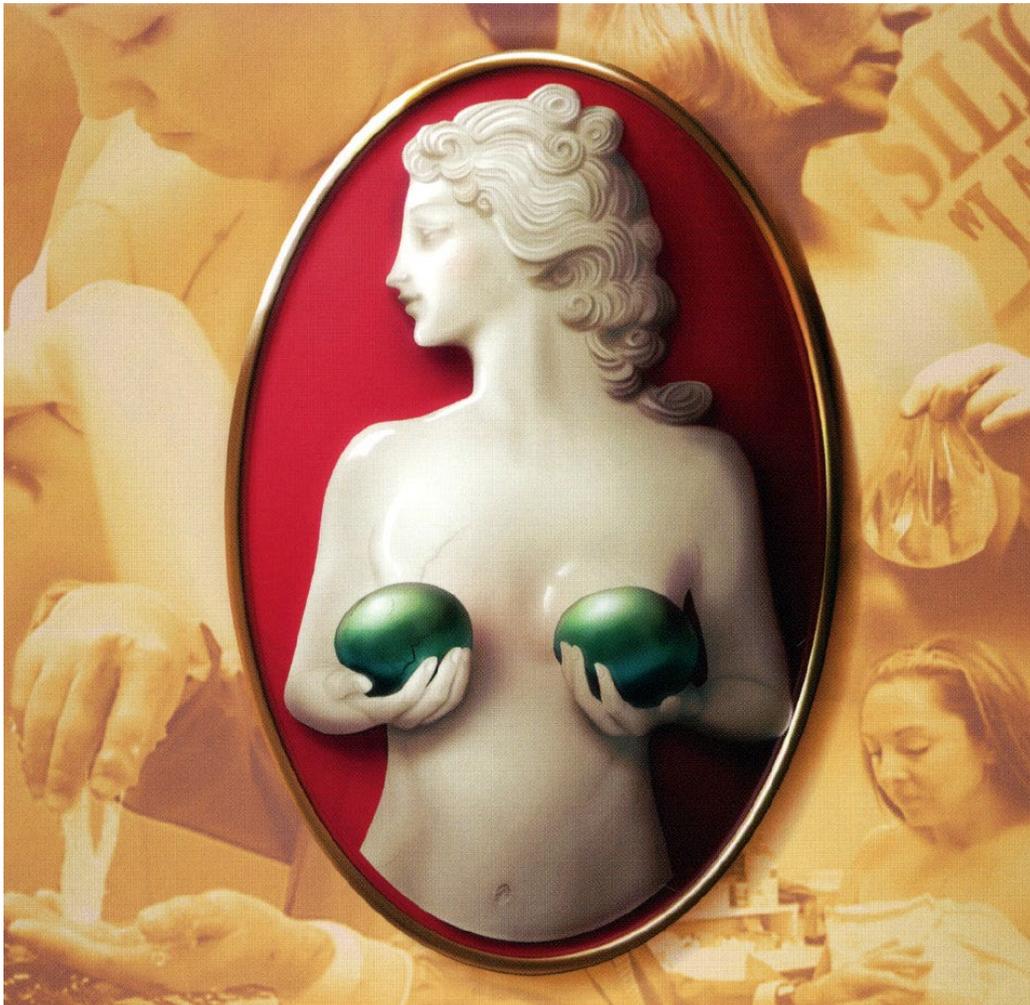

Absolutely Safe

Breast Implant Update



**OUR BODIES
SELVES**
information inspires action

What facts should women consider now?

The health concerns discussed in the film have been further documented in many more women, in case reports and in studies. In addition to health problems such as chronic pain, there are the cosmetic problems with the implanted devices such as rupture, shifting, hardening (capsular contracture), wrinkling, swelling, sagging, and asymmetry. In response to the growing awareness and concern about implants, the U.S. Food and Drug Administration (FDA) (the agency that monitors the safety of medical devices) has created a registry to report problems and provides extensive information about implants on a [web page](#) devoted to the devices. The agency has created an essential [booklet](#) on implants which is based on their scientific advisors' review of the medical literature. It warns women considering implants that there are many serious complications that they could experience including pain, numbness, infections, and difficulty breastfeeding. They emphasize that implants do not last forever and that re-operation due to implant problems is not uncommon, and increases in likelihood with the years that a woman has implants. There are also concerns that implants can interfere with the detection of breast cancer and/or could rupture during mammography.

