From: (b)(6)
To: Williams, Letise
Subject: [EXTERNAL] Advisory Committee Meeting, Docket Number FDA-2021-N-0008
Date: Thursday, September 16, 2021 7:48:56 PM

Dear Ms. Williams,

Below is my written statement for the October 6 Patient Engagement Advisory Committee Meeting:

In 2011, I had Allergan textured saline implants placed for reconstruction following a double mastectomy. I was 43 and had early stage breast cancer, and was told I would need no further treatments if I opted for removing my breasts. I spent the next 8 years getting progressively more ill with symptoms that doctors could not figure out. In spring of 2019, I heard about women testifying at FDA regarding breast implant illness (BII) and breast implant related anaplastic large cell lymphoma (BIA-ALCL). I started researching explant as it seemed likely the implants were harming my health. Then in July 2019 the FDA recalled/banned the exact make of implants in my chest. I heard it on the news and in a BII support group on Facebook. I filed an adverse-effects report online via FDA Medwatch, both prior to my explant and a few months afterward. I received an email that indicated my report was now on file and eventually I also received a letter from Allergan that they received a copy of what I reported to FDA Medwatch. I still have never received a letter from either the FDA or Allergan alerting me to the recall. I had to reach out to my original plastic surgeon and let him know I had explanted. In our conversation, he indicated he was now aware of the recall and had changed consultations in his practice to include full informed consent about all risks with breast implants, including new FDA black box warning.

I explanted in September 2019 and am very slowly regaining my health. I will always be at risk for the breast implant caused lymphoma. I have seen another woman's copy of the letter from Allergan and the statements from FDA that all say:

"FDA Does Not Recommend Removal or Replacement of Textured Breast Implants in Asymptomatic Patients "

I do not agree with a "watch and wait" approach. I had cancer and was implanted with a faulty product that might cause a different cancer. I had symptoms, but not the ones indicative of BIA-ALCL. I was lucky to have insurance that paid for my explant surgery but other woman are not as fortunate. I happened to hear the news and find information via social media. Otherwise, I might still have the recalled devices in my chest, potentially allowing a new cancer to develop. Patients should always be given full, informed consent prior to agreeing to a medical device and also be properly notified if there is a recall. I believe the FDA Medwatch reporting system works well, but more people need to be made aware of it.

Thank you for taking the time to read my statement.

Sincerely,

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