FDA Patient Engagement Advisory Committee Meeting: Medical Device Recalls

October 6, 2021

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President + Co-founder

Breast Implant Safety Alliance (BISA Nonprofit)

MARIA GMITRO

- Former educator, harmed patient, patient advocate/consumer rep
- President & Cofounder, *Breast Implant Safety Alliance (BISA Nonprofit)*
- Director of Community Outreach & Patient Advocacy
  TrackMy Solutions
- Board Certified Patient Advocate, (expected November 2021)

MARIA GMITRO

- Board Member, *Breast Implant Collaborative Council*
- Board Member, *USA Patient Network*
- Representative/Advocate, *Medical Device Problems*
- Member, *NCHR Breast Implant Working Group*
- SC Delegate, *Patients Rising*
- Former Member, *Breast Device Collaborative Community*

THE PROBLEM

- Not enough “patient speak”
- Patients unaware of their UDI, what is actually implanted
- Patients keep devices longer than doctors keep records
- Manufacturers lost track of patients
- Scared, confused patients

Allergan is trying to track down women with breast implants it recalled nearly a year ago

The new ad campaign, aimed at women with 52,000 recalled implants, comes after an FDA request and a Fortune investigation.

BY **MARIA ASPAN**

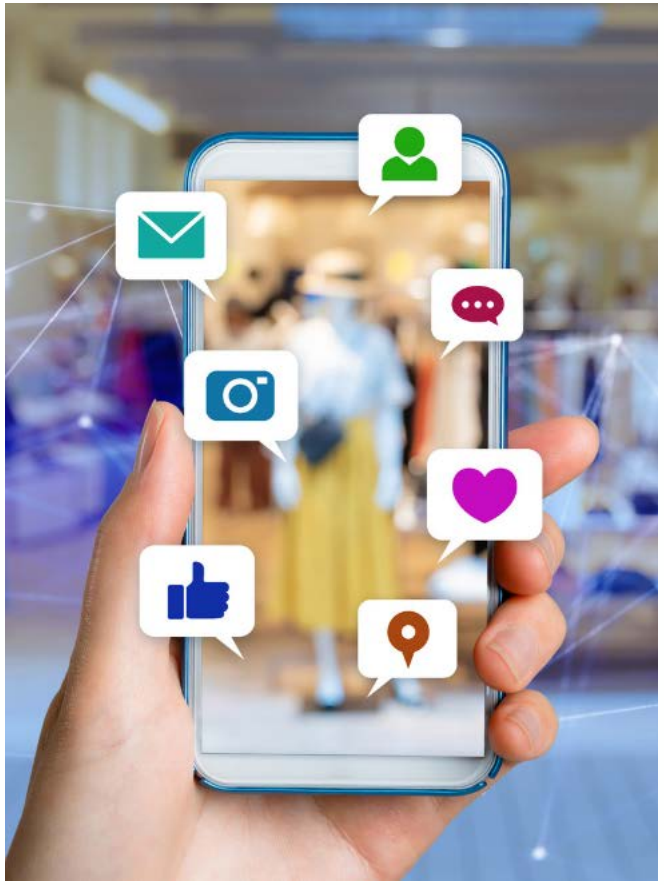
June 03, 2020 10:33 AM EDT

PATIENTS WANT TRUST AND...

- Trust the FDA, trust their doctors
- Device has been recalled with ability to search
- To know EXACTLY is in their bodies - UDI
- To know which devices have the most AERs
- Digital alerting notification in real time
- Simple symptom reporting
- Ability for caregivers to monitor
- Quick check for MRI safety usage

RECOMMENDATIONS…

- Bring into the digital age rather than just snail mail, use text messages and email
- Use social media to spread recall information (like the CDC on Covid-19, FDA on nutrition labels)
- Update MedWatch/bring back MedWatcher
- Use “patient speak” or language the average patient will understand (such as symptoms vs. AE)



RECOMMENDATIONS CONTINUED…

- Mandate UDI adoption and make patients aware of UDI
- Stop the sale of recalled medical devices
- Scan medical devices with UDI barcode to be sure the medical device is not recalled before it is placed into the patient
- Consult the auto industry - easily connect with consumers on recalls

MOST IMPORTANT

Three more women have died from cancer linked to Allergan's recalled breast implants, FDA says

At least 36 women have now died, according to new FDA data, and it's possible that more fatalities have yet to be counted.

BY **MARIA ASPAN**
August 24, 2020 12:48 PM EDT

- **Increase reviewing** of adverse event reports to identify possible recalls sooner
- When recalls happens, **review similar** devices already on the market.
- **Consider the patient harm** when a medical device is withdrawn rather than recalled - implications can be devastating or life changing
- **Better Informed** Consent/Communication
- **Bridge gap:** Patient/Physician/Manufacturer

FINAL THOUGHTS

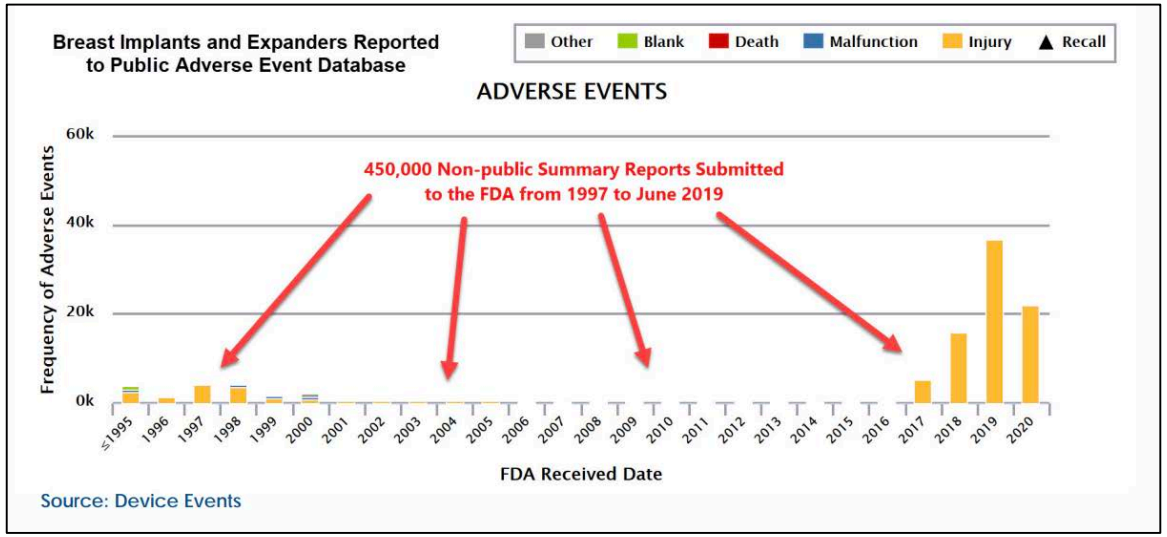
PATIENT SAFETY

FDA Kept Hundreds of Thousands of Breast Implant Incidents Hidden From Public

On the eve of a hearing about breast implant safety, the U.S. regulator revealed it has long known about vastly more complications than previously disclosed.

By Sasha Chavkin
Image: Scilla Alecci / ICIJ
March 25, 2019

- More **accurate data**
- **Increase funding** for post market surveillance
- FDA needs to **review AER faster**
- **Strict Consequences** for noncompliance



"Engage your patients. We are the ultimate stakeholders."

-Terri McGregor, Patient Advocate

Harmed patient, BIA-ALCL Cancer patient with recalled Allergan breast implants

THANK YOU

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