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Everything You Wanted to Know About Breast Augmentation Surgery But Were Afraid To Ask: A Medical - Legal Overview

Samuel D. Hodge

Marshall G. Miles

James B. Pancio

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EVERYTHING YOU WANTED TO KNOW ABOUT BREAST AUGMENTATION SURGERY BUT WERE AFRAID TO ASK: A MEDICAL - LEGAL OVERVIEW

Samuel D. Hodge, Jr., Marshall G. Miles** and James B. Pancio****

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* **Samuel D. Hodge, Jr.** is a professor of Legal Studies at Temple University where he teaches both law and anatomy. He has authored more than 150 articles in medical and legal journals and has written six medical/legal texts. Professor Hodge is one of the most popular CLE speakers in the country, enjoys an AV Preeminent rating and has been named a top rated lawyer in Pennsylvania.

** **Marshall G. Miles, D. O.** is a board certified plastic and reconstructive surgeon who currently serves as the Associate Program Director of the Plastic Surgical Residency training program, as well as the Associate Chief of the Division of Plastic Surgery at Lehigh Valley Health Network in Allentown, PA. He maintains a full scope active clinical practice of Plastic and Hand Surgery and has done so for the last 8 years.

*** **James Pancio** is a former teaching Assistant to Professor Hodge and law clerk to the Chief Judge of the Superior Court of Pennsylvania.

"I wish I had a twin, so I could know what I'd look like without plastic surgery."

—JOAN RIVERS¹

Jessica Lee² was unhappy with her appearance and underwent breast augmentation surgery to obtain a shapelier figure. She was overjoyed with her new look until the ill-fated day that her body started to reject one of the implants. Much to her dismay, the saline-filled insert started to protrude and eventually broke through the skin. Jessica had to have revision surgery to fix the problem³ caused by a capsular contracture, a difficulty that occurs when tight scar tissue forms around an implant.⁴

INTRODUCTION

Breast augmentation is one of the most popular cosmetic procedures in the United States.⁵ The surgery is performed by the uses of different substances, such as saline or fat to enlarge breast size, to reestablish breast dimension or to reconstruct the chest area after a mastectomy or injury. Common difficulties include capsular contracture, additional surgery, implant removal, rupture or deflation of the implant and bleeding. Occasionally, patients are not pleased with the aesthetics of the implants, claiming that they are improperly positioned, asymmetrical, too large or too small, fake in appearance, or their scars are too wide or thick.

Cosmetic surgery has become more accessible to a wider portion of society⁶ resulting in 15.9 million operations and minimally-invasive procedures being performed in the United States in 2015.⁷ This is a

1. *Joan Rivers*, BBC NEWS (Sept. 5, 2015), <http://www.bbc.com/news/entertainment-arts-29075239>.

2. This is a fictitious name.

3. This story is based upon: Anna Hodgekiss, *Boob Job Horror for Woman*, DAILY MAIL (May 18, 2016), <http://www.dailymail.co.uk/health/article-2295139/Boob-job-horror-woman-25-implant-fell-OUT-chest—leaving-lopsided-seven-months.html>.

4. *Id.* As noted in *Toole v. McClintock*, 999 F.2d 1430 (11th Cir. 1993) capsular contracture is "a condition in which a capsule of scar tissue forms around the implant and gradually contracts, deforming or hardening the breast."

5. Portions of this article have been reprinted with permission. Samuel D. Hodge Jr., et al., *When Breast Augmentation Surgery Goes Awry: Litigation and Liability Issues*, PENN. B. ASS'N Q., Jan. 2017, at 21-30.

6. THE INCREASE IN POPULARITY OF COSMETIC SURGERY OVER THE LAST DECADE, 22 FACIAL PLASTIC SURGERY TODAY (Facial Plastic Surgery, Alexandria, Va.), 4 Q 2008, http://www.aafprs.org/patient/fps_today/vol22/04/pg1.html.

7. *Annual Plastic Surgery Statistics*, SCIENCE DAILY, (Feb. 25, 2016), <https://www.sciencedaily.com/releases/2016/02/160225181636.htm>.

