Breast Implant FDA/Regulatory History

2006
- 4/1992: investigational devices
- 1/1992: voluntary moratorium on the sale and implantation
- 4/1991: Final Rule call for PMAs
- 1988: Reclassified as Class III
- 1978: Class II device (panel)
- 1963: silicone gel-filled Bi on market (pre-amendment)

Before 2006
- 11/2006: FDA approved two silicone gel-filled PMAs with 6 PASs each
- 3/2006: FDA updated BIA-ALCL website with new MDR and literature data
- 2011: NBIR pilot phase II

2016
- 2/2013, 6/2013: approved two silicone gel BIs (higher degree of cohesivity) with 6 PASs each
- 2012
- 2011 initiated development/data collection of PROFILE registry
- 8/2011: Bi Postmarket Advisory Panel
- 5/2011: updated safety of silicone gel-filled Bi
- 1/2011: posted ALC on FDA website

2011
- 10/2012: started working on developing National BI registry
- 3/2012: approved a silicone gel-filled Bi from a new manufacturer

2010
- 12/2010: completed NBIR pilot phase I

2010
- 12/2010: updated PROFILE protocol and data collection forms

National Breast Implant Registry (NBIR)

- Collaboration between ASPS, PSF, FDA, and Breast Implant Device Manufacturers
- Safety Surveillance Registry and Quality Improvement Initiative
- Tracking patient safety, effectiveness, and outcomes for reconstructive and aesthetic procedures
- Multi-year registry that collects patient demographic, risk/co-morbidity, procedural, and complication/adverse event data related to breast implants
- Vehicle in which Device Tracking Data elements can get to the Manufacturers for their federally mandated Device Tracking purposes, as well as pre and post market studies.
- Plans to launch broadly in early 2018

Patient Registry and Outcomes for Breast Implants and ALCL Etiology and Epidemiology (PROFILE)

Primary goal: to better understand the role of breast implants in the etiology of primary ALCL in patients with breast implants, and to identify potential risk factors and criteria detection and management of this disease.

ALCL Post-Market Surveillance

Methods

Two data sources (literature and medical device adverse events reports (MDRs)) are extracted and cleaned systematically. Analyses are conducted by each data source, regarding:

- implant fill (e.g. silicone gel, saline)
- implant surface (e.g. textured, smooth)
- time to diagnosis/reporting
- ALCL biomarkers
- Other clinical data

Results

Through February 1, 2017, the FDA received a total of 359 medical device reports (MDRs) of breast implant associated anaplastic large cell lymphoma (BIA-ALCL), including nine deaths. There are 231 reports with data on surface information at the time of reporting. Of these, 203 were on textured implants and 28 on smooth implants. There are 312 reports with data on implant fill type. Of these, 186 reported the use of silicone gel-filled implants, and 126 reported the use of saline-filled implants.

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