

Williams, Letise

From: (b)(6)
Sent: Thursday, September 16, 2021 7:43 PM
To: Williams, Letise
Subject: [EXTERNAL] Comment re: Patient Engagement Advisory Committee
Attachments: collage text bi.jpg; Rash collage (1).jpg

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Dear Ms. Williams

I am commenting on BIOCELL implants. Please forgive me I am going to try and convey as best as I can. I am still very ill from the BIOCELL breast implants and it makes it very difficult for me to communicate at times.

I appreciate your time.

What factors should the FDA and industry consider to effectively communicate medical device recall information to patients and the public, including but not limited to content, format, methods used to disseminate the message, and timing of communication?

To date I have not received from my plastic surgeon or the industry regarding any recall information re: Biocell breast implants. I would like to see that the FDA put more effort into seeing that ALL medical community receive this info should their patients exhibit symptoms.

What concerns do patients have about changes to their device in response to a recall?

I am still struggling with my health and am concerned with the LONG TERM affects on my health and down the road.

Such LONG TERM & lingering affects should be address for patients who are still struggling and ill from BIOCELL implants but have not been, so far, diagnosed with cancer.

If these implants are known to cause cancer, then certainly they can cause sever and chronic Inflammation.

I am dealing with adenoma, severe skin rashes/chronic inflammation, brain lesions, auto immune issues, anemia, numerous health issues and so forth, and would like to see this being discussed and or addressed more in depth.

Even though I have not formally been diagnosed with cancer, I feel at this point that I am almost as sick and am frustrated by the lack of medical community not fully having any knowledge on how to handle or proceed or help me.

I feel having a medical device "Recall" should not put an end to or "closure" and then NOT address those of us who are sick with lingering affects feeling like sitting ducks, without any further and concise clear instructions on how to proceed.

Again, so far none of my physicians have heard of the recall. I would like to see this change.

Thank you again. I've included photos of just some of the rashes I deal with on a daily basis.

Sincerely,

(b)(6)



Textured Implants Continue To Elicit Inflammation, Swelling & Rashes



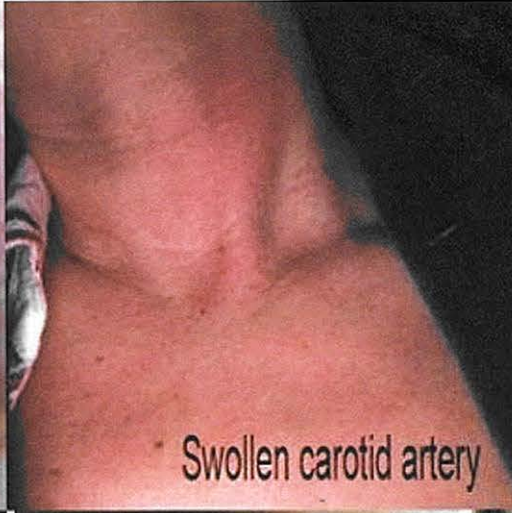
Textured "BIOCELL" Implants Have Been Implicated in BIA ALCL, Then It Only Makes Sense That "Textured Silicone" or "Microscopic Flakes" Are Imbedded In Our Body Tissue



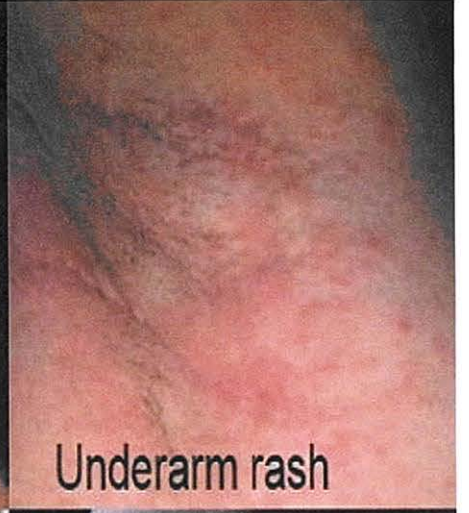
Hand



Hand



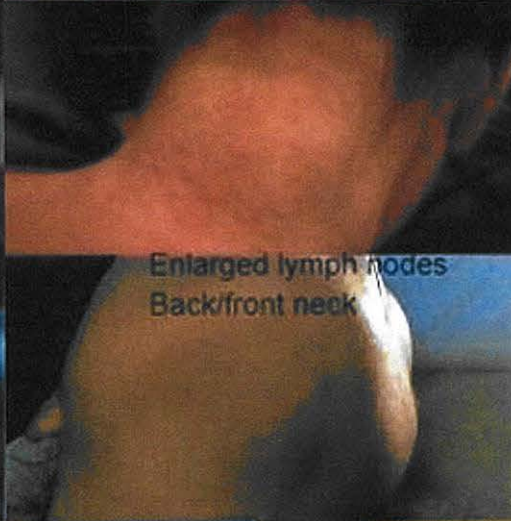
Swollen carotid artery



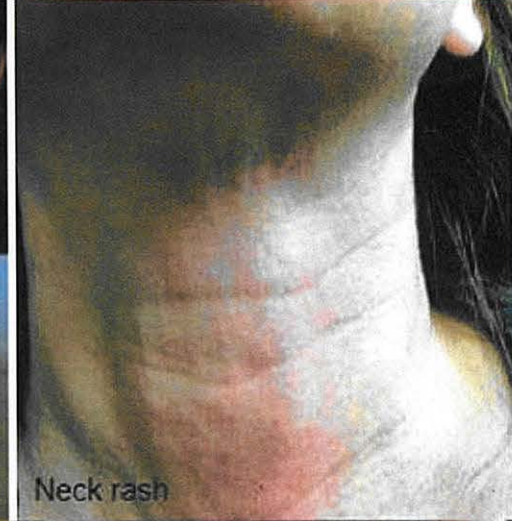
Underarm rash



Leg rash



Enlarged lymph nodes
Back/front neck



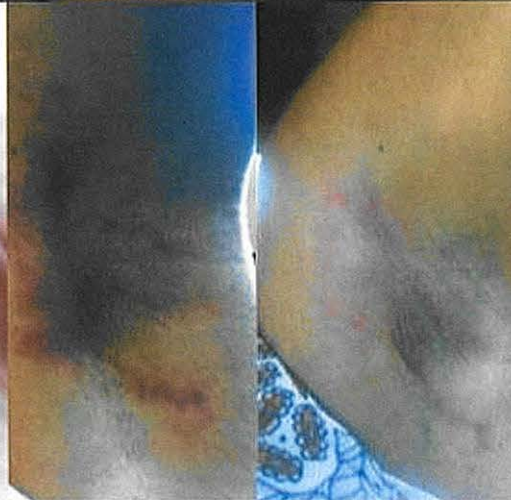
Neck rash



Breast rash



der breast-incision rash



Enlarged lymph node
Axilla

