Building National Infrastructure for Postmarket Surveillance of Silicone Breast Implants

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Overview of Presentation

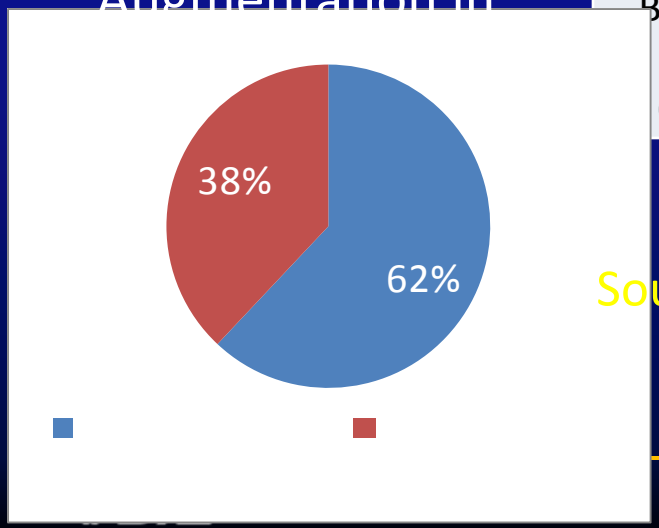
- Breast Implant Procedure Trends
- Silicone Gel Breast Implants Regulatory History
- Post-Approval Studies (PAS) as Conditions of Approval
- Innovative Methodologies for PAS
- Development of Breast Implant Registries
- Next Steps and Final Remarks

