Possible Link Between Breast Implants, Rare Ca

BY KERRI WACHTER

FROM A FOOD AND DRUG ADMINISTRATION TELECONFERENCE

The Food and Drug Administration is asking health care professionals to report any confirmed cases of anaplastic large cell lymphoma (ALCL) in women with silicone gel- or saline-filled breast implants, citing concerns about a possible association.

The agency's announcement during a teleconference is based on a review of scientific literature published between 1997 and 2010, along with information from other international regulators, scientists, and breast implant manufacturers.

"ALCL is rare and has occurred in a very small number of women when compared to the millions who have breast implants," said Dr. William Maisel, chief scientist and deputy director for science in FDA's Center for Devices and Radiological Health. The literature review identified 34 unique cases of this rare cancer in women with both saline and silicone breast implants. There have been roughly 60 cases of ALCL in women with breast implants worldwide, according to the FDA. It's estimated that 5-10 million women have breast implants worldwide.

"Data reviewed by the FDA suggest that patients with breast implants may have a very small but significant risk of ALCL in the scar capsule adjacent to the implant," the agency noted in a press release. Most of the cases reviewed by the agency were diagnosed when patients sought treatment for implant-related symptoms such as pain, lumps, swelling, or asymmetry.

The FDA recommends that health care professionals consider the possibility of ALCL if a patient has late onset, persistent fluid around the implant (peri-implant seroma). When implant seroma is found, fresh seroma fluid should be sent for pathology tests to rule out ALCL. Patient information about breast implants and ALCL can be found in the FDA's Consumer Updates

Health care providers should discuss the risks and benefits with women who are considering breast implant surgery. The FDA published its literature review in a document posted on its Web site titled "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.

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

The FDA also provides general information about breast implants to share with patients. ■

3-D Mammography System Approved

Hologic's Selenia Dimensions digital breast tomosynthesis system (Dimensions 3-D) is the first three-dimensional mammography system to reach the U.S. market following premarket approval by the Food and Drug Administration. The low-dose x-ray device provides both 2-D and 3-D images of the breast for breast cancer screening and diagnosis.

Conventional 2-D mammography systems have limitations caused by overlapping tissue in the breast that may hide lesions or cause benign areas to appear suspicious, the company explained. Clinical trials of Dimensions 3-D showed significant gains in specificity and other benefits, including improved lesion and margin visibility and the ability to accurately localize structures in the breast, the firm noted.

The approval follows endorsement of the product's safety and efficacy data by the FDA's Radiological Devices advisory panel last September.

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–Jessica Bylander
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