115 percent increase in the number of procedures since the turn of the 21st century.⁸ This surge is the result of a multitude of factors such as the number of healthcare professionals performing the techniques, the influence of the media, and the less-invasive nature of the surgeries.⁹ It is also a reflection of our fascination with celebrities, the numerous stories about their appearance enhancing surgeries, and the information available through the Internet about the different procedures.¹⁰

Cosmetic procedures offer immediate satisfaction but they are not without risk.¹¹ Complications range from an infection at the incision site to permanent nerve damage and even death.¹² For example, it has been projected that those who undergo breast augmentation surgery experience more than a 25% chance of developing complications that mandate an additional procedure.¹³ The Food and Drug Administration has even published a booklet that highlights the most common problems encountered with silicone gel-filled and saline-filled breast implants.¹⁴

This article will provide a medical/legal perspective to breast augmentation surgery. Written by an attorney who teaches anatomy and a plastic surgeon who routinely performs the procedure, it will initially offer a medical analysis of how the procedure is performed along with its attendant risks. The second part will focus on the court cases and legal theories that have arisen when things go wrong. The article will explain the convoluted litigation history involving breast augmentation when suits were common place and a group of experts linked breast implants to the development of autoimmune disease without any real scientific basis to support their opinions. It will conclude with a discussion of the various legal theories currently being asserted when the surgery does not live up to the patient's expectations.

8. *Annual Plastic Surgery Statistics*, *supra* note 7.

9. See Adrian Furnham & James Levitas, *Factors that Motivate People to Undergo Cosmetic Surgery*, 20 CAN. J. PLAST. SURGERY Winter 2012, at 47-50, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3513261/> (last visited July 12, 2017).

10. THE INCREASE IN POPULARITY OF COSMETIC SURGERY OVER THE LAST DECADE, *supra* note 6.

11. *Statistics on Complications of Cosmetic Surgery*, MODERN MOM, <http://www.modernmom.com/2e31d432-051f-11e2-9d62-404062497d7e.html> (last visited June 27, 2017).

12. *Id.*

13. *Id.*

14. *Breast Implants: Local Complications and Adverse Outcomes*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm259296.htm> (last visited June 27, 2017).

I. BREAST AUGMENTATION – AN OVERVIEW

As noted in *Calvin v. Allure Medical Spa*, “breast augmentation goes to the essence of what plastic surgeons do.”¹⁵ This procedure uses various materials, such as saline or fat to enlarge the breasts, to reestablish breast size as the result of weight loss or childbirth or to restructure the chest area after a mastectomy or injury.¹⁶ The American Society of Plastic Surgeons further notes that augmentation mammoplasty is a highly personal decision that serves several purposes: it can enhance fullness and projection of the breasts, it can improve a person’s body image, and it can boast an individual’s shape.¹⁷ It will not, however, correct breasts that severely sag. That requires a breast lift.¹⁸

Historically, Japanese prostitutes were the first to enlarge their breast during World War II to attract American military personnel. Paraffin, sponges and non-medical grade silicone were used to achieve this purpose. The idea of breast enlargements really gained traction as the result of the busty appearance of Marilyn Monroe and Jane Russell, who emphasized their curvy shapes, and started women thinking about increasing their breasts size.¹⁹

Silicone implants were developed by two physicians in Texas, and in 1962, Timmie Jean Lindsey became the first person to receive these enhancements.²⁰ Breast augmentation surgery is now the second-most popular cosmetic procedure worldwide, after liposuction.²¹ In addition to those who want to improve their shape, the cosmetic procedure has found another very valuable use; to help those who have undergone mastectomies to regain their self-esteem.²² On the other hand, about 43,000 implants were removed in 2015 for a variety of reasons demonstrating that the surgery is not always a panacea or a permanent solution.²³

15. *Calvin v. Allure Medical Spa*, 2012 WL 8009769, at *5 (Mich. Cir. Ct. July 16, 2012).