Breast Implants Procedure Trends

- Breast augmentation continues to be the top cosmetic surgical procedure

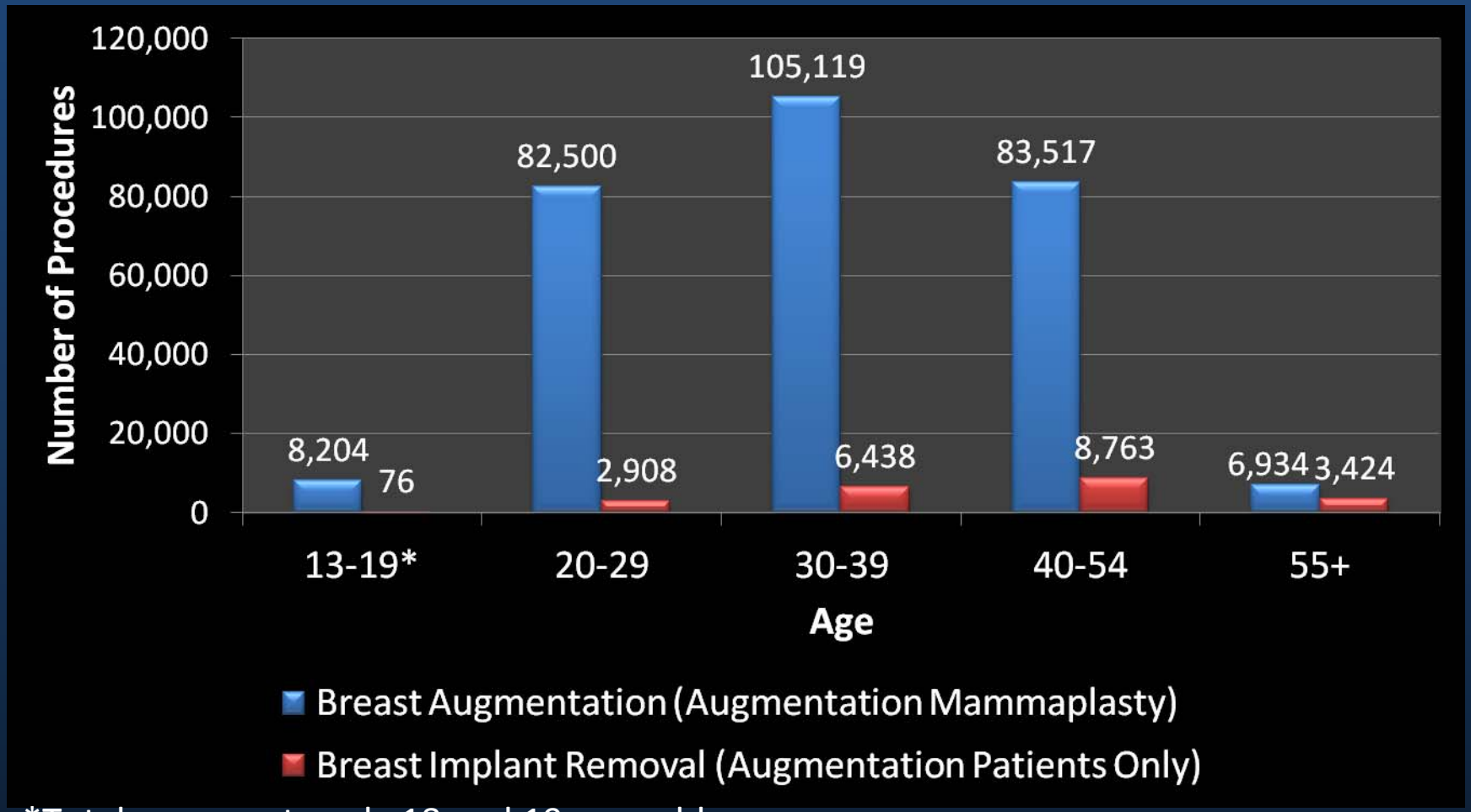
- Breast Augmentation in

Procedure	2012	2011	2000	% Change 2012 vs. 2000
Breast Augmentation	286, 274	307,180	212,500	35%
Breast Implants Removals (Augmentation)	21,609	22,271	40,787	-47%
Breast Reconstruction	91,655	96,277	78,832	16%
Breast Implants Removals (Reconstruction)	16,596	15,735	16,287	2%



Source: ASPS Plastic Surgery Statistics 2012 Report

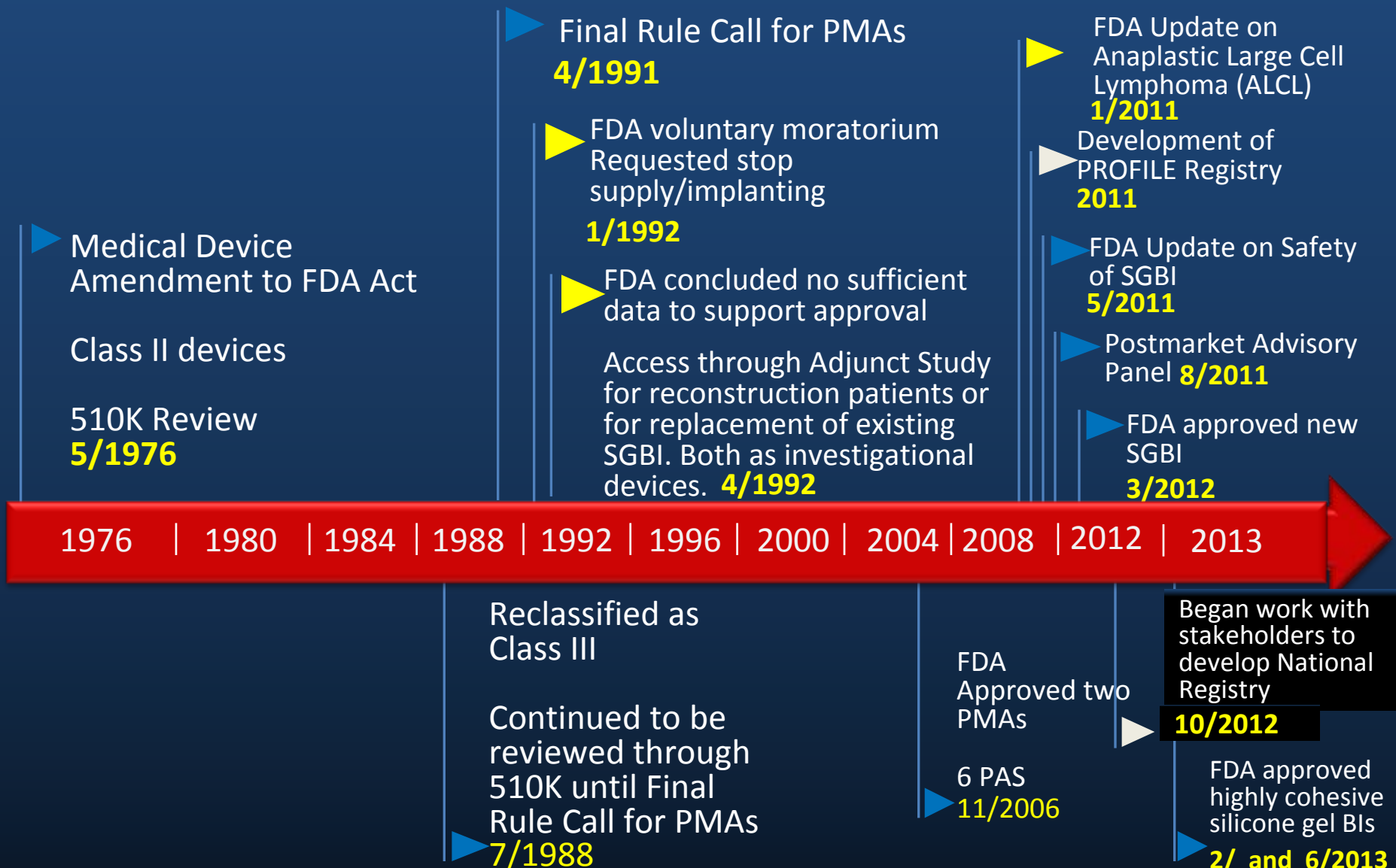
Breast Implants Procedures by Age



*Total represents only 18 and 19 year olds.

