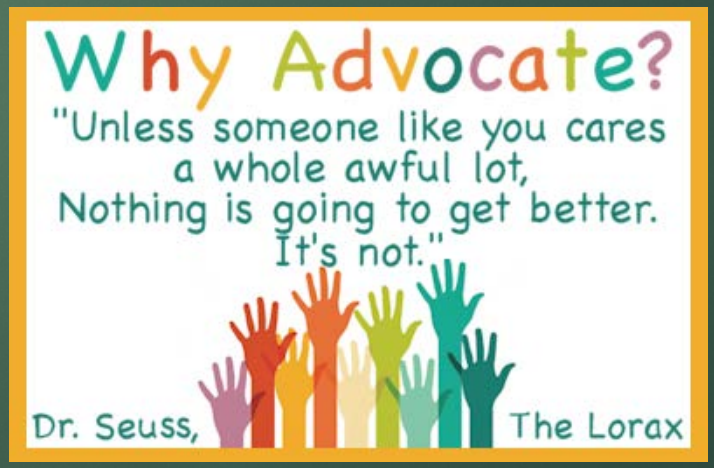
Life after…
The Breast Implant Recall & Breast Implant Associated Anaplastic Large Cell Lymphoma BIA-ALCL

KIMBERLY PLATT MSN RN CAPA



WHO AM I AND THE PURPOSE OF THIS PRESENTATION….

- 2004 volunteered to take part in the 410 McGhan textured breast implant study
- Survivor of and Advocate for BIA ALCL
- Presented my BIA ALCL case to the FDA March 2019
- Believes my story was part of what led to the Biocell recall
- Assist and comfort patients who have no idea what type of implants they have

July 2019

Allergan Voluntarily Recalls BIOCELL® Textured Breast Implants and Tissue Expanders

After the recall...

- Women realized they did not know the types of implants they had
  - Cards lost, never received, surgeons office closed records destroyed
  - Some women chose to prophylactically remove their implants for emotional safety because they simple did not want to take the risk
- Manufactures have very little knowledge about who have their implants
- A year after the Biocell Recall, the FDA messaged to Allergan they were not dedicating enough effort to find patients with their implants

Electronic Medical Record (EMR) Hinder or Help??

- With implementation of the EMR for large healthcare organization, will finding of the implant information be easier?

- With HIPPA restrictions, what can be done to assist patients that have implants of any kind, to find out what they exactly have?

Recalls and Supply Chain

Which Stores Sold Onions Recalled For Possible Salmonella?

August 6, 2020 by News Desk

ALDI

ALDI, in partnership with Onions 52, recalled red, white and yellow onions from select stores in Alabama, Arkansas, Florida, Georgia, Iowa, Illinois, Kentucky, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee and Texas. Sweet onions were removed from select stores in Arkansas, Iowa, Illinois, Missouri, Oklahoma and Texas. The onions were also available through Instacart orders. More details on the recalled onions:

- Sweet onions were packaged in a 2 pound bag, with UPC number 033383602912 in Arkansas, Iowa, Illinois, Missouri, Oklahoma, and Texas.
- Red onions, also packaged in a 2 pound bag with UPC number 033383601014, White onions sold in 2 pound bags with UPC number 033383600512, and Yellow onions, sold in a 3 pound bag with UPC number 033383600024, were sold in Alabama, Arkansas, Florida, Georgia, Iowa, Illinois, Kentucky, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, and Texas.

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

BY

MARIA ASPAN

June 3, 2020 10:33 AM EDT

More than 10 months after recalling some of its breast implants, Allergan is making a new effort to find tens of thousands of women who still have the dangerous devices.

Informed Consent for Augmentation vs. Reconstruction

- Breast Augmentation is the number 1 plastic surgery procedure
- Expanders and implants primary option for breast reconstruction after mastectomy
- Took part in the FDA survey for informed consenting of breast implants

FDA Box Warning and Consenting Process

(fda.gov, 2020)

Breast Implants - Certain Labeling Recommendations to Improve Patient Communication

Guidance for Industry and Food and Drug Administration Staff

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 29, 2020.

FDA believes it is important for patients considering breast implants to have the information need for a balanced discussion with their physicians regarding the benefits and risks of breast implants. To help ensure that patients have this information, a boxed warning, a patient decision checklist, and a patient information booklet/brochure specific to the breast implant should be provided by manufacturers and given to patients prior to implantation. For those patients who decide to have breast implants, a patient device card should also be provided to patients after surgery. FDA intends to work with manufacturers of new breast implants through the premarket approval application (PMA) process, and manufacturers of currently marketed breast implants through the PMA supplement process, to integrate these important labeling recommendations.

A. Boxed Warning

FDA believes that a boxed warning should be part of physician and patient labeling materials for breast implants. In general, boxed warnings are noticeable and easy to read and understand, and FDA believes a boxed warning would be particularly useful in communicating risks that have been identified in new information and for which patients may be unaware. To achieve the goals described above, FDA recommends that a boxed warning generally inform patients that:

- Breast implants are not considered lifetime devices;
- The chance of developing complications increases over time;
- Some complications will require more surgery;
- Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL);

B. Patient Decision Checklist

FDA also believes that a patient decision checklist highlighting key information regarding risks should be included at the end of the patient information booklet/brochure.

To help ensure the checklist is read and understood by patients, FDA is providing recommendations regarding content and organization below. First, FDA recommends that the introduction for the checklist include a description of the purpose and importance of the checklist, as well as instructions to patients on how to review and complete the document prior to deciding whether to undergo the implant procedure. Next, to achieve the goals described above, FDA recommends that the body of the checklist include the following:

- Situations in which the device should not be used or implanted;
- Considerations for a successful breast implant candidate;
- Risks of undergoing breast implant surgery;
- Importance of appropriate physician education, training and
- Risk of BIA-ALCL;
- Risk of systemic symptoms; and
- Discussion of options other than breast implants, as

Appendix C: Materials Device Description Example

2. **Chemicals Released by Breast Implants**

Volatiles: Chemicals that are released by breast implants as a gas.

Extractables: Chemicals that are released by breast implants following soaking in water and/or organic solvent (liquid).

Volatiles		Extractables	
Compound	Whole Device (ppm*)	Compound	Whole Device (ppm)
D_3 Siloxane	0.18	D_3 Siloxane	0.5
D_4 Siloxane	0.46	D_4 Siloxane	<2.5
D_5 Siloxane	1.47	D_5 Siloxane	<4.8
Methoxytrimethylsilane	0.43	D_6 Siloxane	<8.4
Dimethoxydimethylsilane	0.03	D_7 Siloxane	<8.4
Methoxytriethoxysilane	ND	D_8 Siloxane	<8.3
Tetramethyldiethyldisiloxane	0.04	D_9 Siloxane	<10.92
Acetone	0.18	D_{10} Siloxane	<21.86

Thank you for this opportunity as an avenue to continue my advocacy

- Questions????

- Contact information
  - Kimberly Platt
    - plattk@ccf.org
    - @K_B_Platt
    - @k_b_platt