Several women in the film remark that they didn't feel that they had the facts on implants when they were deciding to get them.

Serious problems that have been documented in the medical literature include rare cancers (Anaplastic Large Cell Lymphoma) and autoimmune/inflammatory syndrome induced by adjuvants (ASIA) due to silicone implant incompatibility. (More on these below). While the FDA and physicians recommend that women with silicone gel breast implants have regular MRI screenings to detect ruptures, MRI's and other health procedures related to implants are often not covered by health insurance. MRI's are expensive and less expensive procedures such as ultrasound, mammography, and physical exam are much less likely to detect problems. Most ruptures of silicone gel implants are "silent ruptures," meaning that they generally don't have noticeable symptoms that are detected by the woman with implants. Women with implants need regular medical care and monitoring, which is much more likely with health insurance. Explantation (removal) of ruptured implants without replacement is also rarely covered by insurance. (Grady 2014)

In addition to these health and financial issues, concerns persists that the media and the plastic surgery industry are promoting unhealthy body image for teens and women and capitalizing on the market for "solutions" to the insecurity about breast size that they help to create. Finally, it is not clear that plastic surgeons are fully aware of the risks associated with breast implants or, if they

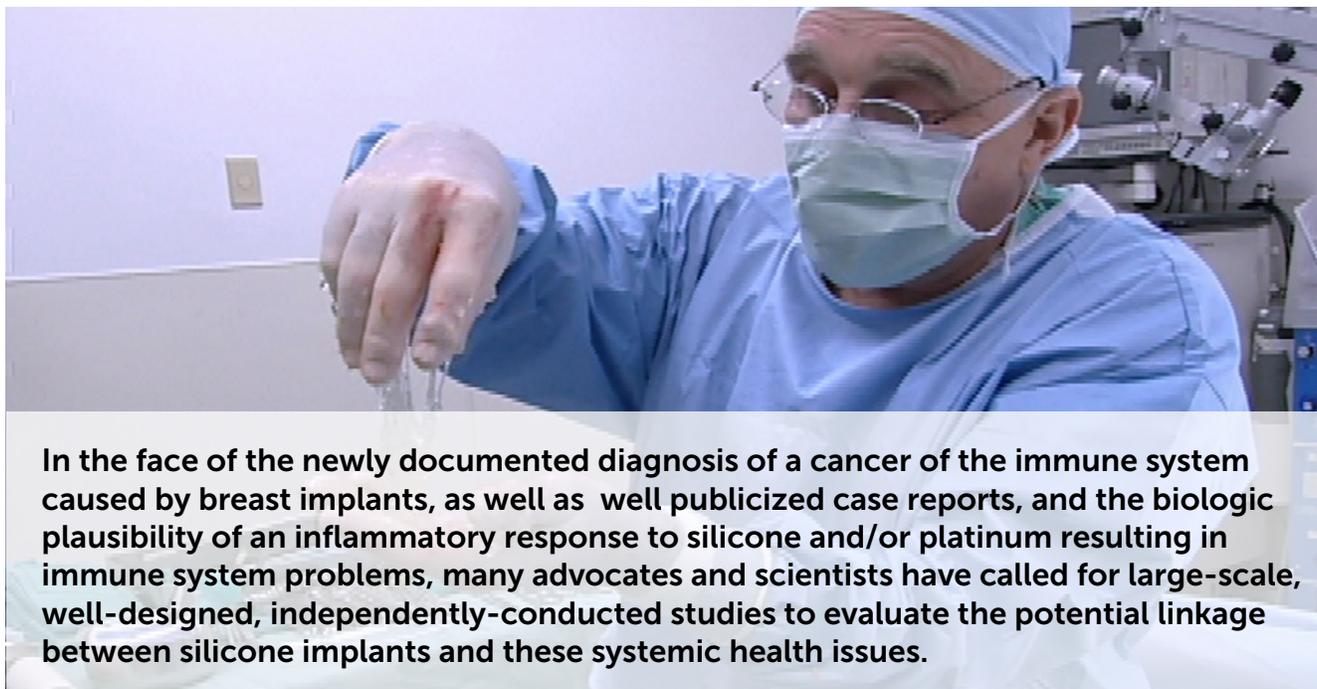
The film presents conflicting views on illnesses related to the migration of silicone or platinum out of the implant into other parts of the body.

are aware, they include a full discussion of risk in their informed consent process with patients. A 2016 study showed that only 30% of U.S. plastic surgeons discussed the risk of immune system cancer with patients as part of obtaining informed consent for implant surgery. (Pittman 2016)

What does the medical and scientific literature say?

