FDA CDRH General and Plastic Surgery Devices Advisory Committee Meeting

March 25 & 26, 2019

FDA White Oak Campus Building #31, Great Room
10903 New Hampshire Avenue
Silver Spring, Maryland

Considering the patient perspective, the committee will discuss the long-term benefits and risks of breast implants for achieving breast augmentation and reconstruction in light of the safety concerns related to breast implant associated anaplastic large cell lymphoma (BIA-ALCL) and several symptoms informally referred to as breast implant illness (BII). The committee will consider the post approval studies performed for silicone gel filled breast implants, the collection of real-world evidence through breast implant registries, and MRI screening for silent breast implant rupture recommendations. In addition, there will be a discussion on issues associated with use of surgical mesh in breast procedures such as breast reconstruction and mastopexy. The deliberations will conclude with the development of action items for all stakeholders to improve patient education and informed consent about the risks and benefits of breast implants.

Breast implants for breast augmentation/reconstruction include implants manufactured by Allergan, Ideal Implant Inc., Mentor Worldwide LLC and Sientra.

March 26, 2019

8:00 a.m.	Call to Order and Opening Remarks Introduction of the Committee	Frank R. Lewis, Jr., MD Panel Chair
8:05 a.m.	Conflict of Interest Statement	Patricio Garcia, MPH U.S. FDA/CDRH
8:10 a.m.	Day 1 Summary and Overview of Day 2	Cynthia Chang, PhD U.S. FDA/CDRH

Use of Surgical Mesh in Breast Reconstruction and Mastopexy

8:20 a.m.	The Use of Surgical Mesh in Breast Reconstruction and Mastopexy – Clinical Overview	Michael Delong, MD U.S. FDA/CDRH
8:30 a.m.	The Regulation of Surgical Mesh for Breast Indications	Joe Nielsen, PhD U.S. FDA/CDRH
8:35 a.m.	Mastectomy Reconstruction Outcomes Consortium (MROC)	Edwin Wilkins, MD University of Michigan

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9:05 a.m.	Clarifying Questions from the Panel	
9:20 a.m.	Open public comment	
10:20 a.m.	Break	
10:30 a.m.	Clarifying Questions from the Panel	
10:45 a.m.	Recommended Next Steps	Panel Deliberations
12:45 p.m.	*Lunch*	

Utility of MRI for Breast Implant Silent Rupture Screening
Patient Education and Informed Consent

1:15 p.m.	The History of Silent Rupture Screening and Informed Consent for Breast Implants	David Krause, PhD U.S. FDA/CDRH
1:20 p.m.	Industry Presentations on Core Study MRI Data/Patient Education and Informed Consent	Allergan Mentor Sientra Ideal
1:50 p.m.	FDA Presentations on Core Study MRI Data/Patient Education and Informed Consent	Sung W. Yoon, MD U.S. FDA/CDRH
2:00 p.m.	MRI for Breast Implant Rupture Screening	Stamatia Destounis, MD American College of Radiology (ACR)
2:15 p.m.	Patient Inform Consent Best Practices	Jonathan Green, MD National Institutes of Health
2:30 p.m.	The ASPS/PSF's Commitment to Patient Education, Safety and Research.	Lynn Jeffers, MD American Society of Plastic Surgeon and the Plastic Surgery Foundation (ASPS/PSF)

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2:40 p.m.	The ASAPS/ASERF's Commitment to Data Collection and Scientific Data-driven Research to Support Physician Education, Patient Access and Choice	W. Grant Stevens, MD American Society for Aesthetic Plastic Surgery and Aesthetic Surgery Education and Research Foundation (ASAPS/ASERF)
2:50 p.m.	Clarifying questions from the panel	
3:05 p.m.	*Break*	
3:15 p.m.	Open Public Session	
4:15 p.m.	Clarifying questions from the panel	
4:30 p.m.	Recommended Next Steps	Panel Deliberations
6:30 p.m.	Day 2 Adjourns	