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.
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

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)
The ASAPS/ASERF’s Commitment to Data Collection and Scientific Data-driven Research to Support Physician Education, Patient Access and Choice

Clarifying questions from the panel

Break

Open Public Session

Clarifying questions from the panel

Recommended Next Steps

Panel Deliberations

Day 2 Adjourns