The film presents conflicting views on illnesses related to the migration of silicone or platinum out of the implant into other parts of the body. Several women in the film discussed their experience of illnesses they and their doctors believe are related to the “bleeding” of silicone from their implants. The scientific panels in the film conclude that there is no evidence of a link between implants and such illnesses. What does the medical and scientific literature say now about implants and connective tissue diseases such as Lupus, rheumatoid arthritis, scleroderma, and fibromyalgia?

Patients, doctors, and researchers continue to report cases of systemic immune system illnesses, including connective tissue diseases, among with women with silicone breast implants. Many of these diagnoses are supported by positive antinuclear antibody (ANA) blood tests indicating autoimmune disease. Symptoms reported include fatigue, cognitive impairment, joint and muscle pain, fevers, dry eyes and mouth, and rashes. Explantation usually resolves these symptoms, however a subset of women continue to experience symptoms after their implants are removed.(de Boer 2017) One recent review stated “a growing body of evidence from the past two decades links silicone with subsequent autoimmunity-related complications, collectively known as autoimmune/inflammatory syndrome induced by adjuvant--ASIA.” (Goren 2015). Although a review funded by the Plastic Surgery Foundation concluded that studies have failed to prove that these diseases are more likely among those with breast implants (Balk 2016), the National Center for Health Research points out that almost all the studies were funded by implant manufacturers or plastic surgeons, and that the design and interpretation of data were often biased. For example, numerous studies focused on whether the women were diagnosed with diseases with rigid diagnostic criteria, rather than whether they reported the serious symptoms that women with implants frequently report.



In the face of the newly documented diagnosis of a cancer of the immune system caused by breast implants, as well as well publicized case reports, and the biologic plausibility of an inflammatory response to silicone and/or platinum resulting in immune system problems, many advocates and scientists have called for large-scale, well-designed, independently-conducted studies to evaluate the potential linkage between silicone implants and these systemic health issues.

As part of the approval of breast implant devices, the FDA required the manufacturers to fund and conduct a large, long-term prospective cohort study of women who had implant surgery between 2006-2016. This study attempted to enroll and follow almost 40,000 women with silicone and saline implants. Unfortunately, the study lost track of most of the women in the study, and was terminated before the 10 years were completed. Nevertheless, as of this year, there had been 500 reports of “rheumatologic symptoms” in women with silicone implants versus less than five “events” among women with saline implants. (Post-Approval Studies, 2017). In the face of the newly documented diagnosis of a cancer of the immune system caused by breast implants, as well as well publicized case reports, and the biologic plausibility of an inflammatory response to silicone and/or platinum resulting in immune system problems, many advocates and scientists have called for large-scale, well-designed, independently-conducted studies to evaluate the potential linkage between silicone implants and these systemic health issues.

What is the connection between breast implants and cancer?

Since the film was produced, the World Health Organization and the FDA have issued warnings about the connection between textured breast implants and cancer. Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare type of non-Hodgkin’s lymphoma cancer (cancer of the immune system) (Clemens 2017). Additionally, there have been case reports of Breast-Implant Capsule-Associated Squamous Cell Carcinoma. Implants have not been linked to breast cancer, but may interfere with the detection of breast cancer. Women with implants report a hesitancy to undergo mammography. One study also found that women with implants and breast cancer had a lower survival rate and larger tumors, which may be due to delayed detection.(Lavinge 2013)

What are today’s options?