Source: ASPS Plastic Surgery Statistics 2012 Report

Silicone Breast Implants Regulatory History



Post-Approval Studies (PAS) for 2006 PMA Approvals

1. CORE Study- 10-years
2. Adjunct Study- 5-years
3. New Enrollment: LARGE Study, 10-years
4. Informed Decision Survey
5. Focus Group Study
6. Device Failure Studies

- Both PMAs have fulfilled conditions no. 1-2, 4-5
- LARGE studies ongoing
  - Completed enrollment of 40,000+ subjects
  - Difficulty with follow-up rate

Innovative Approaches for New Approvals

- Post-Approval Studies
  - Case-Control Studies for rare endpoints
  - Smaller cohort studies for less rare endpoints
    - Informed decision process and device failure analysis within the smaller cohort studies
  - Continued follow-up of premarket cohorts
  - Focus Groups
  - Non-PAS explant analyses
- Possibility of Using National Infrastructure

Development of National Breast Implant Registries

Patient **R**egistry and **O**utcomes **F**or breast **I**mplants and anaplastic large cell **L**ymphoma etiology and **E**pidemiology (PROFILE) study

- Covered in NBIR CRADA between ASPS and FDA, with additional participation from manufacturers and NIH.
- To collect data on suspected and/or confirmed cases of ALCL among women with Breast Implants
- Pathology reports reviewed by subject matter expert for case confirmation
- Currently accepting case reports
  - http://www.thepsf.org/research/clinical-impact/profile.htm

National Breast Implant Registry

- Collaboration via CRADA between:
  - Food and Drug Administration (FDA)
  - American Society of Plastic Surgeons (ASPS)
  - Manufacturers and Patient Representatives
- To collect data on all subjects who receive breast implants in the US
- Vehicle for:
  - Postmarket Surveillance
  - Post-Approval Studies
  - Device Tracking
  - Quality Improvement
  - Observational Research
  - Patients Contribution towards Improving Outcomes among Women with BI; and information source

National Breast Implant Registry (cont.)

- Collaborators have Identified
  - Surveillance Questions
  - Questions that can be answered with predetermined sample size
  - Questions for evidence review by a third party

National Breast Implant Registry (cont.)

- Intake and re-op Case Report Forms developed
  - Harmonization with Australian Registry
- Data Collection
  - Intake: Procedure data, patient characteristics, device data, physicians data, for all subjects
  - Re-op: reasons, device information, etc.
- Follow-up
  - As needed for surveillance (all enrolled)
  - As needed for specific questions
    - Sub-groups of subjects enrolled in studies

Next Steps

- NBIR Registry expected to be launched this year
  - Methodology for long term follow-up
- Systematic Evidence Review
- PROFILE collecting cases
- Continue process to identify more efficient methodologies to address difficulties with ongoing PAS

Final Remarks

- Strengthening National Infrastructure for Postmarket Surveillance of Medical Devices
  - Communicates timely, accurate, systematic, and prioritized assessments devices throughout their marketed life using high quality, standardized, structured, electronic health-related data;
  - Identify potential safety signals in near real-time from a variety of privacy-protected data sources;
  - Reduces the burdens and costs of medical device postmarket surveillance; and
  - Facilitates the clearance and approval of new devices, or new uses of existing devices

Final Remarks (Cont.)

- Strengthening National Infrastructure for Postmarket Surveillance of Medical Devices: Proposed Actions
  - Establishment of the (UDI) system and promote its incorporation into electronic health information;
  - Promote the development of national and international device registries for selected products;
  - Modernize adverse event reporting and analysis; and
  - Develop and use new methods for evidence generation, synthesis, and appraisal.

- Each stakeholder has important contribution
- Continue collaboration
- Address public health need

Questions?

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Resources

- National Medical Device Postmarket Surveillance Plan

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm

- FDA Update on the Safety of Silicone Gel-Filled Breast Implants

http://www.fda.gov/downloads/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/breastimplants/ucm260090.pdf

- ALCL in Women with Breast Implants: Preliminary FDA Findings and Analyses

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm

- PROFILE, Investigating ALCL and Breast Implants

http://www.thepsf.org/research/clinical-impact/profile.htm