16. *What Is Breast Augmentation?*, AM. SOC’Y OF PLASTIC SURGEONS, <https://www.plasticsurgery.org/cosmetic-procedures/breast-augmentation> (last visited June 27, 2017).

17. *Id.*

18. *Id.*

19. Claire Bowes & Cordelia Hebblethwaite, *A Brief History of Breast Enlargements*, BBC NEWS (Mar. 29, 2012), <http://www.bbc.com/news/magazine-17511491>.

20. *Chronology of Silicone Breast Implants*, PBS, <http://www.pbs.org/wgbh/pages/frontline/implants/cron.html> (last visited July 12, 2017).

21. Bowes & Hebblethwaite, *supra* note 19.

22. *Id.*

23. Diana Zuckerman, et al., *Facts About Breast Implants*, OUR BODIES OURSELVES (Oct. 25, 2016), <http://www.ourbodiesourselves.org/health-info/facts-about-breast-implants/>.

A. Anatomy of the Breast

Breasts are not uniform in size, weight or shape but they have the same anatomic construction. These tear-shaped glands cover the chest muscles and are suspended over the ribs. In turn, they are kept in position by supporting soft tissues which give breasts their shape.²⁴ Anatomically, the female breast is composed of an array of fat cells known as adipose tissue.²⁵ The mammary glands have no muscle and the volume of fat establishes their size.²⁶ The milk producing part of the breast will have 10 to 20 sections positioned in a circular pattern dubbed “lobes.”²⁷ Each lobe consists of a number of smaller lobules, the glandular tissue that creates milk in nursing women.²⁸ Milk ducts connect the lobes and lobules and serve as conduits to transport the milk to the nipple.²⁹ The darker aspect of the breast encircling the nipple is the areola or focal point of the gland.³⁰ They come in a variety of sizes and colors and include tiny sweat glands called Montgomery’s glands which secrete the liquid that lubricates the nipple during breastfeeding.³¹

The breast also contains a series of blood and lymph vessels as well as lymph nodes.³² These lymphatic vessels, which resemble tubes, drain to the lymph nodes located in the underarm and underneath the sternum.³³ The breast obtains its blood supply principally from the internal mammary artery. This blood vessel is located below the core breast tissue and delivers oxygen and other nutrients to the gland.³⁴

24. Robert Valdes, *How Breast Implants Work*, HOW STUFF WORKS, <http://science.howstuffworks.com/innovation/everyday-innovations/breast-implant1.htm> (last visited July 12, 2017).

25. *Breast Anatomy*, NAT’L BREAST CANCER FOUND., <http://www.nationalbreastcancer.org/breast-anatomy> (last visited June 7, 2016).

26. *Picture of the Breasts*, WEBMD, <http://www.webmd.com/women/picture-of-the-breasts> (last visited July 12, 2017).

27. *Breast Anatomy*, *supra* note 25.

28. *Id.*

29. *Id.*

30. *Picture of the Breasts*, *supra* note 26.

31. Melissa Stoppler, *Breast Anatomy*, MEDICINET.COM, http://www.medicinenet.com/breast_anatomy/article.htm (last visited July 12, 2017).

32. *Picture of the Breasts*, *supra* note 26; *Lymph Node Status*, SUSAN G. KOMEN, <http://ww5.komen.org/BreastCancer/LymphNodeStatus.html> (last visited July 12, 2017) (defining lymph nodes as “small clumps of immune cells that act as filters for the lymphatic system”).

33. *Id.*

34. *Anatomy and Physiology of the Breast*, JOHNS HOPKINS MED., <http://pathology.jhu.edu/breast/anatomy.php> (last visited November 18, 2016).