Fortunately, surgical advances and women’s advocacy have increased treatment options for women with breast cancer. Most women with early-stage breast cancer or ductal carcinoma in situ (DCIS) may now elect breast-conserving surgeries such as lumpectomy instead of removal of the entire breast. Studies have shown that outcomes are equally favorable for women who undergo lumpectomy vs. mastectomy. Some studies indicate that lumpectomy patients may live longer than mastectomy patients with the same diagnosis.(van Maaren 2016) Of the women

for whom mastectomy is recommended, some choose to not have reconstruction. They may wear prostheses or may “go flat.” Others may elect reconstruction with implant devices or “autologous breast reconstruction” which uses the patient’s own fat and skin tissue from other parts of her body (usually the buttocks). Reconstruction with implants is no longer an automatic “part of the treatment”, but an informed choice for a women to make in consultation with her doctor.

Women in the film who had mastectomies (removal of breast tissue) due to breast cancer or other breast disease felt like they had no choice but reconstruction of the breast with implants.

What studies have been conducted?

Breast implants were initially marketed without safety studies. Several people in the film note the absence of valid scientific evidence of safety. What kind of large-scale, long-term studies have been now been conducted and what have they shown?

As mentioned above, as part of the approval of breast implant devices as safe and effective, the FDA required the device manufacturers to fund and conduct several studies. These studies were the **Core Studies** of several hundred women who had implants between the first hearings in 2003 and approval in 2006 and 2007. The FDA interpreted the findings from these studies as follows: “Despite frequent local complications and adverse outcomes, the FDA determined that the benefits and risks of breast implants were sufficiently well understood for women to make informed decisions about their use.” The Core Studies were designed to follow these women for 10 years after implantation. After three and four years of data, these studies were the basis of approval of Mentor and Allergan silicone implants.

The “post-approval” studies included the **Large Studies** designed to enroll and follow almost 40,000 women with silicone and saline implants from 2006-2016; **Device Failure Studies** investigating the likely causes of failure in explanted devices; **Focus Group Studies** to improve patient understanding of the device labels and their warnings; **Annual Physician Informed Decision Studies** to monitor the process by which surgeons provide information on devices (labels) to patients; and **Adjunct Studies** of women who received implants 1992-2006, prior to approval, when implants could only be used for reconstruction and replacement of existing implants. The findings of some of these studies were compiled in a [report published](#) by the FDA in 2011. Although data continues to be collected, analyzed, very briefly reported on the FDA’s post-approval [studies page](#), the FDA has not updated their report nor conclusions since their June 2011 report.

Many journal articles have appeared, however, based on data from these studies. Authors tend to be associated with manufacturers directly or through funding; or they are plastic surgeons. Most articles based on these studies conclude that implants rupture at a rate of between 1-10%;



In the face of the newly documented diagnosis of a cancer of the immune system caused by breast implants, as well as well publicized case reports, and the biologic plausibility of an inflammatory response to silicone and/or platinum resulting in immune system problems, many advocates and scientists have called for large-scale, well-designed, independently-conducted studies to evaluate the potential linkage between silicone implants and these systemic health issues.

ruptures increase particularly after 6 years; failures are generally attributable to damage by surgical instruments during implantation; implants can cause local complications described in the FDA booklet; re-operation is common; and implants are not associated with systemic illnesses including adverse pregnancy outcomes. However, the FDA admitted that the studies that they mandated are not designed to detect long-term adverse effects and, in fact, BIA-ALCL was discovered outside of these data sets. For many reasons, these large-scale studies are considered inadequate by advocates and scientists who suggest that better designed large-scale studies should be conducted by scientists who do not have financial conflicts of interest.

Study authors tend to be associated with manufacturers directly or through funding; or they are plastic surgeons.

What other concerns with implants have been raised since the film was finished?

Researchers have documented that the most common reasons that women seek breast augmentation are to improve self-esteem and their relationships. Unfortunately, despite the fact that women are seeking to improve their lives through this surgery, women who get breast implants are at increased risk of suicide.(Zuckerman 2016) Pre- and post-operation assessments of mental health suggest that rather than depressive women seeking implants, women’s mental health declines post-implant. Surprisingly, this is true of breast augmentation patients of different ages in different countries. The rate of suicide was especially high in mastectomy patients who elected reconstruction with breast implants, compared to mastectomy patients who did not undergo reconstruction.

