FDA PUBLIC MEETING:

MDUFA and Post-market Surveillance Topics

TrackMy™ Solutions

ENGAGE • EDUCATE • INFORM • INVOLVE

Maria Gmitro

Director of Community Outreach & Patient Advocacy, TrackMy Solutions

Co-founder & President, Breast Implant Safety Alliance

Board Member, Breast Device Collaborative Community

Board Member, Breast Implant Collaborative Council

Breast Device Representative/Advocate, Medical Device Problems

Member, NCHR Breast Implant Working Group

Harmed Patient

TrackMy™ Solutions

ENGAGE • EDUCATE • INFORM • INVOLVE

New does not necessarily mean safe.

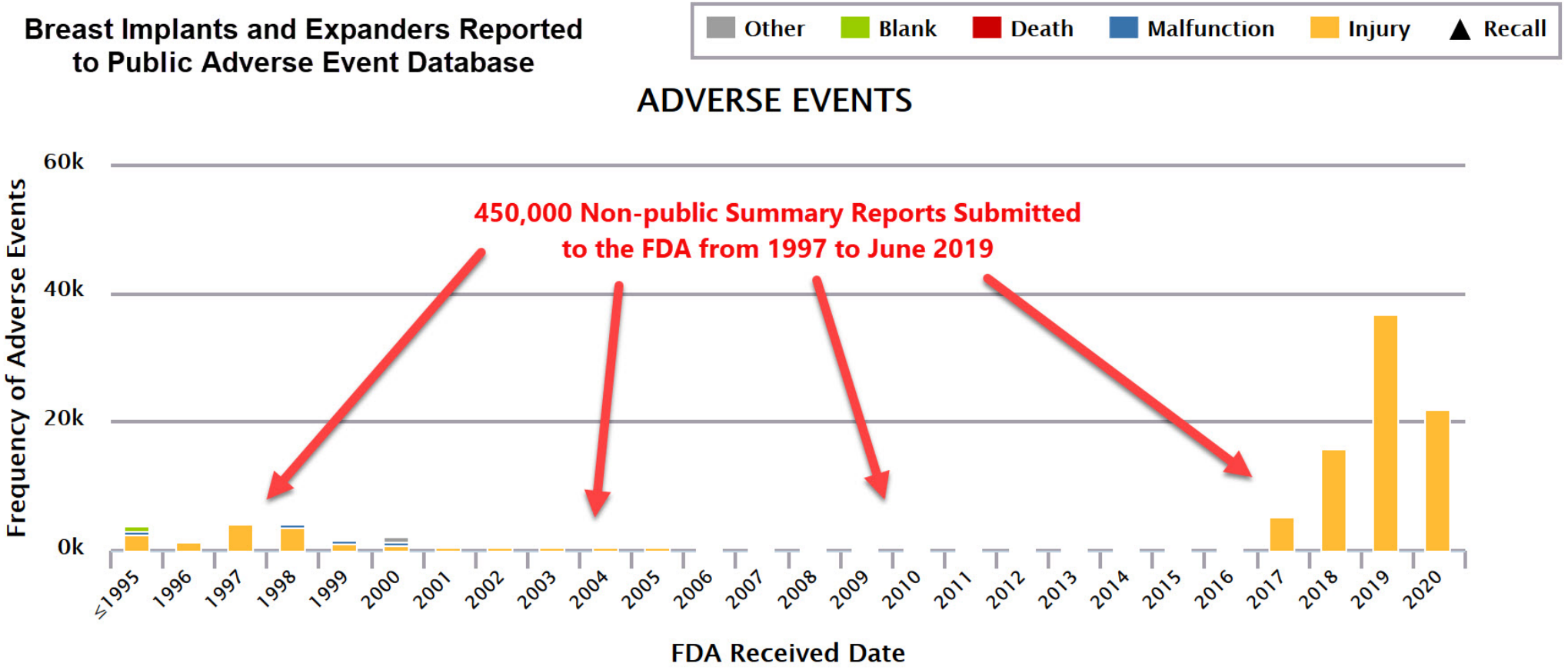
TrackMy™ Solutions
ENGAGE • EDUCATE • INFORM • INVOLVE

Problem

Adverse Events increase as devices are rushed to market.

TrackMy™ Solutions
ENGAGE • EDUCATE • INFORM • INVOLVE

Breast Implants and Expanders Reported to Public Adverse Event Database



Source: Device Events

TrackMy™ Solutions
ENGAGE • EDUCATE • INFORM • INVOLVE

How can healthcare professionals and patients make informed decisions without more accurate data?

TrackMy™ Solutions
ENGAGE • EDUCATE • INFORM • INVOLVE

Problem

Recalls drive the need for UDI utilization and better device tracking.

TrackMy™ Solutions
ENGAGE • EDUCATE • INFORM • INVOLVE

2019 - Allergan Recalls Natrelle Biocell Textured Breast Implants Due to Risk of BIA-ALCL Cancer

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

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

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

Source: Fortune

TrackMy™ Solutions
ENGAGE • EDUCATE • INFORM • INVOLVE

Device tracking and recall alerting is vital to patient safety.

TrackMy™ Solutions
ENGAGE • EDUCATE • INFORM • INVOLVE

Issues for Patients

DEVICE INFORMATION	DEVICE RECALLS	ADVERSE EVENTS
Unaware of exact device implanted or UDI	Unaware that a recall has occurred	Unaware that they can file an adverse event report
Unable to locate implant ID card or device information	Not informed by manufacturer or doctor of a recall	Adverse event reports not linked to UDI, less accurate
Keep device longer than records are kept	Learn about recall from TV commercial or social media	
Unable to locate data, records destroyed		

TrackMy™ Solutions
ENGAGE • EDUCATE • INFORM • INVOLVE

What now?

- Involve patients and public health experts from the start
- Increase funding for post market surveillance efforts
  - Increase efforts for analyzing adverse event reports
  - Better device tracking/alerting
  - Better communication to healthcare professionals and patients
- Issue mandatory recalls over voluntary
- Overall more patient focused - patient involvement

TrackMy™ Solutions
ENGAGE • EDUCATE • INFORM • INVOLVE

Patient Safety should always be the top priority.

TrackMy™ Solutions
ENGAGE • EDUCATE • INFORM • INVOLVE

Contact Information

Maria Gmitro

maria.gmitro@trackmysolutions.us

843-501-6873

www.trackmysolutions.us

TrackMy™ Solutions

ENGAGE • EDUCATE • INFORM • INVOLVE