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**FDA Plastic Surgery Devices Panel Remarks
March 26, 2019**

Good morning. My name is Lisa Schlager. I'm a patient with breast implants, a cancer advocate, and an employee of Facing Our Risk of Cancer Empowered. FORCE is a national nonprofit representing people affected by hereditary cancers, including those with inherited genetic mutations associated with increased risk of breast, ovarian, and other cancers. Tens of thousands of our constituents have undergone mastectomies due to cancer diagnoses or high risk of the disease.

For those who undergo mastectomy, access to reconstruction is crucial. Some women may opt for reconstruction using fat, but it's not a viable choice for all; petite women and those with certain health conditions may not be candidates.

When I was facing my own mastectomy, I was assured that the new gel implants were 100% safe. After 12 years in cancer advocacy, I know there are caveats. Some women have adverse events: infections, ruptures, capsular contracture, and a small risk of BIA-ALCL. But many women *don't* know this. Better education for informed decision-making is desperately needed.

Recent articles on ailments afflicting those with implants have caused alarm and confusion in the community. Even experts don't agree on the findings. The media amplifies this, further stoking fears. Clearly, more high-quality research is needed.

Confusion also exists around monitoring women with implants. Some organizations endorse regular screening mammograms. This seems counterintuitive given that implants can rupture. In 2006, the FDA recommended MRI screening for everyone with silicone implants. Conversely, the American Society of Breast Surgeons and American College of Radiology recommend against MRIs for asymptomatic women.

Conflicting information abounds. I was told to have an MRI every few years but many women have never heard this. Those who try to follow the FDA recommendations often incur large out-of-pocket costs as insurers often don't pay for implant screening. Adding coverage of implant monitoring to the Women's Health and Cancer Rights Act could remedy this for at least part of the population.



FORCE applauds efforts to look more closely at these issues. We encourage a measured approach based on sound science, including:

- balanced information on reconstruction safety,
- access to well-tested devices,
- best practices, consensus guidelines, and insurance coverage for implant monitoring,
- comprehensive, high-quality research, and
- an easy path to report adverse events

This month's issue of [*Plastic and Reconstructive Surgery*](#) features an article proposing a collaborative effort encompassing international alliances, breast device registries, routine surveillance pathways, and better analyses of possible immune-related disease. We support these steps and hope stakeholders will work together to ensure that the most accurate, evidence-based information is available to women and their providers.

Thank you.

