

# Breast Implant Safety

**Mentor Worldwide, LLC**

**Day 1: March 25, 2019**

**General and Plastic Surgery Devices Panel (GPSDP) Meeting**



# Agenda

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## BIA-ALCL: Risk Factors and Monitoring

## Systemic Symptoms and Mentor Clinical Data

**Raina Dauria, MS**

Vice President, Regulatory Affairs

Mentor Worldwide, LLC

## Registries for Breast Implant Surveillance

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## Additional Q&A Responders

**John Canady, MD**

**Michael Schwiers, MS**

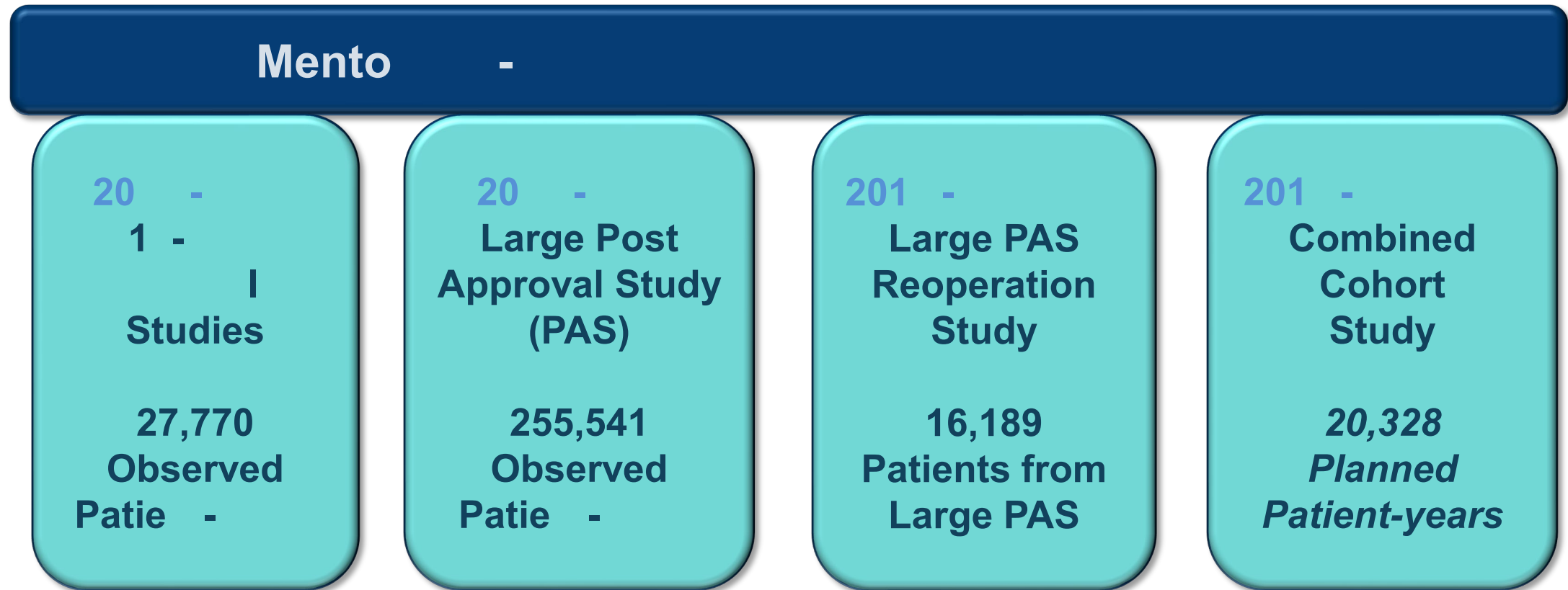
**Laura Vellucci, PhD**

**Warren Foust**

**Roger Wixtrom, PhD**

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# Data from Long-Term Clinical Studies Provide Support for Safety of Mentor Gel-filled Breast Implants