Are newer implants safer and stronger?

The FDA has approved new implants since the hearings presented in the film. The first generation of silicone implants had a firm shell, a fabric patch on the back to hold them in place, and a 100% tendency to cause capsular contracture (hardening).(Hillard, 2017) A second generation were designed to be more “natural,” with a thinner silicone gel and shell, and, as a result, were fragile enough to produce a rapid 60% rupture rate and bleed silicone out of the implant and into the woman’s body. To lower the rupture rate, manufacturers experimented with putting a polyurethane coating on the outside of the implant that promoted an inflammatory response in women’s breasts stimulating the formation of a scar-tissue “shell” to protect the implant. Unfortunately, in the breast, the chemicals in the coating broke down to form a cancer-causing chemical. In part due to concerns about silicone implants, saline-filled silicone implants were developed and used alongside the evolving silicone implants. Local complications and cosmetic defects are common with saline implants and saline implants are still made with silicone.

Study authors tend to be associated with manufacturers directly or through funding; or they are plastic surgeons.

Changes in the third generation of implants — those that were presented for FDA approval — included multiple layers of the outer shell to prevent both rupture and bleeding and a larger particle sized silicone thought to not migrate through these layers. The next generation of implants included a stronger outer elastomer coating and a more cohesive and shaped gel inside the implant. These devices were most often made with a textured surface to prevent shifting after implantation. The relatively rare cancer BIA-ALCL is more common among women with textured implants, whether silicone or saline. The current generation of implants, the so-called “gummy bear” breast implants have a stronger outer shell designed to prevent rupture and bleeding of silicone, and a firmer, more cohesive gel. Despite these purported design advances, women with these implants continue to face significant rates of re-operation, rupture and capsular contracture. (Stevens 2016) The rupture rate for Sientra cohesive gel implants at 10 years was 9% overall as determined by MRI studies. Studies conducted in other countries tend to show higher rupture rates. A large percentage of the problems with breast implants that are reported to the FDA in recent years are for gummy bear implants. (Zuckerman 2017)

For many years, manufacturers marketed their products without safety testing or clinical studies of health effects on women with implants. That has now changed, but weaknesses and potential bias in the studies are important to consider in interpreting safety claims based on these long-term studies. Breast implant manufacturers are required to submit safety data to the FDA prior to marketing their products. The required safety data is outlined in FDA guidelines issued in 2006, over 10 years ago. While the data from the FDA-mandated studies continues to be accumulated, the FDA still asserts that they are unable to assure anyone that breast implants are absolutely safe, despite approvals of the devices. Approved devices must only have benefits that outweigh the risks and be as safe and as effective as currently marketed devices, which means that all documented health effects are considered “normal” and subjective judgements of “benefit” and “risk” take precedence over a growing body of evidence of health effects.



In the face of the newly documented diagnosis of a cancer of the immune system caused by breast implants, as well as well publicized case reports, and the biologic plausibility of an inflammatory response to silicone and/or platinum resulting in immune system problems, many advocates and scientists have called for large-scale, well-designed, independently-conducted studies to evaluate the potential linkage between silicone implants and these systemic health issues.

FDA and others note that safety data and health studies on both older and newer devices is limited in several important respects. Hillard et al. reports that the manufacturers' studies of rupture rates of "modern" implants vary considerably between implants and different types of patient surgeries (primary augmentation versus reconstruction). They also note that there is very little consistency between the studies of implant performance and significant concern about high numbers of women "lost to follow-up" and therefore not included in the studies. Authors of one of the most respected medical reviews, the Cochrane Database, complained that despite the fact that almost 1 million women have had breast reconstruction with implants, there was no coherent recommendations based on the data available that they could offer women and their surgeons regarding preferred implants and approaches. (Rocco 2016) In other words, it is fair to say that the devices are still being tested on the women who are electing to implant them.

It is fair to say that the devices are still being tested on the women who are electing to implant them.

What efforts have been made to reduce the impact of financial conflicts of interest?

