labeling also states that if implant rupture is noted on an MRI, the implant should be removed and replaced, if needed.

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.

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 postapproval studies will be closely monitored by FDA. FDA anticipates that data from the studies will provide important information for patients and physicians, and may lead to improvements in device labeling.

For more information, visit www.fda.gov/cdrh/breastimplants.

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