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 a number of 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 25, 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
National and International Perspectives, Meeting Scope, and the Patient Perspective		
8:10 a.m.	Opening Remarks	Binita Ashar, MD U.S. FDA/CDRH
8:15 a.m.	Welcome from FDA's Office of Women's Health	Kaveeta Vasisht, MD, PharmD U.S. FDA/Office of Women's Health
8:20 a.m.	European Union Taskforce Statement	Josef Zündorf, MD German Federal Institute for Drugs and Medical Devices
8:30 a.m.	Ongoing Regulatory Actions and Activities – Breast Implants	Amanda Jones Patrick Fandja Health Canada

8:40 a.m.	Breast Augmentation and Reconstruction – Clinical Overview	Steven Nagel, MD U.S. FDA/CDRH
8:50 a.m.	What patients who have had breast implants think that patients contemplating breast implants should know	Jamee Cook Breast Implant Victim Advocacy
Status of Industry Sponsored Breast Implant Studies and reports of Breast Implant Illness (BII) and BIA-ALCL		
9:20 a.m.	Overview of FDA mandated Post-Approval Studies	Nilsa Loyo-Berrios, PhD U.S. FDA/CDRH
9:25 a.m.	Industry Presentations on PAS status/Breast Implant Illness/BIA-ALCL	Allergan Mentor Sientra Ideal
10:15 a.m.	*Break*	
10:25 a.m.	Clarifying questions from the Panel	
10:40 a.m.	FDA Presentation on BII and BIA-ALCL Medical Device Reporting (MDR)	Karen Nast, RN U.S. FDA/CDRH
10:55 am	FDA Presentation on BII from PAS	Michael DeLong, MD U.S. FDA/CDRH
11:10 am	Clarifying questions from the Panel	
11:20 am – 12:20 pm	Open Public Comment	
12:20 pm	Clarifying questions from the panel	
12:35 pm	*Lunch*	
The Use of Registries to Understand of BII and BIA-ALCL		
1:10 pm	U.S. National Breast Implant Registry (NBIR) and Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma etiology and Epidemiology (PROFILE) Status Update	Andrea Pusic, MD Plastic Surgery Foundation
1:25 pm	MD Anderson Experience in BIA-ALCL	Mark Clemens, MD M.D. Anderson Cancer Center

1:40 pm	Autoimmune Syndrome Induced by Adjuvants (ASIA) and BII	Jan Willem Cohen Tervaert, MD, PhD University of Alberta
2:05 pm	Analysis of symptoms and diagnoses of 400 women before and after having their breast implants removed: Implications for BII, Registries, and Informed Consent	Diana Zuckerman, PhD National Center for Health Research
2:20 pm	Clarifying questions from the panel	
2:35 – 3:35 pm	Open public comment	
3:35 pm	*Break*	
3:45 pm	Clarifying questions from the panel	
4:00 pm	Recommended Next Steps	Panel Deliberation
6:00 pm	Day 1 Adjourns	