# BIA-ALCL

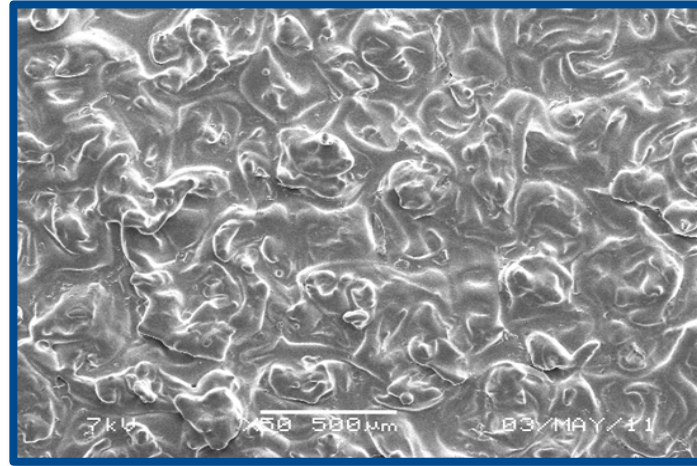
## Risk Factors and Monitoring

# Many Factors May Contribute to Development of BIA-ALCL

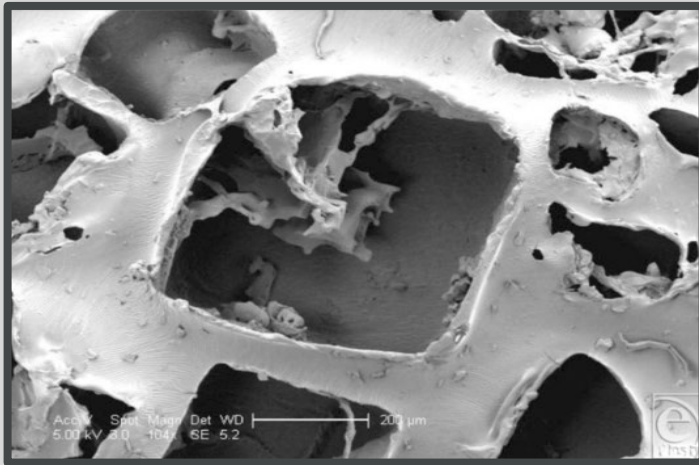
- Etiology likely multifactorial
  - Bacterial contamination/biofilm
  - Particulate matter in breast implant capsule
  - Genetic predisposition
  - Surface texture

