FDA STATEMENT

Statement from FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D., and Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health on FDA's new efforts to protect women's health and help to ensure the safety of breast implants

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Statement From:

There has been a growing discussion in recent months around the safety of certain breast implants, with regulatory agencies around the world weighing the risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). It's an issue that has been a priority for us at the U.S. Food and Drug Administration since 2011 when we warned women that the available information at the time indicated that there is a risk for women with breast implants, especially those with textured implants, for developing this disease.

Since that time, we have worked diligently to fill the gaps in knowledge, such as evaluating the body of available evidence regarding the safety and risks of breast implants, including concerns specific to textured implants and the risk of BIA-ALCL. The agency has undertaken several steps to better understand this issue, including an in-depth review of post-approval study data, medical device reports, scientific literature and breast implant-specific registries, and public discussions. But this is not the only issue we've been considering with respect to breast implants. The agency has regularly communicated about additional risks associated with breast implants (/medical-devices/breast-implants/risks-and-complications-breast-implants), such as capsular contracture and implant rupture. And we have heard from patients concerned that their implants may be connected to health conditions involving their immune system's response to these devices, resulting in a variety of symptoms like chronic fatigue, cognitive issues, joint and muscle pain. While the FDA doesn't have definitive evidence demonstrating breast implants cause these symptoms, the current evidence supports that some women experience systemic symptoms that may resolve when their breast implants are removed, referred to by some

patients and health care professionals as breast implant illness. We believe women considering a breast implant should be aware of these risks. As we describe below, we are taking steps to better characterize the condition and its risk factors, and are considering ways to help to ensure women have all of the information they need to make informed decisions about whether to obtain breast implants or to remove existing breast implants in an effort to reverse systemic symptoms.

Most recently, we discussed these important issues in a public advisory committee meeting in March (/advisory-committees/advisory-committee-calendar/march-25-26-2019-general-and-plastic-surgery-devices-panel-medical-devices-advisory-committee). In the pursuit of our mission to protect the public health, one of the most important things we do as regulators is to listen to the experiences and perspectives of patients, medical and scientific experts and other stakeholders related to medical products. The meeting covered a range of important topics on breast implant safety, including the use of surgical mesh in breast implant surgery, characterization of BIA-ALCL incidence and risk factors, and methods for assessing systemic symptoms. During the two-day meeting, we listened carefully to the insightful comments and personal stories from a broad range of public, scientific, medical and other stakeholders. These insights have been invaluable in growing our understanding of the potential risks associated with breast implants and the need for further efforts to help to ensure appropriate patient protections and improve breast implant safety.

To that end, the information we've garnered, from this meeting and other ongoing efforts, makes clear there is an opportunity to do more to protect women considering breast implants. And today, we are announcing several new steps we have taken and are considering aimed at helping to ensure that women have access to the information they need about breast implants to make informed decisions and to further drive evidence generation that will help the FDA make the most appropriate scientific regulatory decisions moving forward.

First, we will take steps to improve the information available to women and health care professionals about the risks of breast implants that would include addressing the risk of BIA-ALCL, the greater risk of BIA-ALCL with textured implants, and the risk of developing systemic symptoms that would contribute to the patient-provider discussion about breast implants. We are also looking at ways to incorporate product ingredient information into the labeling in a way that is easy for patients to understand. The FDA would work with stakeholders, including patient groups, on the content and format of any labeling changes proposed or recommended by the FDA, which could include a boxed warning and a patient decision checklist, and would work with manufacturers on implementing any changes to the information they provide to health care professionals and patients, including labeling.

We are considering these actions to help to ensure that all women who consider breast implants have the information they need to have thoughtful and balanced discussions with their health care professional about both the benefits and risks of breast implants based on clear information reflecting the most current understanding of these issues.

As we undertake this effort, we recognize that there is a need to help to ensure that information reaches health care professionals and women. We are aware that there are some health care professionals, such as gynecologists, dermatologists, internists and pathologists, who may not be fully aware of these breast implant risks, like BIA-ALCL and systemic symptoms. We are committed to doing what we can to reach them with this important information, including continuing the outreach we started with our Letter to Health Care Providers (/medical-devices/letters-health-care-providers/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl-letter-health-care-providers) to educate the medical community about BIA-ALCL and other risks of breast implants. We also plan to work with the pathology community to educate pathologists about testing for this lymphoma specific to breast implants. In addition, we're committed to continuing to update the public about any new information related to breast implant risks, as well as updating and improving the communication tools we have for women on our website.

We will continue our regular updates about the known global medical device reports for BIA-ALCL (/medical-devices/breast-implants/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl), as we have done since 2011. Moving forward, we plan to also regularly communicate information we receive through medical device reports about systemic symptoms experienced by patients with breast implants. We provided information at the two-day advisory committee meeting on medical device reports we've received that mention systemic symptoms described by some as breast implant illness, and we plan to continue sharing the numbers of medical device reports on these symptoms.

