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Breast implants linked to rare lymphoma

Federal health officials announced Wednesday that they were investigating a possible association between saline and silicone gel-filled breast implants and very rare form of cancer known as anaplastic large cell lymphoma (ALCL).

In a statement released in advance of a briefing for reporters, the FDA said it had found a "a very small but significant risk of ALCL in the scar capsule adjacent to the implant" after reviewing data worldwide and was asking doctors to report any cases of ALCL in women with breast implants.

"We need more data and are asking that health care professionals tell us about any confirmed cases they identify," said William Maisel, the FDA's chief scientist in a written statement. "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."

In the meantime, the agency planned to work with breast implant manufacturers warn women considering implants of the possible risk.

The announcement was prompted by a a review of scientific literature published between January 1997 and May 2010 and "information from other international regulators, scientists, and breast implant manufacturers," the FDA said. The literature review identified 34 unique cases of ALCL in women with both saline and silicone breast implants. So far, the FDA has found a total of only about 60 cases of ALCL in women with breast implants worldwide, according to the statement. But the agency stressed "this number is difficult to verify because not all cases were published in the scientific literature and some may be duplicate reports."

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

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," the FDA said. These symptoms were due to

collection of fluid, hardening of breast area around the implant or masses surrounding the breast implant.

ALCL is diagnosed in about one out of 500,000 women in the United States each year, the FDA said. ALCL located in breast tissue is found in only about three out of every 100 million women nationwide without breast implants

The FDA stressed that there was "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," the FDA said. "Women who are considering breast implant surgery should discuss the risks and benefits with their health care provider."