# Implant Surface Texture Varies Greatly Across Manufacturers

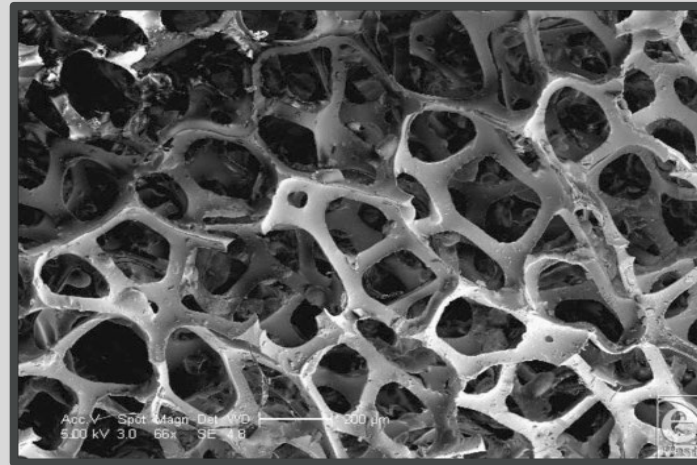
**Mentor  
Texture**



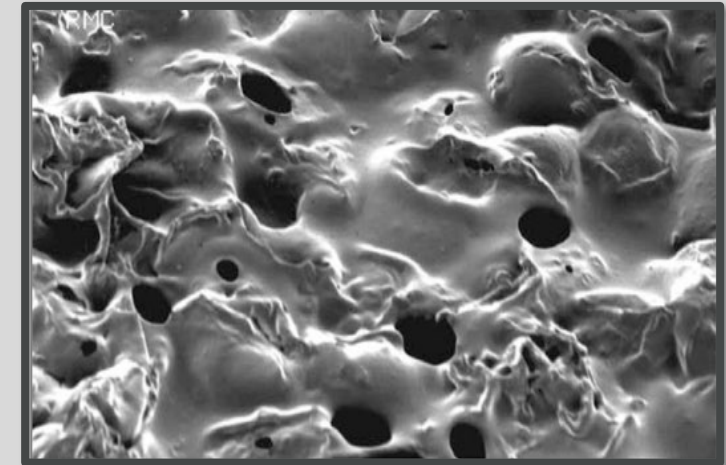
**Salt-Loss**



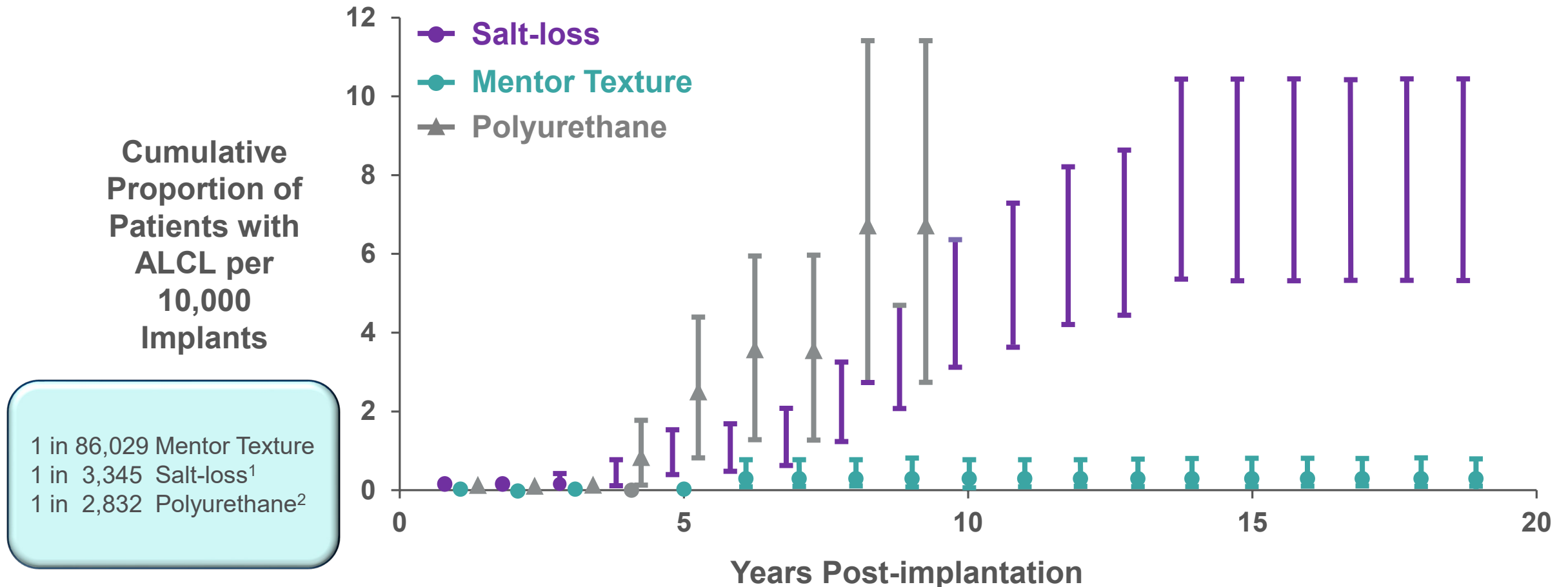
**Polyurethane**



**Gas Expansion**



# Risk of BIA-ALCL with Mentor Texture Implants Remains Low Over Time



# Multiple Studies Show Low Number of BIA-ALCL Cases with Mentor Texture Breast Implants

- Low number of BIA-ALCL cases with Mentor implants compared to total number of cases
- Mentor breast implant market share roughly equal to, or higher than, next leading manufacturer worldwide



# Textured Implants Offer Important Benefits for Patients

- Reduced risk of reoperation due to
  - Capsular contracture in subglandular augmentation patients
  - Asymmetry in reconstruction patients
- Designed to reduce rotation and implant movement
- Shaped implants only available with texturing

# Implant-Specific, Long-Term Clinical Data Best Reflect Implant Performance

- Breast implant classification systems designed to characterize surface properties
  - Not harmonized
  - Bench top; not clinically validated

