FDA Continues Education About Risk of Lymphoma From Breast Implants

Global reports show nearly 250 new cases of non-Hodgkin lymphoma in women with breast implants.

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Statement from Binita Ashar, M.D., of the FDA's Center for Devices and Radiological Health on agency's continuing efforts to educate patients on known risk of lymphoma from breast implants

One of the most important roles we have as a public health agency is educating patients and health care providers about both the benefits and risks of medical products, including breast implants.

I know there are many choices of breast implants available to patients, including the size, implant fill and surface texture. We want to provide patients with the most up-to-date information about the variety of breast implants available so that patients and providers can have thorough and thoughtful discussions weighing the benefits and risks of different products. We also want to be transparent in sharing the information we regularly gather and analyze in a way that provides important context to help inform these discussions.

Today, we are providing an update regarding the number of cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), a type of non-Hodgkin's lymphoma and a known risk from breast implants. In 2011, the FDA was the first public health agency in the world to communicate about the risks of BIA-ALCL, warning women that the available information at the time indicated that there is a risk for women with breast implants for developing this disease. Since then, we have regularly updated the information available on our website regarding known BIA-ALCL cases, including deaths and known risks.

We hope that this information prompts providers and patients to have important, informed conversations about breast implants and the risk of BIA-ALCL. At the same time, we remain committed to working in partnership with all stakeholders to continue to study, understand and provide updates about this important public health issue.

Today, the agency is providing an updated number of medical device reports (MDRs), also known as adverse event reports. After a thorough data analysis, we are reporting that, as of September 2018, the agency has received a total of 660 total medical device reports regarding BIA-ALCL cases since 2010. Of the 660 MDRs, our in-depth analysis suggests that there are 457 unique

cases of BIA-ALCL, including 9 patient deaths. [Note: One February 7, the FDA clarified that these cases are not only in the U.S. and reflect global reports.]

We understand that the information presented shows an increase of 246 new MDRs since last year. Given the agency's continued efforts to communicate with stakeholders about BIA-ALCL risks and our work to encourage patients and providers to file MDRs with the agency, these types of increases in the MDRs are to be expected and may include past cases that were not previously reported to the FDA. The increased number of MDRs contributes to our evolving understanding of BIA-ALCL and represents a more thorough and comprehensive analysis.

The number of unique cases is lower than the total number of reports because the FDA's medical device reporting system allows patients, providers and manufacturers to each file their own reports even if it's about the same case, which can lead to duplicative reports of BIA-ALCL. Through our review of each report, our team of experts works to remove duplicative information and analyze the data provided to help better understand what these reports may or may not tell us about the benefits and risks of the device. For example, our analysis of these reports is better when there is a wide-range of information provided concerning the breast implant texture and implant fill, and other helpful details like a patient's age, how long a patient has been implanted, and time from implantation to diagnosis. This information helps us understand how and why this lymphoma may be occurring. Unfortunately, not every report provides thorough information about each case, including what type of breast implant (e.g., surface texture) the patient received, which makes it more difficult to know if any particular breast implant characteristic is associated with BIA-ALCL or if higher reports of BIA-ALCL are simply due to higher implantation rate of a particular manufacturer. In the interest of transparency, on our webpage, we provide a breakdown of the data and an analysis of that information that was provided to the agency.

For patients, we know the information regarding breast implants can be overwhelming, which is why we are committed to continuing our efforts to provide up-to-date publicly available resources to help understand the known benefits and risks of implants. We encourage patients to review our website and read specific device labeling, including patient labeling information, for any product they may consider implanting. Choosing to obtain a breast implant is a very personal decision that patients and their providers should make based on individual needs and with the most complete information about products.

We are also aware that our counterparts in different countries are taking certain actions or may be reporting different information about breast implant safety than the FDA. The different devices approved in each country, availability of products, variation in market share, extent of medical device adverse event reporting, and availability of information regarding the total number of implants sold differs from country to country. This makes it difficult for the regulatory bodies of different countries to compare data and determine risk rates on a global scale.

We recognize the limitations of medical device reports, which is why we review other sources of information, including medical literature and the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE). PROFILE

collects real world data regarding patients who have a confirmed diagnosis of BIA-ALCL. Our participation in this registry reflects the FDA's commitment to implementing our Medical Device Safety Action Plan, in which we are streamlining and modernizing how we implement postmarket actions to address device safety issues to make our responses to risks more timely and effective.

In addition to updating our medical device reports, we are issuing today a Letter to Health Care Providers to encourage those who regularly treat patients, including primary care physicians and gynecologists, to learn about BIA-ALCL in patients with breast implants. We want to ensure that all providers who treat patients with breast implants have information regarding identification, diagnosis and treatment. Patients are more likely to seek routine care from primary care physicians, gynecologists and others besides their treating plastic surgeon. By providing information to health care providers, we believe more providers will be empowered with information to assist patients who may have BIA-ALCL. We also encourage patients and providers to file medical device reports with the FDA via MedWatch, the FDA Safety Information and Adverse Event Reporting program.

The FDA remains committed to thoughtful, scientific and transparent, public dialogue concerning breast implant safety and effectiveness. We know BIA-ALCL will be one important topic of discussion at the agency's upcoming public meeting of the General and Plastic Surgery Devices Panel at the FDA's headquarters in Silver Spring, Maryland March 25-26, 2019. We look forward to engaging with patients, providers and manufacturers about a range of topics concerning the benefit-risk profile of breast implants in that public forum. The topics we will discuss at this meeting highlight the importance of continuing to monitor, assess and advance our understanding of breast implant safety. We will publish additional information regarding the meeting agenda on our breast implant webpage soon.

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