FDA PUBLIC MEETING:

MDUFA and Post-market Surveillance Topics
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Harmed Patient
New does not necessarily mean safe.
Problem

Adverse Events increase as devices are rushed to market.
Breast Implants and Expanders Reported to Public Adverse Event Database

ADVERSE EVENTS

450,000 Non-public Summary Reports Submitted to the FDA from 1997 to June 2019

Source: Device Events

TrackMy™ Solutions
ENGAGE • EDUCATE • INFORM • INVOLVE
How can healthcare professionals and patients make informed decisions without more accurate data?
Problem

Recalls drive the need for UDI utilization and better device tracking.
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
Device tracking and recall alerting is **vital** to patient safety.
Issues for Patients

**Device Information**
- Unaware of exact device implanted or UDI
- Unable to locate implant ID card or device information
- Keep device longer than records are kept
- Unable to locate data, records destroyed

**Device Recalls**
- Unaware that a recall has occurred
- Not informed by manufacturer or doctor of a recall
- Learn about recall from TV commercial or social media

**Adverse Events**
- Unaware that they can file an adverse event report
- Adverse event reports not linked to UDI, less accurate
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
Patient Safety should **always** be the top priority.
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