# Systemic Symptoms

# Mentor Actively Monitors Systemic Symptoms

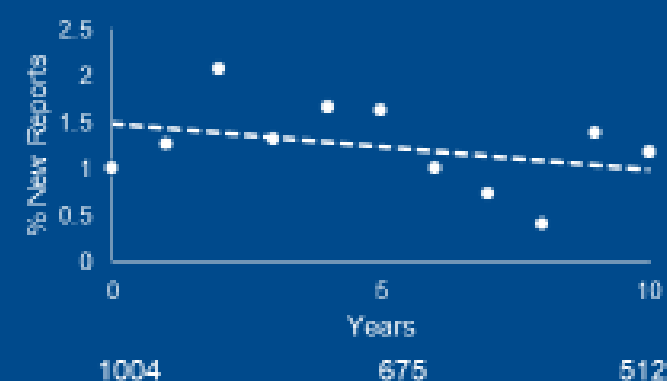
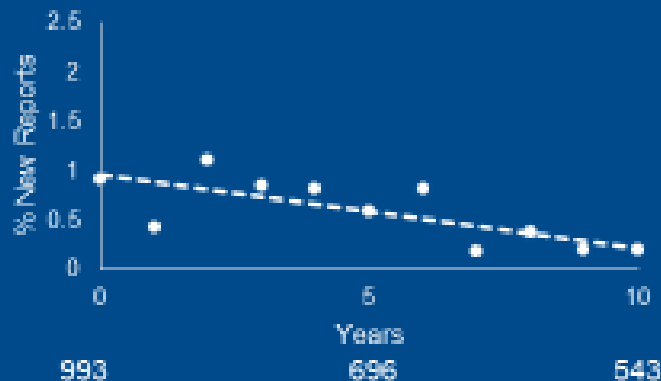
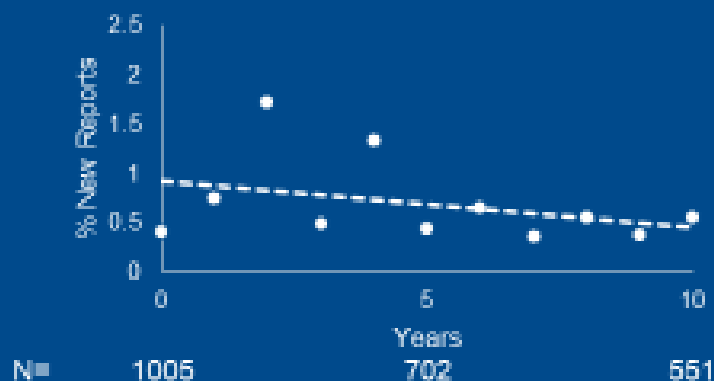
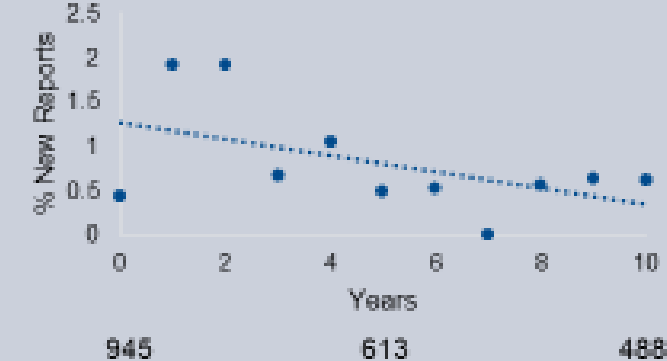
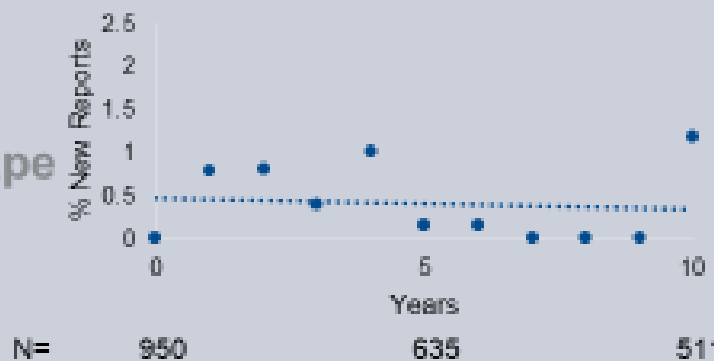
- Some women with breast implants report range of symptoms
- Symptoms may present differently in different patients
- Causes difficult to determine
- Mentor continuously monitors through clinical study data and safety surveillance activities

# Likelihood of Experiencing Systemic Symptoms Did Not Increase with Longer Implant Exposure Time

Fatigue

Insomnia

Joint Pain

MemoryGel  
CoreMemoryShape  
Core

MemoryGel Core (n= 1008)  
MemoryShape Core (n= 955)

# Registries for Breast Implant Surveillance

# Registries Can Address Open Questions Related to Breast Implant Safety

- NBIR allows surgeons and manufacturers to track and trend data
- PROFILE provides number of BIA-ALCL cases and detailed case information

# Recommendation for NBIR Sub-Study: Risk Factors

- Collection at baseline and ongoing
- Expanded patient factors
  - Family medical history
  - Complete breast implant history
  - Detailed medical history including allergies and medications
- Genetic marker testing
- Biofilm testing of capsule at time of explantation



# Recommendation for NBIR Sub-Study: Endpoints

- Collection at baseline and ongoing
- Symptoms (immunological/ rheumatological/ neurological)
  - Captured with severity
  - Pre-implantation, following implantation and post-explantation
- Validated quality of life survey (e.g. BREAST-Q™)

# Mentor Supports Data Transparency to Empower Women to Make Informed Choices