B. Kinds of Implants

This cosmetic procedure increases or reestablishes breast size by using silicone and saline implants or fat transfer.³⁵ Saline implants³⁶ are encased in a silicone shell filled with sterile salt water.³⁷ The casing is empty when first introduced into the breast and then filled with liquid to achieve the preferred size.³⁸ A silicone implant, on the other hand, contains an outer shell that is prefilled with a plastic gel.³⁹ Women tend to favor this category of implant⁴⁰ because it feels more like a natural breast but it presents a greater hazard of leaking.⁴¹

One might be surprised that silicone implants are still being used in view of action by the FDA in 1992 prohibiting their sale and the flurry of litigation that erupted over their use.⁴² After conducting more research on the issue, however, the FDA determined in 2006 to again allow certain silicone breast implants to be utilized in breast augmentations.⁴³

35. *Breast Augmentation*, SMART BEAUTY GUIDE, <http://www.smartbeautyguide.com/procedures/breast/breast-augmentation> (last visited July 12, 2017).

36. Saline implants have several advantages such as they have a detailed history of safe use, the saline is similar to body fluids as it can be reabsorbed into the surrounding tissue if it ruptures and they come in round or anatomical shapes. See *Breast Enlargement (Implants)*, NHS CHOICES, <http://www.nhs.uk/Conditions/Breast-implants/Pages/Considerations.aspx> (last visited July 12, 2017).

37. *Breast Implants*, WEBMD, <http://www.webmd.com/beauty/breast-implants/cosmetic-procedures-breast-augmentation> (last visited July 12, 2017).

38. *Breast Implants: Saline vs. Silicone*, MAYO CLINIC (June 13, 2015), <http://www.mayoclinic.org/healthy-lifestyle/womens-health/in-depth/breast-implants/art-20045957>.

39. *Id.*

40. The benefits of silicone gel implants are that have a prolonged history of safe use, they may be less probable to crinkle than the others forms of implants, they are manufactured in contour shapes known as a teardrop, and the gel can be soft and pliable like the tissues of the breast. The major problem with the silicone implant is a rupture of the shell causing the gel to spread into the breast causing small lumps to develop called siliconomas. See *Breast Enlargement (Implants)*, *supra* note 36.

41. *Breast Implants: Saline vs. Silicone*, *supra* note 38; *Breast Implants*, *supra* note 37.

42. For a chronology of the history of breast implants and related litigation, see *Chronology of Silicone Breast Implants*, *supra* note 20.

43. Stephanie Saul, *F.D.A. Will Allow Breast Implants Made of Silicone*, N. Y. Times (Nov. 18, 2006), <http://www.nytimes.com/2006/11/18/washington/18breast.html>. The female breast continues to develop into a woman's late teens or early twenties. Therefore, the FDA mandates that a female be at least 18 years old before she may receive a saline implant. Silicone implants, however, require that the patient have reached her twenty-second birthday before she is allowed to have this type of breast augmentation surgery. *Breast Implants*, *supra* note 37.

C. Surgery

Breast enhancement, breast augmentation, augmentation mammoplasty, or breast implant surgery is routinely performed by a plastic surgeon and there are a number of methods to perform the operation. The aim is to make an incision in an inconspicuous area to minimize visible scarring.⁴⁴ Incision placement will vary depending upon the type of implant, the amount of the enlargement, the patient's anatomy and the preference of the patient and physician. Typical incision areas include the region around the nipple, under the fold of the breast, in the arm pit or the belly button.⁴⁵ The place of the incision, however, can have an impact on the prominence of the scar and post-surgical complications.⁴⁶

The underside of the breast is the most popular location because the incision can be made in the natural folds of the skin. This placement, however, may cause a more visible scar, particularly in younger and thin women.⁴⁷ An under the arm incision, a technique known as an transaxillary incision, will usually involve the use of an endoscope to assist the surgeon guide the implant into its proper location.⁴⁸ Its obvious advantage is that there will be no visible scar around the breast.⁴⁹ The disadvantages are that of a higher complication rate of malposition, poor symmetry, increased bleeding, and the inability to use silicone implants. A periareolar incision involves cutting around the edge of the nipple but its drawback is that the patient may experience a loss or change of feeling in the areola.⁵⁰

Employing the undersurface of the breast as the incision point will mandate a 4 to 5 cm opening to insert the implant into a generous pocket beneath (submuscular) or above (subglandular) the pectoralis muscle.⁵¹ The submuscular approach allows direct and easy access to the muscle in order to dissect a pocket beneath it, and it provides a

44. *Breast Augmentation - Augmentation Mammoplasty*, AM. SOC'Y OF PLASTIC SURGEONS, <https://www.plasticsurgery.org/cosmetic-procedures/breast-augmentation/procedure> (last visited July 12, 2017).

