24 Hour Summary
General and Plastic Surgery Devices
Advisory Committee Meeting
March 25 & 26, 2019

Introduction:

On March 25 & 26, 2019, FDA conducted a Public Advisory Committee meeting to discuss the risks and benefits of breast implants indicated for breast augmentation and reconstruction. The following are topics that were discussed:

- breast implant associated anaplastic large cell lymphoma (BIA-ALCL)
- systemic symptoms reported in patients receiving breast implants
- the use of registries for breast implant surveillance
- MRI screening for silent rupture of silicone gel filled breast implants
- the use of surgical mesh in breast procedures such as breast reconstruction and mastopexy
- the use of real-world data and patient perspectives in regulatory decision making
- best practices for informed consent discussions between patients and clinicians.

Device Description:

Breast implants are medical devices that are implanted under the breast tissue or under the chest muscle to increase (augment) breast size or to rebuild (reconstruct) breast tissue after mastectomy or other damage to the breast. They are also used in revision surgeries, which correct or improve the result of an original surgery.

There are two types of breast implants approved for sale in the United States: saline-filled and silicone gel-filled. Both types have a silicone outer shell.

Panel Deliberations/FDA Questions:

March 25, 2019 (Day 1): The discussion focused on BIA-ALCL, systemic symptoms reported in patients receiving breast implants, and the use of registries for breast implant surveillance. To provide context for the deliberations, a patient advocate, FDA and international regulators from the European Union Taskforce and Health Canada commented on the important issues to be covered in the meeting.

The next presentations began with an FDA overview of the FDA mandated post-approval studies (PAS) followed by the four breast implant manufacturers presenting data on their PAS studies, BII, and BIA-ALCL. FDA then presented an analysis of the BII and BIA-ALCL Medical Device Report (MDR) data and a summary of the post-approval study data related to BII. The afternoon presentations discussed the use of registries and other institutions efforts to collect data on breast implant safety including the experience from National Breast Implant Registry (NBIR), Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma etiology and Epidemiology (PROFILE), MD Anderson Cancer Center, and the National Center for Health Research. This was followed by a presentation on the Autoimmune Syndrome Induced by Adjuvants (ASIA) and BII.

Finally, the Panel discussed and made recommendations on FDA questions related to BIA–ALCL and BII. The panel discussed risk factors for BIA-ALCL, noting there is a wide range of BIA-ALCL incidences reported depending on the method of texturing. The Panel also stressed the importance of having information on implant surface type. The risks of BIA-ALCL were discussed along with a discussion of benefits plastic surgeons ascribe to the textured breast implants. The Panel also discussed the use of registries and the importance of capturing patient-reported outcomes and the need to strike the right balance between data collection requirements and optimizing participation in the registry.

The BII discussion focused on the constellation of symptoms reported by patients and the lack of defined diagnostic criteria for BII. The Panel indicated that many of the symptoms reported have other causes and stressed the importance of an appropriate control group to investigate how the numbers reported in breast implant patients compare to the incidence in the general population. The Panel also noted that there may be multiple factors which could affect these symptoms including genetic predisposition and patient and family history.

March 26, 2019 (Day 2): The panel completed the discussions on BII and discussed MRI screening for silent rupture of silicone gel filled breast implants, the use of surgical mesh in breast procedures such as breast reconstruction and mastopexy, and best practices for informed consent discussions between patients and clinicians.

FDA began with presentations on clinical and regulatory considerations on the use of surgical mesh in breast reconstruction and mastopexy. This was followed by a presentation on the data available in the Mastectomy Reconstruction Outcomes Consortium. In the afternoon, FDA and the four breast implant manufacturers presented data on MRI screening for silent rupture, as well as perspectives on patient education and informed consent. Finally, the American College of Radiology presented criteria for screening for breast implant rupture. Finally, a presentation on the Patient Informed Consent Best Practices was provided, and representatives of plastic surgery professional societies provided presentations on the importance of patient education, safety and research.

The Panel discussed and made recommendations on FDA questions related to the use of surgical mesh in breast procedures such as breast reconstruction and mastopexy, MRI screening and patient informed consent. The panel discussed risks and benefits of surgical mesh use in breast procedures with a focus on breast reconstruction. The challenges in clinical trial design were also discussed including the importance of an appropriate control group, the difficulty in finding a control for the pre-pectoral approach, and the evidentiary requirements for assessing the safety, effectiveness and benefit/risk profile for the implantation of surgical mesh for these breast surgical procedures. The panel also discussed the use of mesh in mastopexy procedures and potential risks of lactation as well as its impact on imaging of breast tissue.

The Panel made recommendations on MRI screening including a consensus to remove the current FDA MRI screening recommendations, and to adopt screening recommendations that begin between years 5 and 6 post surgery, and every 2-3 years after that. The use of alternatives to MRI were discussed, and ultrasound was recommended as an acceptable alternative for screening asymptomatic patients. For symptomatic patients as well as patients with equivocal ultrasound results, the panel recommended MRI for detection of ruptures. Finally, the panel discussed the informed consent process and agreed that the process should be improved to better inform patients about the risks posed by breast implants, and that this effort should be shared with all parties including FDA, the plastic surgery community the surgeons themselves, professional societies, and patient advocacy groups.

Open Public Hearing (OPH)

The Panel heard 4 hours of presentations on both days from patients, clinicians, and other stakeholders. Patients and patient advocacy groups shared a variety of experiences, many regarding adverse events they had experienced following breast implant placement including BIA-ALCL and BII, and some with positive experiences following breast implant surgeries. A majority of patients highlighted the importance of the informed consent process, with many patients noting that they were not told of the serious risks that accompany breast implants, including the risk of BIA-ALCL and BII. They recommended that a black box warning be added to breast implant labeling, and that a standardized checklist be required as part of the informed consent process. Some speakers recommended that FDA ban textured breast implants or all breast implants, while others emphasized the need to make options available to patients and allow them to make an informed decision. Others discussed the importance of collecting long-term data through registries and other technologies, as well as the potential for patient advocacy groups and professional societies to collaborate on physician and patient education.

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