We are also announcing today a change in how breast implant manufacturers file medical device reports with the FDA. We appreciate the value to the public in ensuring this information from medical device reports is readily available to them. In an effort to promote greater public transparency, the FDA has ended all summary reporting of breast implant medical device reports and has notified breast implant manufacturers of this decision. This is part of a larger effort to end the alternative summary reporting program for all medical devices, which we intend to complete in the coming weeks. This program was established in 1997 to more efficiently review adverse events for well-established risks but was not allowed for patient deaths and unusual, unique or uncommon adverse events, which, in the case of breast implants, included BIA-ALCL. Alternative summary reports

were not previously available in our public database for medical device reports, Manufacturer and User Facility Device Experience (MAUDE (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm)).

Moving forward, breast implant manufacturers will be required to file individual medical device reports that will be publicly available in MAUDE. For past data received through summary reporting, the agency will also be making this data, including alternative summary reports for all devices under the program (/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems), publicly available in the coming weeks.

We believe these steps for more transparent medical device reports will contribute to greater public awareness of breast implant adverse events. Increased public awareness of the number of adverse events may contribute to a woman's own understanding of the risks of breast implants, but, as with any medical device report, it's important to note that generally the number of reports received cannot be used to determine the frequency with which a particular adverse event occurs. The information in medical device reports is important, but they are only one tool that contributes to our understanding of breast implants. Further, it is important that people understand that the reports are just that – a report by an outside party. The agency has not verified that they are accurate, nor that the issue was in fact caused by the device. For this reason, among others, these reports cannot be used alone to determine an incidence rate, causation or associations as many reports can be duplicative or incomplete.

Partnering with registries, such as the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma (ALCL) Etiology and Epidemiology (PROFILE (https://www.thepsf.org/research/registries/profile) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)), which collects real world data on patients with BIA-ALCL diagnoses, and the new National Breast Implant Registry (NBIR (https://www.thepsf.org/research/registries/nbir) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)), which collects real world data on the safety and performance of breast implants, is one way in which we seek to gain greater insight and more comprehensive information about women's experiences with breast implants.

We expect that both breast implant registries will greatly contribute to helping us evaluate data from providers regarding their patients with breast implants. The data already made available to us from the PROFILE registry provides additional information about patients diagnosed with BIA-ALCL. However, more needs to be done to increase the number of health care professionals contributing to the registries and types of information collected by the registries. The FDA continues to encourage stakeholders that have organized these

registries to take steps to expand provider participation; request additional information from providers, such as the patient's family history of autoimmune disorders and details of past operations; and seek ways to make the data collected more public and transparent, so that patients and researchers can access and analyze the information.

We believe this work with the registries, along with our efforts to address concerns (/news-events/press-announcements/fda-issues-warning-letters-two-breast-implant-manufacturers-failure-comply-post-approval-study) in how the post-approval studies are conducted, will help improve the evidence generated on breast implants and can greatly contribute to our understanding and further assessment of BIA-ALCL, systemic symptoms and other potential long-term risks from breast implants. Better evidence generation leads to more robust and scientifically-sound regulatory decisions.

A few of our international counterparts have started to initiate actions to ban or restrict sales of some textured breast implants, based on concerns about BIA-ALCL. In those markets, there are textured implants that are not marketed in the U.S. and where the use of textured implants is much higher, sometimes as high as 80% market share. In 2018, textured breast implants represented less than 10% of breast implants sold in the U.S. The type of macro-textured implants targeted by some of our international counterparts represents less than 5% of breast implants sold here. At this time, the FDA does not believe that, on the basis of all available data and information, the device meets the banning standard set forth in the Federal Food, Drug and Cosmetic Act.

The FDA believes regulatory action must be based on scientific data. While the majority of women who develop BIA-ALCL have had textured implants, there are known cases in women with smooth-surface breast implants and many reports do not include the surface texture of the implant at the time of diagnosis. We are focused on strengthening the evidence generated to help inform future regulatory actions and to assure that women and providers are adequately informed of the risk of BIA-ALCL, including that the risk is higher with the use of textured implants, albeit still low. We are still investigating the cause of the association and we will continue to monitor, assess and report our findings as we continue to strengthen our evidence collected so that women and providers can be better informed about BIA-ALCL as they consider breast implants.

Taken together, we believe these efforts to improve communication and focus on evidence generation will contribute significantly to improving the safety of breast implants and want to share that many of these efforts are already underway. We are committed to making a difference for women's health and will continue working towards ensuring we understand the benefits and risks of these devices, and that women have the most complete information available to make important breast implant decisions.

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.

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Related Information

- FDA: Breast Implants (/medical-devices/implants-and-prosthetics/breast-implants)
- FDA: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting Announcement (/advisory-committees/advisory-committee-calendar/march-25-26-2019-general-and-plastic-surgery-devices-panel-medical-devices-advisory-committee)
- FDA: BIA-ALCL (/medical-devices/breast-implants/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl)
- FDA: Warning letters to two breast implant manufacturers for failure to comply with post-approval study requirements (/news-events/press-announcements/fda-issues-warning-letters-two-breast-implant-manufacturers-failure-comply-post-approval-study)

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