

Dear FDA Commissioner and PEAC members,

My name is (b)(6) and I am an RN, patient advocate, BISA (Breast Implant Safety Alliance) advocate and a patient personally harmed by implanted medical device(s). It is my wish today to convey some of my opinions and experienced-based touchpoints regarding medical device recalls and patient informed consent. (I had also previously submitted to the FDA, draft guidance suggestions, regarding breast implant labeling, communication and informed consent in December of 2019, following the March 2019 public input meeting).

In regards to systematic, uniform approach methodology to identifying and communicating medical device recalls, I'd like to suggest consulting or researching the government's management and monitoring of car safety recalls. Don't let this analogy cause rebuke. It took Legislation in 1966 to prompt such purview of governance and today the National Traffic and Highway Safety Administration within the Department of Transportation supervises this systematic registration and tracking of consumers and their vehicles for communications contacts, when applicable. Recalled automotive parts can be traced back to the manufacturer, the plant in which they were made, and to the day the error had originated. Their surveillance and tracking methods are functionally reliable. A person could change addresses many times and still manage to receive in the mail, airbag recall notices, until the repair is rendered.

Much can be learned from researching or consulting such a vast, safety outcome-based network comprised of many moving parts. Their structured and stream-lined tracking and communication relay methodology is effective in communicating the problem to the consumer and often provoking proper resolution. It is stated on the Consumer Reports website that every owner of a recalled car has the right to know about it. This same concept applies to patients with medical devices that are recalled. Paralleled importance needs to be honored also to remain practicing in accordance to the 'Patient's Bill of Rights and Responsibilities.' Consumer Reports mentions the utilization of a recall tracker and of apps to check to see if a car has been recalled. These approaches are seemingly, dedicatedly organized and readily available to consumers. It would benefit the patient to also have in place a safety oversight of uniform, accessible, up-to-date, device related information. Lifelong device identification with systematic registration, tracking and notification systems could be beneficial to the patient/consumer and to the surgeons, the FDA and all. I do understand the vast differences in these two recall situations; however, it does not reduce the relevance nor ethical cognizance. Cohesive and safety goal-oriented collaborations are necessary for the development of patient safety nets.

((<https://www.consumerreports.org/car-recalls-defects/car-recall-guide-questions-answered/#:~:text=For%20recalls%20of%20all%20sizes%2C%20car%20companies%20must,people%20can%20get%20the%20problem%20corrected%2C%E2%80%9D%20Wallace%20says.>))

I'd like to implore the FDA to encourage the use of proper methods for obtaining a more thorough medical history from patients, with a prompt or form, screening for medical device implantation(s). This could be included along with the medication review/update or tooled as a similar screening to that of pre-CT or MRI (metals, contrast allergies, etc.), for example. It may be best a question or form utilized independently and/or listed next to patient allergies, especially since in my experience, many women have reported a history of allergies to ingredient(s) that breast implants are composed of, but they did not fully realize the ingredients within the implant or that of the shell components. This aspect also

raises awareness of the need to list for the patient, the ingredients of any invasive (or non-invasive) foreign device that their body is going to acclimate to.

As science is well aware, an intrinsic function of the immune system is to identify and launch an attack against any foreign body(s). Implanted medical devices are foreign to the human body. Physicians and medical staff need to be reminded how this can potentially cause systemic symptoms for some individuals. This is an important reason for Medical Device Screening as some symptoms could conceivably be connected. (ex. Adjuvant; ASIA)

The most recent Allergan “Biocell” textured breast implant and tissue expander recall, due to an established link to BIA-ALCL, was shocking to women, particularly those who hosted that type of textured implant(s). There is/was a subset of women who verbalized that they do not/did not know what type of implants they have/had. This should not be occurring, but it is an apparent concern. More reason for streamlined and timely medical device registration initiation & data collection and tracking.

With history revealing many surgeon’s short-comings of reporting adverse events (AE) combined with mis-filed reports within the FDA and via manufacturers does not meld well with the somewhat apparent lack of patient education surrounding breast implantation AE and reporting. This menagerie of communication errors paints a picture of organized chaos, shining a light on the need for organization & structure and an invariable overhaul and for problem resolution. This illuminates the need for a uniform medical device manager.

The timing and method of communicating a device recall event needs to be well thought out and supportive to the patient. If there ever were available, methods or means to devise an intermediary care team to sit with the patient(s) and explain their medical device recall(s), that would be most ideologic, however, this may not be feasible. This person(s) or team could also help facilitate communications to/from or with the surgeon(s).

Another point to consider, related to recalls, is that when an oral medication, for example, is recalled, the medication can usually be ‘held’ or stopped or changed. When an implanted medical device has been recalled, this can cause much immediate concern and anxiety for the then vulnerable patient. Some women in breast implant related support groups shared that they ‘just want(ed) (their) implants cut out” in the midst of feelings of desperation and initial shock. A medically implanted device(s) can nearly feel like a body part to the patient and there can also be subsequent grief and depression with loss, when applicable. A sound, supportive, psychological approach to informing the patient of a recall despite the recommendation for device removal or not, would be best fitting as removal is usually a first-thought to most patients, as they attempt to remove themselves from the potential threat.

Thank you for your time and for the hard work you are doing to help improve patient safety and communications. Feel free to contact me if I can be of further assistance.

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