45. *Id.*; *Breast Implant Surgery*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064176.htm> (last visited July 12, 2017) (The FDA-approved labeling discourages surgeons from placing the breast implant through the belly-button).

46. *See Breast Implant Surgery*, *supra* note 45.

47. *Id.*

48. *Id.*

49. *Id.*

50. *Breast Augmentation - Augmentation Mammoplasty*, *supra* note 44.

51. *Id.*

predictable and reliable result with the lowest complication rate. Additionally, the implant is less likely to become exposed, or “rejected”, so to speak, due to the strong muscle overlying it.

There are variations to this technique. For instance, the surgeon may utilize a saline implant, because it can be rolled up like a cigarette and inserted through an even smaller incision and then filled once in place under the muscle, or some surgeons will use a subglandular approach and place the implant on top of the pectoralis muscle.⁵² The disadvantages of the subglandular technique include slightly increased pain when elevating the muscle, as well as increased anatomical deformity, which is basically the movement of the implant with activation of the overlying pectoralis muscle.

D. Complications

Traditional complications involving breast augmentation include; capsular contracture, nipple numbness, additional surgery, implant removal, and leakage, rupture, or deflation of the implant.⁵³ Patients routinely ask, “What if my body rejects the implant?”⁵⁴ In reality, it is not a case of rejection. The implant, whether saline or a silicone gel, still possesses a silicone shell or outer layer.⁵⁵ That layer is a foreign body, and if one develops even a small infection after the surgery, bacteria can adhere tightly to the implant making it difficult to resolve the infection. As the infection builds, it may erode through the incision and begin to drain fluid or pus. It is through this opening that the implant will extrude. A significant infection is difficult to destroy without removal of the implant much like an infected artificial knee or heart valve.

Bleeding is a rare occurrence, but it can be encountered. Blood can accumulate and form a hematoma. This complication can some-

52. Dr. Miles, the co-author of this piece, prefers going under the muscle, as it is yet one additional layer of well perfused and strong muscle protecting the implant from the outside world. It helps conceal rippling or waviness of the implant that can be seen when it sits just under the skin. It also provides an “internal massage” to the tissue around the implant every time the muscle fires and that helps reduce capsular contracture rates.

53. *Breast Implant Complications Booklet*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm259296.htm> (last visited June 6, 2016).

54. Samuel D. Hodge, et al., *Everything you wanted to know about breast augmentation surgery but were afraid to ask: A medical – legal overview* (forthcoming 2017).

55. See *Silicone Vs. Saline Breast Implants – What Are The Differences*, CTR. FOR AESTHETIC SURGERY, <http://www.epsteinplasticsurgery.com/blog/breast-augmentation/silicone-vs-saline-breast-implants-%E2%80%93-what-are-the-differences> (last visited Nov. 14, 2017).

times lead to additional surgery to locate the source of the bleeding and to evacuate the hematoma. If the patient's body makes an inappropriately thick scar that becomes tight and starts to squeeze the breast, a distortion of the implant and pain can occur. This complication is known as a high grade capsular contracture and sometimes demands additional surgery to resect the tight scar tissue.

Sometimes, patients are unhappy with the look of the implants, maintaining that they are malpositioned, asymmetrical, too large, too small, fake in appearance, or their scars are too wide or thick. Women can also suffer injury to the sensory nerve to the areolar complex. This complication occurs in about fifteen percent of cases⁵⁶ and is significant in that sensual arousal of the nipple will be lost, as will the suckling response of a nursing infant, thus creating an inability to breastfeed. An extremely rare complication is a pneumothorax or collapsed lung. This can happen when dissecting the plane beneath the pectoralis muscle just above the ribs. If the patient is very thin, so too are the tissues in that area and one can inadvertently cause a small hole or tear in the pleura, causing a collapsed lung.

