Office of Health and Constituent Affairs

Food and Drug Administration

U.S. Department of Health and Human Services

Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

Dear Colleague,

In 2011, the FDA identified a possible association between breast implants and the development of anaplastic large cell lymphoma (ALCL), a rare type of non-Hodgkin's lymphoma. At that time, the FDA knew of so few cases of this disease that it was not possible to determine what factors increased the risk. In a report summarizing the Agency's findings, we emphasized the need to gather additional information to better characterize ALCL in women with breast implants. Since 2011, FDA has strengthened our understanding of this condition and concur with the World Health Organization designation of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a rare T-cell lymphoma that can develop following breast implants. At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces.

- **Health care professionals** should continue to provide routine care and support to patients who have breast implants. Be aware that most confirmed cases of BIA-ALCL have occurred in women with textured breast implants. BIA-ALCL is a very rare condition; when it occurs, it has been identified most frequently in patients undergoing implant revision operations for late onset, persistent seroma. Because it has generally only been identified in patients with late onset of symptoms such as pain, lumps, swelling, or asymmetry, prophylactic breast implant removal in patients without symptoms or other abnormality is not recommended.

- **Patients** who have breast implants do not need to change your routine medical care and follow-up. BIA-ALCL is rare; it has occurred in only a few hundred out of the millions of women who have breast implants. For patients considering getting breast implants, educate yourself about breast implants before agreeing to surgery. Breast implants approved in the U.S. can be filled with either saline or with silicone gel. They come in different sizes and shapes and have either smooth or textured surfaces (shells). Additional information is available on FDA's Breast Implants website.

To improve our understanding of this rare finding, patients and health professionals should continue to report all confirmed cases of ALCL in women with breast implants, with as much detail as possible, through the FDA MedWatch program. We will continue to report on significant findings as new information and analyses become available.

For more information:

- Web Update: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm
- MedWatch – FDA's Safety Information and Adverse Event Reporting Program: https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm547622.htm

Thank you,

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