The impact of conflicts of interest in science and medicine has gained increasing attention in recent years. A provision of the Affordable Care Act known as the "Sunshine Act," requires doctors and medical facilities to report payments that they receive from pharmaceutical and medical device companies. These data are publicly available at <https://openpaymentsdata.cms.gov/>. Additionally, medical journals and databases are now requiring greater disclosure of the funding and affiliations of article authors. Under the Patient's Bill of Rights, doctors are supposed to disclose to their patients their potential conflicts of interest that might impact their treatment recommendations, such as if a doctor is invested in a company that manufactures implants. Despite these efforts at greater transparency, it is not clear that they have had a significant impact in reducing money's influence over science and medicine.

How popular are breast implants today?

While there is no mandatory or official registry for implants surgeries, the American Society of Plastic Surgeons reports that breast augmentation remains the most popular plastic surgery in the United States with almost 300,000 women undergoing the operation annually for cosmetic reasons and an additional 100,000 women getting implants for breast reconstruction. Over \$1 billion are paid by women out of pocket for the surgery with an average cost of \$3,719 per surgery. An additional \$71 million are spent on implant removals for operations that cost on average \$2,500. 74% of women undergoing breast augmentation identify as Caucasian; 6% African-American; 6% Asian-American; and 10% Hispanic. (Plastic Surgery Statistics, 2016)

300,000 women undergo breast implant surgery annually for cosmetic reason.

Are there any special issues for people seeking implants as a part of gender affirmation surgery?

Breast augmentation may be one component of a surgical approach to treating gender dysphoria or as an elective component of feminizing gender transition. The American Society of Plastic Surgeons FDA and others note that safety data and health studies on both older and newer devices is limited in several important respects. Hillard et al. reports that the manufacturers' studies of rupture rates of "modern" implants vary considerably between implants and different types of patient surgeries (primary augmentation versus reconstruction).

They also note that there is very little consistency between the studies of implant performance and significant concern about high numbers of women "lost to follow-up" and therefore not included in the studies. Authors of one of the most respected medical reviews, the Cochrane Database, complained that despite the fact that almost 1 million women have had breast reconstruction with implants, there was no coherent recommendations based on the data available that they could offer women and their surgeons regarding preferred implants and approaches. (Rocco 2016) In other words, it is fair to say that the devices are still being tested on the women who are electing to implant them.



References

- Balk, Ethan M., Amy Earley, Esther A. Avendano, and Gowri Raman. "Long-Term Health Outcomes in Women With Silicone Gel Breast Implants: A Systematic Review." *Annals of Internal Medicine* 164, no. 3 (February 2, 2016): 164–75. doi:10.7326/M15-1169.
- "Breast Implant Information." *Breast Implant Information*. Accessed July 7, 2017. <http://www.breastimplantinfo.org>
- Clemens, Mark W., Maurizio Bruno Nava, Nicola Rocco, and Roberto N. Miranda. "Understanding Rare Adverse Sequelae of Breast Implants: Anaplastic Large-Cell Lymphoma, Late Seromas, and Double Capsules." *Gland Surgery* 6, no. 2 (April 2017): 169–84. doi:10.21037/g.s.2016.11.03.
- Colaris, Maartje J. L., Mintsje de Boer, Rene R. van der Hulst, and Jan Willem Cohen Tervaert. "Two Hundreds Cases of ASIA Syndrome Following Silicone Implants: A Comparative Study of 30 Years and a Review of Current Literature." *Immunologic Research* 65, no. 1 (2017): 120–28. doi:10.1007/s12026-016-8821-y.
- De Boer, M. M. Colaris, R. R. W. J. van der Hulst, and J. W. Cohen Tervaert. "Is Explantation of Silicone Breast Implants Useful in Patients with Complaints?" *Immunologic Research* 65, no. 1 (2017): 25–36. doi:10.1007/s12026-016-8813-y
- Goren, Idan, Gad Segal, and Yehuda Shoefeld. "Autoimmune/Inflammatory Syndrome Induced by Adjuvant (ASIA) Evolution after Silicone Implants. Who Is at Risk?" *Clinical Rheumatology* 34, no. 10 (October 2015): 1661–66. doi:10.1007/s10067-015-2931-0.
- Grady, Denise. "A Shocking Diagnosis: Breast Implants 'Gave Me Cancer.'" *The New York Times*, May 14, 2017, sec. Health. <https://www.nytimes.com/2017/05/14/health/breast-implants-cancer.html>.
- Hillard, Christopher, Jason D. Fowler, Ruth Barta, and Bruce Cunningham. "Silicone Breast Implant Rupture: A Review." *Gland Surgery* 6, no. 2 (April 2017): 163–68. doi:10.21037/g.s.2016.09.12.
- Lavigne, Eric, Eric J. Holowaty, Sai Yi Pan, Paul J. Villeneuve, Kenneth C. Johnson, Dean A. Fergusson, Howard Morrison, and Jacques Brisson. "Breast Cancer Detection and Survival among Women with Cosmetic Breast Implants: Systematic Review and Meta-Analysis of Observational Studies." *BMJ* 346 (April 30, 2013): f2399. doi:10.1136/bmj.f2399.
- Olsen, Daniel L., Gary L. Keeney, Beiyun Chen, Daniel W. Visscher, and Jodi M. Carter. "Breast Implant Capsule-Associated Squamous Cell Carcinoma: A Report of Two Cases." *Human Pathology*, July 21, 2017. doi:10.1016/j.humpath.2017.07.011.
- Pittman, Troy A., Kenneth L. Fan, and Megan A. Rudolph. "Anaplastic Large Cell Lymphoma: Emerging Consent and Management Patterns among American and International Board Certified Plastic Surgeons." *Plastic and Reconstructive Surgery* 138, no. 5 (November 2016): 811e–818e. doi:10.1097/PRS.0000000000002622.
- "Plastic Surgery Statistics." *American Society of Plastic Surgeons*. Accessed August 9, 2017. <http://www.plasticsurgery.org/news/plastic-surgery-statistics>.
-

