From: (b)(6)
To: Williams, Letise
Cc: Barbara Wolf; Pam Uresti
Subject: [EXTERNAL] Silicone Implants
Date: Thursday, September 16, 2021 6:42:17 PM

Good afternoon,

My daughter had 2 sets of Allergan silicone textured implants. The first set leaked and she became very sick. The company offered to take defective set out and replace. She agreed to this and became sick again, this time it was her reaction to the substance or the implants themselves. She had brain fog, red and blue hands and feet, dizziness, and very tired/lack of energy. With convincing she removed the second set after she realized symptoms were similar to first set, but worse. I am not telling you all the many doctors she had seen, including the surgeons (2) that placed implants. The 2 surgeons that placed these implants refused to remove them when she had issues. When (b)(6) plastic surgeon head of Dept a (b)(6) would not take them out, she the an explant surgeon who would for $14,000.00 cash. The surgeon noted that he had never seen so much scar tissue in his whole career. Well our family was really hoping she would bounce back now that implants were removed. No, she was somewhat better, but had extreme fatigue. After many visits to doctors, she found out she had hoshimotos which is due to what is an autoimmune response to the implants. She also was not mentally there and experienced brain fog, as well as memory loss. She was at a gas station and was kidnapped and raped. The year after that she committed suicide at the age of 31. Leaving behind a young son and family that miss her dearly.
Silicone implants are very dangerous and should be banned. They cause what is called Breast Implant Illness (BII). I will testify that it caused my daughter to have depression, fatigue, and symptoms that could not be measured. By the way while she had implants she was told that she had Lyme's dx. When implants removed it went away. It is because it causes a false positive on the test.

❤ 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? The FDA she speak and interview patients that have had implants and note all the many signs and symptoms they have. Quantify and decide that it is poison to the human body and stop selling product.

❤ What concerns do patients have about changes to their device in response to a recall? My daughter is dead due to the effects it had on her body. She was lead to believe that they were safe.

❤ How do you think patient perspectives could be incorporated in FDA and industry

benefit-risk decision making, as well as the healthcare provider and patient decision-making process related to a recalled medical device, including implanted devices? I have talked to primary care doctors that have female patients that come in complaining of BII-breast implant illness. They do not know how to help these patients. Pts go on suffering. Most I have spoken to say they present their complaints of signs and symptoms to be dismissed. Doctors perform lab work and nothing shows up, so they send them on their way. BII is an autoimmune response to the breast implants. If the breasts are leaking the silicone is in connective tissues and not in the blood. Very hard to determine or diagnose patient that is suffering from BII. Most patients turn to drugs/pills to treat their symptoms, which is not the answer. THE ANSWER IS NEVER PUTTING SILICONE IMPLANTS IN YOUR BODY IN THE FIRST PLACE!!!!!
Most women if they remove implants and not place any to replace they can recover, but some do not!! Hence my daughter, where BII was not going away.

Kind Regards,

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