The Law: Augmented

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For the past 12 years I have written this article hoping to keep my readers informed of the latest legal news that might affect them or their loved ones. I've tried to augment their knowledge of the law. Some articles succeeded, while others were a bust.

Hopefully this week I can implant some legal wisdom about the U.S. Food and Drug Administration, which recently declared that silicone-gel breast implants are safe and effective when they are used as intended (I'm not sure what else anyone would use them for, but that's what the statement said).

The declaration was made five years after the agency made the implants available again for use. The FDA banned silicone-gel implants from use in 1992 due to safety concerns, but allowed them again in 2006. The announcement coincided with a report that included preliminary data from post-approval studies, an analysis of adverse effects reported to the FDA and a review of clinical studies about the safety and effectiveness of the silicone gel-filled breast implants.

The studies cited in the report were conducted by the two American manufacturers of both silicone-gel and saline breast implants: Mentor, a division of Johnson & Johnson, and Allergan, Inc., the same company that makes saline solution for my contact lenses (I hope it's not the same saline).

Dr. Jeffrey Shuren, head of the FDA's Center for Devices and Radiological Health, explained in a press conference that the data "does not indicate that silicone-gel filled breast implants cause breast cancer, reproductive problems, or connective tissue disease such as rheumatoid arthritis or lupus."

While the FDA pointed out that there is no evidence that silicone breast implants cause breast cancer, it did investigate anaplastic large cell lymphoma, a rare type of cancer that occurred among a small group of women who had breast implants. According to the agency, there are 34 cases of the rare lymphoma in published literature and, at most, 60 cases worldwide, among the millions of women with implants.

In fact, experts estimate that 5 to 10 million women worldwide have breast implants and nearly 300,000 women receive either silicone gel or saline implants every year in the U.S. alone. The FDA also claims its reports show most patients express satisfaction with the results.

While the FDA deemed the silicone-gel implants safe for use, it is quick to warn that women must be diligent in follow-up visits and routine MRI scans to screen for infection and ruptures. Dr. Shuren elaborated saying, "Breast implants are not lifetime devices. The longer a woman has silicone-gel breast implants, the more likely she is to experience complications."

Additional surgeries after the initial implants are typical. "As many as one in five women who receive silicone-gel filled implants to increase the size of their breasts will need to have those implants removed within 10 years," Shuren warned. Further, nearly half of all women who get implants for reconstructive purposes following cancer or some other health problem will need to get them replaced.

The most common complication following implant surgery is called capsular contracture, which is a hardening of the area around the implant. Other typical problems include implant rupture, wrinkling, breast asymmetry, scarring, pain and infection. Accordingly, the follow-up visits are extremely important. Shuren advised patients to, "Pay attention to changes. Women should notify their health care provider if they develop any unusual signs or symptoms."

Dr. Shuren also proclaimed the FDA will continue to evaluate implant data to ensure their safety and to keep the public abreast of any problems.