Hypertrophic scarring occurs in two to five percent of patients.⁵⁷ As noted in *New York v. Coote*, hypertrophic scarring is a bulky red scar that occurs after surgery and "almost looks piled up with scar tissue."⁵⁸ Proper treatment may require additional surgery or steroid injections into the scar area.⁵⁹

II. A RETROSPECTIVE REVIEW OF BREAST IMPLANT LITIGATION

Breast implant litigation enjoys a robust, but controversial history. The first successful lawsuit over ruptured breast implants occurred in 1977, when a Cleveland woman obtained a \$170,000 settlement from Dow Corning.⁶⁰ Three years later, Ralph Nader issued a warning that silicone breast implants caused cancer⁶¹ and the race to the courthouse was set in motion. A few years later, a woman was awarded \$211,000 in compensatory and \$1.5 million in punitive dam-

56. Hodge, *supra* note 54.

57. *The risk of complications from breast augmentation surgery*, OBP MED., <https://obpmedical.com/resource-center/blog/the-risk-of-complications-from-breast-augmentation-surgery/> (last visited June 7, 2016).

58. *People v. Coote*, 110 A.D.3d 485, 485 (S. Ct. N.Y. 2013).

59. *The risk of complications from breast augmentation surgery*, *supra* note 57.

60. *Chronology of Silicone Breast Implants*, *supra* note 20.

61. *Id.*

ages after a jury determined that the plaintiff's systemic autoimmune disease was caused by her silicone breast implants.⁶²

Breast implant litigation received a lot of attention in 1991 when a jury awarded a woman \$840,000 in compensatory damages and \$6.5 million in punitive damages.⁶³ The facts show that in 1976, Mariann Hopkins had a mastectomy and implants made by Dow Corning were used to reconstruct her breasts. Subsequently, she was diagnosed with a mixed connective tissue disease. Continued difficulties with her implants required additional surgery which revealed that her implants had ruptured.⁶⁴ The implants were sent to Dow for analysis who determined that upon "examination and testing of both envelopes [it] found no evidence to indicate that any of the damage was manufacturer related."⁶⁵ Two years later, the plaintiff's mother learned that there might be a link between the ruptured implants and her daughter's immune disorder.

The plaintiff sued Dow claiming fraud, strict products liability, and breach of warranties. Plaintiff's counsel presented evidence that the defendant rushed the development of the implants, failed to properly test them, and disregarded knowledge of unfavorable health outcomes associated with the units.⁶⁶ The evidence also revealed that the implants had a high rate of rupture and Dow was aware of the toxic effects of silicone on the body.⁶⁷

The media's coverage over silicone breast implants exploded in 1991 as the result of a lawsuit filed by Pamela Johnson.⁶⁸ The plaintiff asserted that silicone leaked from her implants thereby compromising her immune system. This resulted in her having a partial mastectomy. A jury awarded Ms. Johnson \$25 million which was the largest award against a breast implant manufacturer up to that time.⁶⁹

This verdict was criticized in the American Medical Association's Journal of Ethics which pointed out that the plaintiff was a smoker with no known autoimmune disease. Instead, she had a mix of

62. *Chronology of Silicone Breast Implants*, *supra* note 20.

63. *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116 (9th Cir. 1994).

64. *Id.* at 1121.

65. *Id.* at 1119.

66. *Hopkins*, 33 F.3d at 1124.

67. *Id.*

68. See Kristin E. Schleiter, *Silicone Breast Implant Litigation*, *AMA J. OF ETHICS: 12 VIRTUAL MENTOR* (5), 389-94, <http://journalofethics.ama-assn.org/2010/05/hlaw1-1005.html> (last visited July 4, 2017).

