



Breast Implant Safety Alliance BISA NONPROFIT

September 16, 2021

Dear FDA,

I am President and Cofounder of Breast Implant Safety Alliance (BISA Nonprofit) and writing this letter as a harmed patient and a patient safety advocate. BISA Nonprofit is an organization created by women and our mission is to raise awareness, optimize outcomes and ensure informed consent for patients considering breast implant surgery. We empower patients and work collaboratively with all stakeholders including healthcare providers, regulators and legislators, to support systems of education and accountability that promote patient safety.

First of all, thank you for the opportunity to provide written feedback and advice to the FDA and also allowing me the opportunity to speak at the upcoming Patient Engagement Advisory Committee Meeting on October 6, 2021 regarding Medical Device Recalls. What the FDA does is so incredibly important because many countries rely on the FDA to provide leadership in important decisions like recalls. Also, doctors who want to do right by their patients are relying on the FDA for guidance.

This subject is very near to my heart. I have been involved with advocacy since I developed systemic symptoms (Breast Implant Illness) from breast implants. I have connected to thousands of patients that have been harmed by breast implants and other medical devices, some of which have been recalled or withdrawn. This cause is so important to me that I started working with a company that is solving the issue of medical device management and recall notification because of the lack of communication between the FDA, the manufacturers, the medical community and most importantly, the patients with the implanted devices.

The Allergan textured implant recall has been a scary and sad experience for thousands of patients. Allergan lost track of thousands of patients and doctors were not easily aware of which patients had the recalled breast implants and patients were also unaware of which type were implanted. I am contacted almost daily by a patient that has no idea what is implanted into their body and can not find the implanting surgeon or any identifying information. These patients are scared about the possibility of developing BIA-ALCL, a cancer of the immune system. It is not just the Allergan implants that cause this cancer, however this is the only textured implant manufacturer with a current recall. Women who have these recalled breast implants can not have these devices removed easily from their bodies, as Allergan will only pay for the breast implants to be replaced rather than removed. Many women have to pay out of pocket to remove these recalled, cancer causing devices from their bodies.



Breast Implant Safety Alliance BISA NONPROFIT

These are some of my recommendations:

- Bring the solution into the digital age and create or utilize a system that allows patients to register devices and be notified in real time by email or text message rather than snail mail
- Use social media to spread recall information (like the CDC is doing know to spread accurate information on Covid-19)
- Update MedWatch or bring back MedWatcher because the current system in place is not easy for patients to navigate or update
- Increase reviewing of adverse event reports to identify possible recalls sooner
- Use “patient speak” or language the average patient will understand
- Mandate UDI adoption
- Consider the patient harm when a medical device is withdrawn rather than recalled. The implications can be devastating or life changing for a patient.
- Stop the sale of recalled medical devices
- Scan medical devices with the UDI barcode to be sure a recalled medical device is not recalled before it is placed into the patient
- Removal of a recalled medical device and care for the patient should be covered by insurance
- Consult the auto industry as they seem to be able to easily connect with consumers on recalls

Thank you again for the opportunity to provide feedback and advice. The medical community in the US and around the world rely on the FDA for guidance and the work you do has a global impact. I look forward to presenting and participating at the Patient Engagement Advisory Committee.

Sincerely,

Maria Gmitro

President + Cofounder

Breast Implant Safety Alliance (BISA Nonprofit)

maria.gmitro@breastimplantsafetyalliance.org

(843) 501-6873