FDA NEWS RELEASE

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FDA review indicates possible association between breast implants and a rare lymphoma
Agency requesting health care professionals to report confirmed cases

Today, the U.S. Food and Drug Administration announced details from an internal review suggesting a possible association between saline and silicone gel-filled breast implants and the development of anaplastic large cell lymphoma (ALCL), a very rare type of lymphoma.

ALCL is not breast cancer. According to the National Cancer Institute, ALCL appears in different parts of the body including the lymph nodes and skin. Each year ALCL is diagnosed in about 1 out of 500,000 women in the United States. ALCL located in breast tissue is found in only about 3 out of every 100 million women nationwide without breast implants.

While the risk is very low, the FDA is requesting that health care professionals report any confirmed cases of ALCL in women with breast implants.

"While our comprehensive review of the existing literature suggests an association exists, we need more data before drawing any conclusions and we're asking health care professionals to notify us of any confirmed cases they identify," said William Maisel, M.D., M.P.H., deputy director for science in FDA's Center for Devices and Radiological Health. "We are working with the American Society of Plastic Surgeons and other experts in the field to establish a breast implant patient registry, which should help us better understand the development of ALCL in women with breast implants."

FDA's review of existing literature published between January 1997 and May 2010 identified 34 unique cases of ALCL in women with saline and silicone breast implants. In total, the agency is aware of as many as 60 cases of ALCL in women with breast implants worldwide based on information from other international regulators, scientists, and breast implant manufacturers. These figures are difficult to verify because not all cases were published in the scientific literature and some may be duplicate reports.

Most cases reviewed by the FDA were diagnosed when patients sought medical treatment for implant-related symptoms such as pain, lumps, swelling, or asymmetry that developed after their initial surgical sites were fully healed. These symptoms were due to collection of fluid (peri-implant seroma), hardening of breast area around the implant (capsular contracture), or masses surrounding the breast implant. Examination of the fluid and capsule surrounding the breast implant led to the ALCL diagnosis.

The FDA is recommending that health care professionals and women pay close attention to breast implants and do the following:

- Health care professionals are requested to report all confirmed cases of ALCL in women with breast implants to Medwatch, the FDA's safety information and adverse event reporting program. Report online at http://www.fda.gov/Safety/MedWatch/default.htm or by calling 800-332-1088.

- Health care professionals should consider the possibility of ALCL if a patient has late-onset persistent fluid around the implant (peri-implant seroma). In cases of implant seroma, send fresh seroma fluid for pathology tests.

- There is no need for women with breast implants to change their routine medical care and follow-up. ALCL is very rare; it has occurred in only a very small number of the millions of women who have breast implants.

- Women should monitor their breast implants and contact their doctor if they notice any changes.

- Women who are considering breast implant surgery should discuss the risks and benefits with their health care provider.

Because the risk of ALCL is very small, the existing data support the continued marketing and use of breast implants. FDA will provide additional updates as new information becomes available. FDA will continue working with breast implant manufacturers in the months ahead to update their product labeling materials for patients and health care professionals.

The FDA published its literature review in a document posted on FDA's website site, The report is "Anaplastic Large Cell Lymphoma (ALCL) in Women with Breast Implants: Preliminary FDA Findings and Analyses."

The FDA also plans to provide an update on its review of silicone gel-filled breast implants in the spring of 2011. This update will include interim findings from ongoing post-approval studies for silicone gel-filled breast implants currently sold in the United States, adverse event reports submitted to the FDA, and a review of the scientific literature on these products.

An estimated 5 million to 10 million women worldwide have breast implants.

For more information:

ALCL and Breast Implants
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm

Breast Implants
www.fda.gov/breastimplants

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