69. *Record \$25 Million Awarded In Silicone-Gel Implants Case*, *N.Y. TIMES*, (Dec. 24, 1992), <http://www.nytimes.com/1992/12/24/us/record-25-million-awarded-in-silicone-gel-implants-case.html>.

non-specific complaints including chronic fatigue, muscle pain, joint pain, headaches, and dizziness. It was claimed that the plaintiff's lawyer generated great sympathy for his client by hiring a public relations firm that obtained interviews with a variety of television shows including *60 Minutes*.⁷⁰ The large verdict fueled an explosion of lawsuits.⁷¹

Contemporaneously, the FDA ordered manufacturers of silicone gel breast implants to provide additional studies noting that the existing research was insufficient to prove the safety of the devices.⁷² In 1992, the agency determined that the sale of implants should be limited to women who have had mastectomies, breast deformities, or to replace a broken gel implant.⁷³ This ruling was greeted with mixed results. Some found the determination a much needed prophylactic measure, while others condemned the FDA's order and the decision-making process that produced it.⁷⁴ Critics claimed that the FDA only focused on the issue after the court cases surrounding implants had increased and the news had focused on the issue.⁷⁵ In other words, the critics maintained that the ruling was "swayed by politics and other extra-scientific concerns instead of being directed by science."⁷⁶

In any event, the consequence of the negative pronouncement by the FDA was immediate and devastating. Despite the agency's reassurances that people who had implants were in no danger, the damage was done. The public felt that the FDA would not have taken such a dramatic step unless there was a substantial risk. This resulted in a

70. See Schleiter, *supra* note 68.

71. Henry J. Reske, *Record Implant Verdict*, ABA J., Apr. 1993, at 24.

72. *The FDA & Breast Implants*, BREAST IMPLANT INFO, <http://www.breastimplantinfo.org/what-you-need-to-know/aathe-fda-breast-implants/> (last visited July 4, 2017).

73. *Id.*

74. See Shelly Friedland, *FDA's Role in the Silicone Breast Implant Story*, HARV. (Jan. 24, 1997), <https://dash.harvard.edu/bitstream/handle/1/8846748/sfriedla.html?sequence=2>.

75. Dr. Jack Fisher, a plastic surgeon, who has authored a book on the saga of breast implants believes that problem and controversy over silicone gel breast implants occurred during the late 1980's and 1990's as the result of a single person, David Kessler, head of the FDA at the time. The author notes that Kessler "relied on dubious legal testimony to cast doubt on the implants' safety while ignoring the ubiquity of silicone polymers in our environment and their successful application in hundreds of medical devices over the previous five decades." Monique Kenney, *The Sad Saga of Silicone Breast Implants*, SCOOP.IT, <https://www.scoop.it/t/health-and-beauty-by-monique-kinney/p/4038621558/2015/03/07/the-sad-saga-of-silicone-breast-implants> (last visited Nov. 14, 2017) (citing Henry Miller, *The Sad Saga of Silicone Breast Implants*, FORBES, (Mar. 4, 2015 6:00 A.M.), <https://www.forbes.com/sites/henrymiller/2015/03/04/infuriating-titbits-about-silicone-breast-implants/#7d2076f02141/0>

76. *Id.* (other criticisms focused based on the opinion and the fact that it was corrupted by both improper information and the prejudice or lack of credentials of panel members).

stream of women who returned to their surgeons demanding that their implants be removed.⁷⁷

These developments, and the growing financial toll, caused several manufacturers to withdraw from the silicone breast implant business.⁷⁸ Breast implant companies continued to suffer setbacks when, in 1994, a jury awarded three plaintiffs \$27.9 million in compensatory and punitive damages based upon allegations of atypical lupus, neurological impairment, or a "silicone induced" autoimmune problem.⁷⁹

Increasingly, women with breast implants stepped forward asserting a multitude of issues, and a small group of experts continued to link breast implants to the development of autoimmune disease without any real scientific basis to support their conclusions.⁸⁰ Needing to limit their financial losses, the breast-implant manufacturers consented to a very large class-action settlement.⁸¹ A fund of \$4.25 billion was created for women with breast implants.⁸² This sum was split with \$1.2 billion being devoted to women asserting current implant-related issues and the balance would be set aside for those with implants who became sick over the next three decades.⁸³

