FDA Updates Analysis of Medical Device Reports of Breast Implant Illness and Breast Implant-Associated Lymphoma

The agency also announced the qualification of a tool to aid in the effectiveness assessment of devices used in breast reconstruction.

September 3, 2020 By Food and Drug Administration (FDA)

Today, the U.S. Food and Drug Administration is providing an update on adverse events reported to the Agency related to breast implants, including breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), and systemic signs and symptoms referred to by patients as breast implant illness (BII), which some patients report after receiving breast implants. The FDA is also qualifying the BREAST-Q Reconstruction Module as a medical device development tool (MDDT) to aid in the assessment of certain medical devices such as breast implants. Qualification of the BREAST-Q Reconstruction Module MDDT included the Physical Well-being (Chest), Psychosocial Well-being, Sexual Well-being and Satisfaction with Breasts scales. An MDDT is scientifically validated and can be qualified for use in device evaluation and to support regulatory decision-making. Examples of MDDTs are clinical outcome assessments, assessments of biomarkers, and non-clinical assessment methods or models. The use of a qualified MDDT by a product sponsor is voluntary.

“The FDA has been diligently monitoring adverse events associated with breast implants for decades and has been working to better understand the quality of life and satisfaction a breast reconstruction patient may experience in order to refine our evaluation of breast implant benefits and risks. Our qualification of the BREAST-Q Reconstruction Module as a validated tool to assess outcomes of breast reconstruction surgery in terms of quality of life and satisfaction helps accomplish this,” said Binita Ashar, M.D., director of the Office of Surgical and Infection Control Devices in the Center for Devices and Radiological Health. “In addition, we continue to increase our scientific knowledge regarding BIA-ALCL and systemic symptoms referred to as BII, and remain committed to keeping the public informed.”

Medical Device Reports of BIA-ALCL

The FDA analysis of global medical device reports for BIA-ALCL covers reports received through January 5, 2020. It updates the FDA’s last public report with new information from July 7, 2019 to

January 5, 2020. Today, the FDA updated the table on the agency's BIA-ALCL webpage to include a total of 733 unique cases and 36 patient deaths globally, which reflect an increase of 160 new cases and 3 deaths since the early-July, 2019 update.

Specifically, of the 733 total unique cases of BIA-ALCL reported to FDA, 620 cases were reported for Allergan implants, and 47 cases involved implants with an unknown manufacturer. With respect to implant surface for the 733 total unique cases of BIA-ALCL, 496 cases were reported to have textured implants, and 209 cases did not specify the implant surface. Of the 36 total patient deaths reported to FDA, 15 of the 16 patients for which the manufacturer of the implant is known, are reported to have had an Allergan breast implant at the time of their BIA-ALCL diagnosis. In terms of implant surface, of the 36 cases reported of patient deaths, 16 cases reported textured implants, and 19 cases did not contain information on the implant surface.

BIA-ALCL is not breast cancer—it is a type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread throughout the body. At this time, the overall incidence of developing BIA-ALCL is low; however, a BIA-ALCL diagnosis is serious and can lead to death, especially if not diagnosed early or promptly treated. In most patients, BIA-ALCL is treated successfully with surgery to remove the implant and the scar tissue surrounding the implant; however, some patients may require treatment with chemotherapy and/or radiation therapy.

Medical Device Reports of Systemic Symptoms Referred to as BII

In addition to today's update on BIA-ALCL, the FDA is updating data on medical device reports received concerning systemic signs and symptoms referred to by patients as BII. A new table on FDA's website summarizes unique BII medical device reports from the U.S. and worldwide that the FDA has received from Jan. 1, 2008 to Oct. 31, 2019. The data show that the FDA received 2,497 medical device reports containing symptoms consistent with BII from Nov. 2018 to Oct. 2019. The FDA's data from Jan. 2008 to Oct. 2018 showed 1,080 reports that contained such symptoms. More patients and providers are reporting these conditions, likely due to increased awareness from press, social media, and FDA's General and Plastic Surgery Devices Advisory Committee meeting held in March 2019.

While there is limited use of the term "breast implant illness" in medical literature, symptoms such as fatigue, memory loss, rash, "brain fog," and joint pain may be associated with breast implants, and some patients and clinicians may use the term "breast implant illness" to describe these symptoms or use these terms when reporting them to the FDA. The top 10 most common symptoms reported to the FDA's medical device report database for patients with breast implants include fatigue (49 percent), brain fog (25 percent), joint pain (25 percent), anxiety (24 percent), hair loss (21 percent), depression (19 percent), rash (18 percent), autoimmune diseases (18 percent), inflammation (18 percent) and/or weight problems (18 percent). Researchers are investigating these symptoms to better understand their origins and connection to breast implants.

While the FDA doesn't have definitive evidence demonstrating breast implants cause these symptoms, the current evidence supports that some patients experience systemic symptoms that may resolve when their breast implants are removed. The FDA is committed to communicating information the agency receives about systemic symptoms reported by patients with breast implants.

Qualification of the BREAST-Q Reconstruction Module as a Medical Device Development Tool

The FDA also announced today the qualification of a validated, self-administered questionnaire—the BREAST-Q Reconstruction Module—through the agency's MDDT program.

The paper and electronic self-administered versions of the BREAST-Q Reconstruction Module's Psychosocial Well-being, Sexual Well-being, Physical Well-being (Chest), and Satisfaction with Breasts scales are used to quantify different aspects of a woman's quality of life and satisfaction with breast reconstruction surgery. These scales may be used by medical device sponsors and sponsor-investigators in feasibility, pivotal, and post-approval studies to support the effectiveness of breast reconstruction-related medical devices, such as an implant or mesh, befitting the clinical meaningfulness of the scale to support the proposed indication.

The FDA remains committed to thoughtful, scientific and transparent public dialogue concerning breast implant safety and effectiveness. Health care professionals and consumers should report any adverse events related to breast implants to the FDA's Adverse Event Reporting Program. The FDA monitors these reports and takes the appropriate action necessary to help ensure the safety of medical products in the marketplace.

Lastly, today the FDA released a video on seven things patients should know about breast implants, including risks, complications and information about BIA-ALCL and systemic symptoms.

The FDA will continue to analyze all available information regarding risks associated with breast implants, routinely update the BIA-ALCL and BII analysis published on our website and take additional actions when and where necessary.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

This announcement was originally published on the Food and Drug Administration website.

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