Statement on FDA's Commitment to Studying Breast Implant Safety

Our perspective today is based the decades of work we have done to assess and communicate the benefits and risks of breast implants.

September 14, 2018 By Food and Drug Administration (FDA)

Statement from Binita Ashar, M.D., of the FDA's Center for Devices and Radiological Health on agency's commitment to studying breast implant safety

Choosing to obtain a breast implant, whether for augmentation or reconstruction, is a deeply personal choice, from the initial decision to undergo breast implant surgery to the size, material and surface texture. These types of decisions should be discussed between a patient and their provider in a transparent and balanced way with clear information about the benefits and risks of the breast implants and the procedure.

As a public health agency, we play an important role in ensuring that patients seeking breast augmentation and breast reconstruction have accurate information regarding the benefits and risks of breast implants to make informed decisions on whether implants may be right for them. Part of this role is to continuously monitor the safety of devices, like implants, once they are being used in patients, including examining adverse event reports that are submitted to the agency as well as reviewing postmarket studies and available scientific literature to enhance our understanding of a device's benefit-risk profile.

The FDA has worked extensively to monitor, assess and take action to protect patients with regard to breast implant safety over the last several decades. We have regularly communicated about risks associated with breast implants, such as capsular contracture, implant rupture and breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). Part of our efforts in continuously monitoring device risks include a responsibility to communicate clearly about our perspective on the safety and efficacy of the products we regulate when new information becomes available. That is why today we're communicating about the editorial response we published in the Annals of Surgery regarding an external assessment of data that the researchers claim shows evidence of an increased risk of certain connective tissue conditions, such as rheumatoid arthritis and scleroderma, in patients with breast implants. We commend the work of our peers in studying the benefits and risks of breast implants. However, we respectfully disagree with the authors conclusions. In our editorial response, we note our concerns with significant shortcomings with the study's methodology and how the data is presented and concluded, including inconsistences in the

data and potential sources of bias. Because of these concerns, we urge the public and healthcare community to view this external assessment's conclusions with caution.

We understand that there are concerned patients with breast implants who are experiencing a range of symptoms that may or may not be related to their breast implants. We take these concerns seriously and are committed to continuing to work with patient groups, surgeons and scientists to further assess this issue. While the agency continues to believe that the weight of the currently available scientific evidence does not conclusively demonstrate an association between breast implants and connective tissue diseases, we respect studies like the ones published in Annals of Surgery by our peers. These studies contribute to our discourse on this topic, but more evaluation is required.

The FDA has in the past thoroughly assessed and reported the results of the large post-approval studies that were used as a basis for today's Annals of Surgery study. Our interim and final findings were communicated in a 2011 Safety Update and on the FDA post-approval study websites (for manufacturers Allergan and Mentor) in 2015 and 2018. We noted at the time of the Safety Update that breast implants are not lifetime devices and there is insufficient information to show an association between silicone gel-filled breast implants and connective tissue disease, breast cancer or reproductive problems.

Our perspective today is based the decades of work we have done to assess and communicate the benefits and risks of breast implants. The steps we've taken date back to 1988, when, based on emerging safety concerns, the FDA upclassified breast implants from Class II (moderate risk) to Class III (high risk) devices requiring manufacturers to submit a premarket approval application before the device could be marketed. In 1992, the FDA expressed concern about the available safety data for silicone implants and announced a voluntary moratorium on all silicone implant sales in the U.S. pending further review of safety information. This moratorium was lifted in 2006 with the approval of new silicone implants that met the FDA's standards for safety. As conditions of approval, each manufacturer was required to conduct six post-approval studies to further characterize the safety and effectiveness of their silicone gel-filled breast implants and to answer additional scientific questions about the long-term safety of breast implants that the premarket clinical trials were not designed to answer. As part of these post-approval studies, the FDA collected data from the studies totaling nearly 100,000 patients. We communicated the results of these post-approval studies in our 2011 report, which noted that that breast implants are not lifetime devices and have a reasonable assurance of safety and effectiveness when used as labeled.

Also 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 2011, the FDA has regularly updated the information available on our website regarding known BIA-ALCL cases, including deaths and known risks.

Collectively, all of our actions demonstrate our commitment to fulfilling our public health mission

of ensuring patient access to safe and effective products. As part of our recently released Medical Device Safety Action Plan, we committed to streamlining and modernizing how we implement postmarket actions to address device safety issues to make our responses to risks more timely and effective.

For instance, we have coordinated with the American Society of Plastic Surgeons and the Plastic Surgeons Foundation to develop the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma (ALCL) Etiology and Epidemiology (PROFILE), which collects real world data regarding patients who have a confirmed diagnosis of BIA-ALCL. The data collected from this registry as well as medical literature, meetings with patient advocates, and our own post-approval studies have contributed to our understanding of BIA-ALCL and our communication updates to the public regarding BIA-ALCL.

Additionally, we are working with multiple stakeholders to facilitate the development of the National Breast Implant Registry (NBIR) to provide a platform for evaluating real world data on the safety and performance of breast implants that will greatly contribute to helping us evaluate data from providers regarding their patients with implants. We have heard from patients who are concerned that their implants may be connected to other health conditions, like chronic fatigue, cognitive issues and muscle pain. While the FDA does not have evidence suggesting breast implants are associated with these conditions, information from NBIR may help us identify risk factors for complications, such as a patient's own medical history, the specific type of operation, the type of implant used, and concomitant use of other medical devices. Greater information-gathering from a registry like NBIR will add helpful information to the FDA's already extensive review of our own medical device reports, review of medical literature, assessment of post-approval studies, and meetings with patients.

The FDA remains committed to thoughtful, scientific, transparent, public dialogue concerning breast implant safety and effectiveness.

Last week, the FDA's multi-disciplinary breast implant team and I had the opportunity to meet with a patient advocacy group focused on breast implant related issues. This group provided their perspectives as patients and researchers regarding breast implants and identified several opportunities for improved understanding and communication regarding breast implant risks and benefits. The information they shared is valuable and important for us to be aware of to be effective regulators serving the needs of patients.

We appreciate feedback directly from patients and are looking for more ways to incorporate the patient experience so that we focus on the things that matter to them. In light of the growing science regarding the benefits and risks of breast implants, we intend to hold a public meeting of the General and Plastic Surgery Devices Panel of our Medical Devices Advisory Committee in 2019 to ensure that patients and health care providers continue to have accurate, scientifically sound information about breast implant safety and effectiveness, and to promote public dialogue on the issue. Advisory committees like this one serve to provide the FDA with independent advice from outside experts. This committee will include several members from the medical community, academia and industry and, importantly, patient representatives. These individuals will engage in

thoughtful discussion on currently available scientific information. There will also be an opportunity during the advisory committee meeting for members of the public to provide comments regarding specific topics to the panel and the FDA.

To date, our work has resulted in important new information about breast implant risks being communicated to patients to ensure they understand the benefits and risks of these devices. We respect the work of those in the research community to add to the thoughtful discussion on this topic. It highlights the importance of continuing to monitor, assess and advance our understanding of breast implant safety.

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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 statement was originally published on the Food and Drug Administration website on September 14, 2018.

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