

From:

(b)(6)

To:

[Williams, Letise](#)

Subject:

[EXTERNAL] Implants

Date:

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My life with implants started after I had a mastectomy in 1991 after being diagnosed with breast cancer.

It took me to 1998 before I had my first breast implant which was saline as silicone implants had issues and were not recommended at that time .

In 2007, the saline implant ruptured and I awoke one morning to find my "breast" was completely flat.

I had moved to another town, so sought a consult with a new plastic surgeon who advised me that the saline implant had to be removed ASAP as there was a risk of infection. Since, I had difficulty with the first surgery I was reluctant to consider going through this again but he assured me that he would utilize expanders again for a few months before implanting with the new implant and I should not have the discomfort that I had experienced with the first implant. I can only describe waking up after the first surgery and feeling that I had an elephant on my chest.

He recommended a silicone implant this time as it was now back in favor and he assured me that I would not suddenly have a flat chest as any leaks would be gradual.

Again, two surgeries. One to remove the saline implant and place the expanders and a few months later the surgery to implant the silicone one. Surgery was uneventful as he promised.

I had follow up with the surgeon for a number of years until he left the area and I participated in a breast implant study for five years.

I was never able to have the recommended MRI of the implanted breast as I was implanted with a pacemaker in 2009 and it was not MRI compatible.

In 2012, 2015 and 2017 (revision) I had total knee replacements. I recently attempted to obtain the UDI numbers for these devices by first contacting the surgeon in question. I was told that the records for 2012 was in a warehouse and the office was not sure if they were responsible for keeping records of the UDI. I contacted the hospital where I had the surgery only to be transferred from department to department before being referred back to the surgeon. I eventually received the information after persistence.

I later had cataract surgery which involved implants but I was given a card with the needed information.

In 2018, my pacemaker battery needed replaced so I had surgery to place a new pacemaker which was MRI compliant. I have a card with the UDI numbers for the pacemaker and it is closely monitored.

In July, 2018 I began to read on social media about problems with breast implants in relation to a lymphoma which is a type of cancer related to textured breast implants. I was not aware of what type of implant had been placed in my breast so I attempted to contact the surgeon for information. He had left the area but I tracked him to a clinic in Miami but was told he no longer had my records

as only required to maintain them for five years.

I began searching through some medical records that I had kept related to my breast cancer and found a form and a card that had an UDI number for the implant.

From my research on the internet, I realized that I probably had a recalled implant which led me to call Allegran who confirmed my belief. Their advise to me was to call my primary provider to discuss follow up. I provided Allegran with my updated demographic information as I had moved since the implant was registered but I never received any formal letter from Allegran regarding my implant until the summer of 2021.

I requested an order for a breast MRI from my primary but it involved many telephone calls with appointments made and cancelled by local imaging centers as they were not capable of imaging my breast since I had a pacemaker. I reached out to Mayo Clinic, (b)(6) where the process was seamless. The result was no indication of malignancy or leakage from the implant but my chest lymph nodes were enlarged and necessitated further follow up with another MRI in July, 2020 when it was discovered that my mammary lymph nodes were even more enlarged. This necessitated a pet scan that indicated the mammary glands were suspicious for a malignancy. Since neither the breast surgeon nor the interventional radiology were able to reach the area in question, I had a thoracotomy which revealed that five of the mammary lymph nodes were attached to my mammary artery. This was dissected and the subsequent biopsy indicated it was benign but with foreign body giant cell reaction related to the implant., My insurance has covered all costs but the emotional roller coaster seems never ending as I read about the cases and complications related to having textured breast implants. It involves a two hour round trip drive for multiple visits to surgeons and X-ray departments to monitor the implant.

In summary, as a 75 year old woman, who has a Masters Degree in Social Work and worked in medical settings for most of my career, I nevertheless, found it a very frustrating experience trying to determine that I indeed had a recalled implant.

Surgeons and patients are highly mobile and often loose touch so it's imperative that the UDI number be imbedded in a patient's medical record.

It's imperative that a system such as "Track My Solutions" where I have now registered my implants be made known to patients with implants and the information be registered with their permission at the time of implantation.

A central system such as a used for vaccinations could be employed at the federal level so those with implants and their providers can reach out for information on recalls and such.

In addition, Primary care physicians who see patients most often should be required to be more knowledgeable about implants and recalls.

I am 76 years of age and have lived with various implants for 30 years and still lead a vigorous life. Therefore, it is imperative that these implants be closely monitored for the rest of a patient's life.

Thank you. (b)(6)

Sent from my iPhone

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