

Breast Implants May Be Linked to Rare Cancer, FDA Says

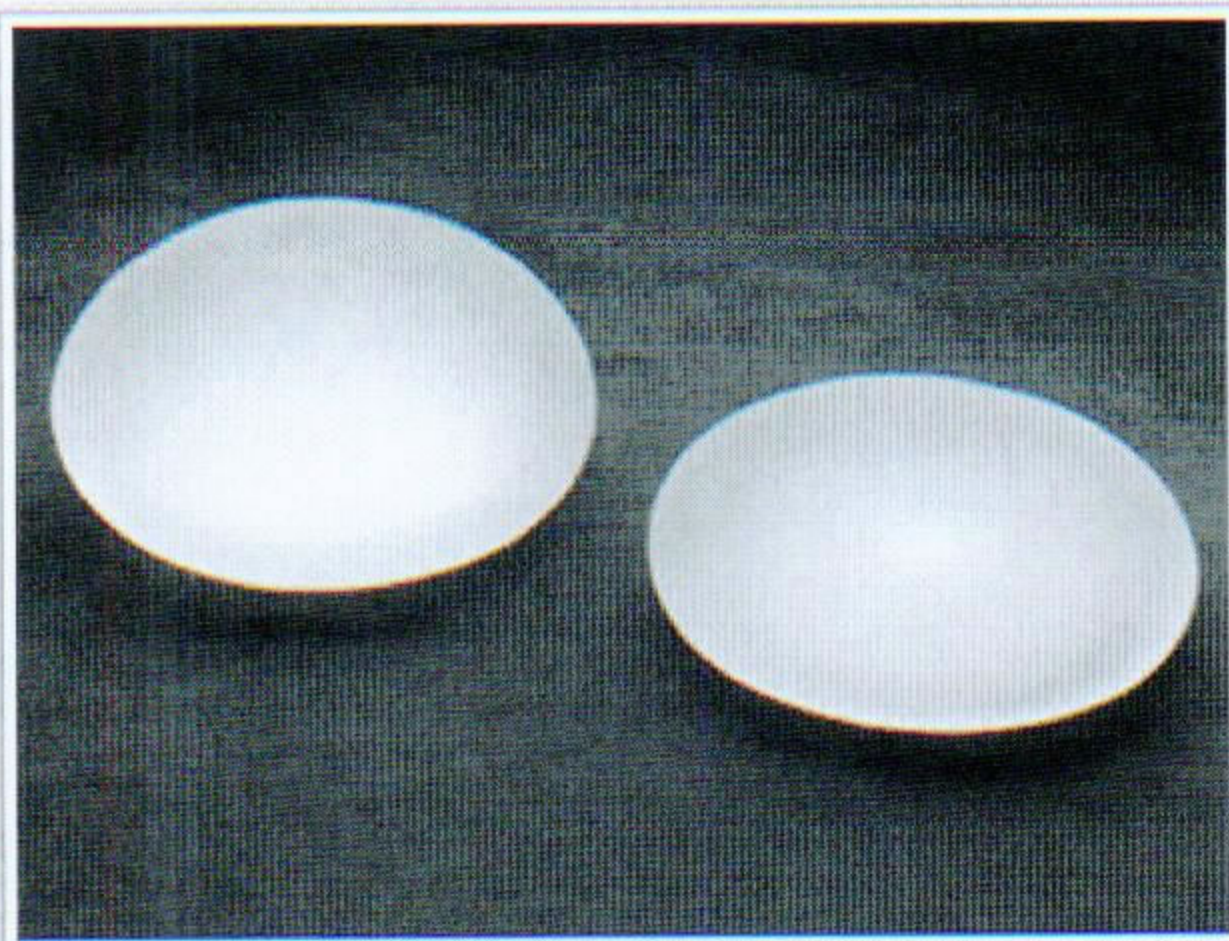
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Authors and Disclosures

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January 26, 2011 — Patients with either saline- or silicone gel-filled breast implants may have a very small but significant risk for a rare cancer called anaplastic large-cell lymphoma (ALCL) adjacent to the implant, the US Food and Drug Administration (FDA) announced today.

While the agency continues to investigate the possible association between ALCL and breast implants, it is advising clinicians to consider the possibility of the cancer in patients with breast implants with late onset of fluid build-up called persistent peri-implant seroma. Clinicians also should report any confirmed cases of ALCL in women with breast implants to the FDA.



Saline-filled breast implants

The agency is advising women with breast implants not to change their routine medical care and follow-up. Because the risk for ALCL appears to be very small, the agency believes the weight of evidence "supports a reasonable assurance that FDA-approved breast implants are safe and effective when used as labeled."

A rare cancer of the immune system that can occur anywhere in the body, ALCL is diagnosed in 1 of every 500,000 women per year in the United States. ALCL in the breast is rarer still, diagnosed annually in roughly 3 of every 100 million women without implants. In women with breast implants, it is usually inside the fibrous scar tissue — called a capsule — surrounding the implant. It is not a cancer of the breast per se.

Treatment options for ALCL are chemotherapy, radiation, and surgery, said William Maisel, MD, MPH, chief scientist and deputy director for science in the FDA's Center for Devices and Radiological Health, at a press conference today. The evidence suggests that the kind of ALCL found in conjunction with breast implants is less aggressive and is sometimes treatable by simply removing the implant, the capsule, and collected fluid, according to Dr. Maisel.

An FDA review of scientific literature published from January 1997 through May 2010 uncovered 34 unique cases of ALCL in women with breast implants throughout the world. The agency is aware of 60 cases in all, some of them identified through other channels. The FDA does not know how many of the 60 may be duplicates of cases found in the literature. An estimated 5 million to 10 million women worldwide have received breast implants, according to the FDA.

Of the 31 published cases of ALCL, 24 involved silicone implants, and 7 saline implants. The median time from implant to ALCL diagnosis was 8 years. For most of the women, the cancer was diagnosed when they sought treatment for implant-related symptoms, such as pain, lumps, swelling, or asymmetry, after their surgical sites had healed. These symptoms result from persistent peri-implant seroma, hardening of the breast area around the implant, or masses surrounding the implant.

Plastic Surgeons and FDA Will Develop Patient Registry

The vast majority of data suggesting a link between ALCL and breast implants emerged only after the FDA approved silicone gel breast implants made by Allergan and Mentor in 2006, said Dr. Maisel. From 1992 to 2006, such silicone gel implants were available only on an investigational basis.

Dr. Maisel noted that silicone from ruptured and even intact implants has been found in nearby breast tissue. According to one theory about the origins of ALCL, this silicone chronically stimulates immune system T cells and induces lymphoma.

"Please understand that is speculative, and a hypothesis," said Dr. Maisel.

To get to firmer scientific ground, the FDA will collaborate with the American Society of Plastic Surgeons and other groups to develop a registry to collect more information that would better characterize ALCL in women with breast implants. The agency also is asking implant manufacturers to report ALCL cases. And for the sake of patient and clinician education, the FDA will work with these manufacturers to update product labeling materials.

More information about today's announcement is available on the FDA Web site. The FDA's preliminary findings and analyses are available [here](#).

To report adverse events related to breast implants, contact MedWatch, the FDA's safety information and adverse event reporting program, by telephone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, online at <http://www.fda.gov/medwatch>, or by mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, Maryland 20852-9787.