References...continued

- “Post-Approval Studies (PAS).” Accessed August 1, 2017. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm?c_id=73&t_id=90235.
- Rocco, Nicola, Corrado Rispoli, Lorenzo Moja, Bruno Amato, Loredana Iannone, Serena Testa, Andrea Spano, Giuseppe Catanuto, Antonello Accurso, and Maurizio B. Nava. “Different Types of Implants for Reconstructive Breast Surgery.” *The Cochrane Database of Systematic Reviews*, no. 5 (May 16, 2016): CD010895. doi:10.1002/14651858.CD010895.pub2.
- Stevens, W. Grant, M. Bradley Calobrace, Jennifer Harrington, Kaveh Alizadeh, Kamakshi R. Zeidler, and Rosalyn C. d’Incelli. “Nine-Year Core Study Data for Sientra’s FDA-Approved Round and Shaped Implants with High-Strength Cohesive Silicone Gel.” *Aesthetic Surgery Journal* 36, no. 4 (April 1, 2016): 404–16. doi:10.1093/asj/sjw015.
- U.S. Food and Drug Administration. “Breast Implants.” WebContent. Accessed June 28, 2017. <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/>
- van Maaren, Marissa C. et al. “10 Year Survival after Breast-Conserving Surgery plus Radiotherapy Compared with Mastectomy in Early Breast Cancer in the Netherlands: A Population-Based Study.” *The Lancet Oncology* 17, no. 8 (August 1, 2016): 1158–70. [https://doi.org/10.1016/S1470-2045\(16\)30067-5](https://doi.org/10.1016/S1470-2045(16)30067-5).
- “What You Need to Know If You Have Breast Implants - The New York Times.” Accessed August 7, 2017. <https://www.nytimes.com/2017/05/14/health/what-you-need-to-know-if-you-have-breast-implants.html?action=click&contentCollection=Health&module=RelatedCoverage®ion=EndOfArticle&pgtype=article>.
- Zuckerman, Diana M., Caitlin E. Kennedy, and Mishka Terplan. “Breast Implants, Self-Esteem, Quality of Life, and the Risk of Suicide.” *Women’s Health Issues* 26, no. 4 (July 1, 2016): 361–65. doi:10.1016/j.whi.2016.03.002.
- Zuckerman, Diana M., Madris Tomes, and Ameila Murphy, “Are ‘Gummy Bear’ Breast Implants the Safer Implants?,” in *Breast Implants*, ed. Rene Simon. Nova Science Publishers, 2017.