**Williams, Letise**

**From:** (b)(6)
**Sent:** Thursday, September 16, 2021 2:28 AM
**To:** Williams, Letise
**Subject:** [EXTERNAL]

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My suggestion to this Committee is to implement a notification system/code given to the patient before the surgery date that alerts them of any recall. If this system is now in place, it's not working. I was never notified of the Allergan implant recall or that these implants can cause lymphoma.
Why aren't manufacturers not held accountable?
Why do doctor's not tell their patients the dangers of implants?
I am one of the vast number of women suffering from Breast Implant Illness. The FDA needs to re-address this life-threatening illness/s with the medical insurance companies to code Breast Implant Illness and finally give testimony that BII is real.
I am willing to participate/testify and include pictures of my breast cancer/Implant journey, as requested.
Thank you.

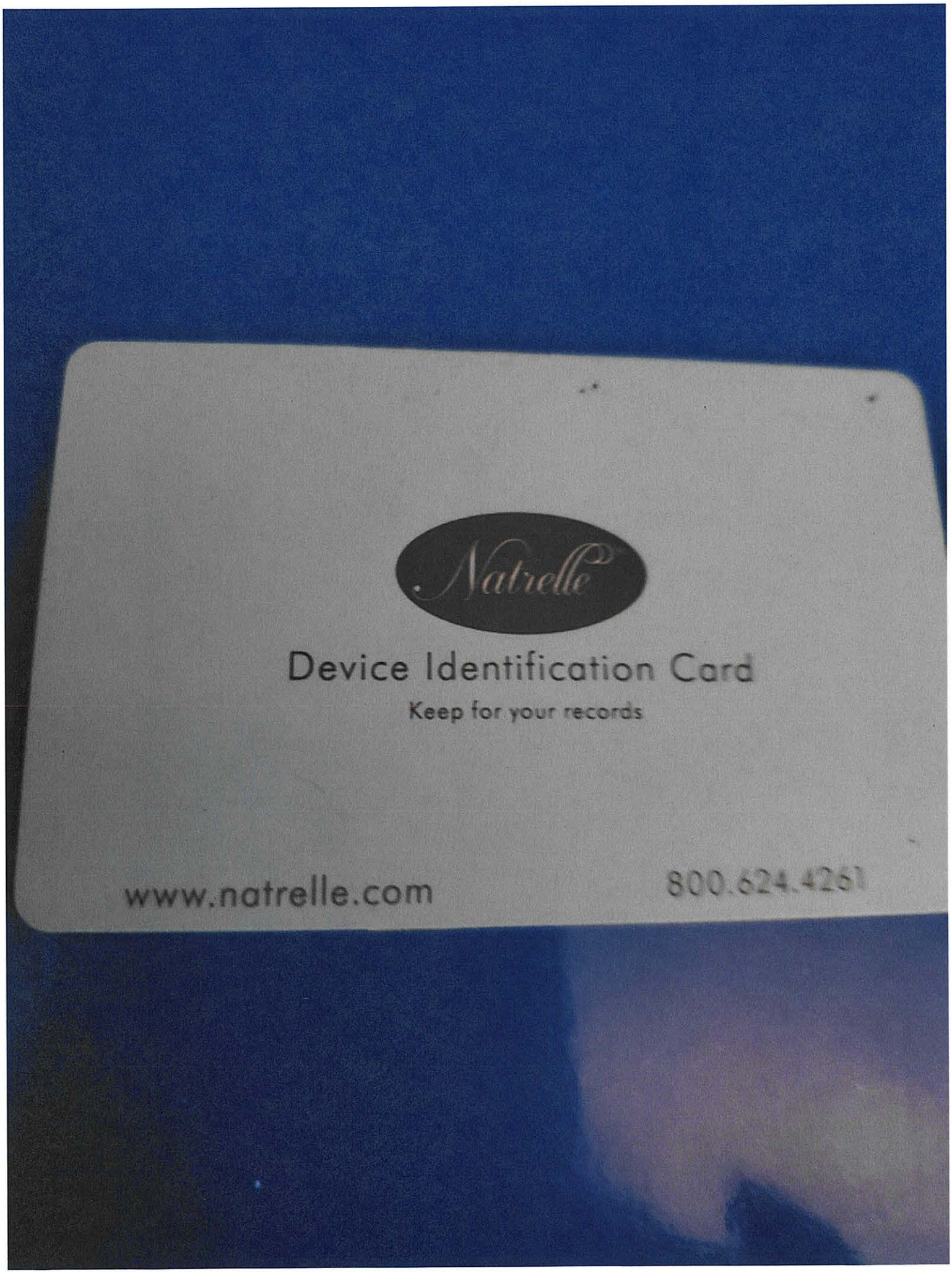
(b)(6)

## Williams, Letise

**From:** +15515873047@mymetropcs.com
**Sent:** Thursday, September 16, 2021 2:47 AM
**To:** Williams, Letise
**Subject:** [EXTERNAL] Fwd:



I, MaryAnn Bracero, would like to present my input for the October 16th Patient Engagement Advisory Committee Meeting. I had bilateral mastectomies with placement of expanders in March, 2015. In June, 2016 I had exchange surgery to remove the expanders and replace with implants. My implants were Allergan gummy bear tear dropped silicone. I had problems and complications since. Prior to this, I was hospitalized two weeks later with C diff, sepsis and hemorrhagic colitis. That same month back in the hospital with Hives. In 2017 a biopsy was performed on my right breast incision line for a lump. The pain, swelling, bilateral lymphedema, weakness, chronic debilitating fatigue, memory problems/loss of concentration, heat/cold intolerance, fibromyalgia, Gerd, Hashimotos, asthma, chronic bronchitis, bloating, peripheral neuropathy, osteopenia, constant noise/ringing in ears, weight gain, anemia, muscle and bone pain, tenderness, soreness, stiffness, swelling; incontinence; restless legs; anxiety; gallbladder surgery; iron infusions; feeling sick every day; pains each and every day.
I learned about the Allergan recall online. My original surgeon's, breast and plastic, never notified me and Allergan never notified me. I then began a search for a different plastic surgeon who could perform total capsulectomies. This was done in December 2019.
To this date, I have been to numerous specialists (oncologist, rheumatologist, neurologist, physical therapy) and have had multiple tests done.
All of what I have stated since the 2015 surgeries to present added more medical conditions. I know I have BREAST IMPLANT ILLNESS (BII). It has and continues to negatively impact my immune system.
I would like to know why a patient isn't notified of a recall..phone, text, email, doctor's office? I will never know, if I would've known sooner, would it not have caused so much damage to my body.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Device Identification Card
Keep for your records
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410 STYLE MF *NATRELLE*® 410 Highly Cohesive
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Silicone-Filled Breast Implant

640cc

REF MF-410640

SN 19859833

L R

ALLERGAN

410 STYLE MF *NATRELLE*® 410 Highly Cohesive
Anatomically Shaped
Silicone-Filled Breast Implant

640cc

REF MF-410640

SN 19239268

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ALLERGAN

Back of implant (circle one)

4 OR 3

Front of implant

LEFT SIDE

Surgeon Name

Back of implant (circle one)

4 OR 3

Front of implant

RIGHT SIDE