The wheels came off the wagon in the plaintiffs' successful run of breast implant litigation in 1994 as the result of a study conducted by the Mayo Clinic.⁸⁴ The 30-year study published in the *New England Journal of Medicine* found no connection between breast implants, connective-tissue diseases, and other disorders.⁸⁵ The article further noted the earlier studies examining the link between silicone-containing breast implants and connective-tissue disorders were methodologically flawed with a lack of objective validation of the results.⁸⁶ The American College of Rheumatology weighed in on the issue one year later.⁸⁷ This organization noted there was no persuasive proof that silicone im-

77. Marcia Angell, *Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion*, 334 *NEW ENG. J. MED.* 1513, 1514 (1996).

78. *Chronology of Silicone Breast Implants*, *supra* note 20.

79. *Id.*

80. Angell, *supra* note 77.

81. *Id.*

82. *Id.*

83. *Id.*

84. See Sherine E. Gabriel et al., *Risk of Connective-Tissue Diseases and Other Disorders after Breast Implantation*, 330 *NEW ENG. J. MED.* 1697 (1994).

85. *Id.*

86. *Id.*

87. See *Statement on Silicone Breast Implants: Am. C. of Rheumatology*, PBS (Oct. 22, 1995), <http://www.pbs.org/wgbh/pages/frontline/implants/medical/positionstate.html>.

plants subjected women to any additional threat for connective tissue or rheumatic disease.⁸⁸ They went on to say that anecdotal evidence should no longer be utilized in an attempt to create such an association in the courts or by the FDA.⁸⁹ A variety of other organizations and studies found no association between breast implants and the increased risk for disease.⁹⁰ The Food and Drug Administration reversed its position after a 14-year ban on the use of silicone gel implants when, in 2006, it approved implants by two manufacturers for breast reconstruction and augmentation.⁹¹

The public again became comfortable with breast augmentation surgery and the raging controversy over the safety of implants seems to be a thing of the past in most circles.⁹² Breast enhancement surgery remains one of the most common cosmetic procedures with more than 350,000 operations being performed annually in the United States.⁹³

III. CURRENT LITIGATION

Dockets are replete with thousands of lawsuits involving breast implants. The volume of cases, however, is much less than 40 years ago during the frenzy over the safety of the devices. Nevertheless, breast augmentation is still a surgical procedure with its attendant complications and unfulfilled expectations by some patients. The types of lawsuits and theories of liability run the gamut from cases of malpractice to whether an exotic dancer can claim breast augmentation surgery as a proper business expense. Interestingly, the cases involving breast implant litigation are not limited to the United States.⁹⁴ A number of courts from around the world have heard cases involving breast implants. This summary, however, will focus on the lawsuits

88. *Statement on Silicone Breast Implants*, *supra* note 87.

89. *Id.*

90. A chronological listing of studies which found no link between disease and breast implants can be found at David Bernstein, *The Breast Implant Fiasco*, 87 CALIF. L. REV. 457, 457-510 (1999).

91. Saul, *supra* note 43.

92. There is still a small number of people who believe that breast implants are dangerous. See Nalini Chilkov, *25 Reasons Not to Get Breast Implants*, HUFF POST (Feb. 1, 2011), http://www.huffingtonpost.com/nalini-chilkov/breast-implant-surgery-_b_816077.html.

93. Jennifer Whitlock, *Most Popular Plastic Surgeries*, VERYWELL (Apr. 1, 2015), <https://www.verywell.com/most-popular-plastic-surgeries-3157239>.

94. *Women May Have to Pay Back Dodgy Breast Implant Damages*, CBS NEWS (July 2, 2015), <http://www.cbsnews.com/news/french-court-rules-no-compensation-over-faulty-pip-french-breast-implants/> (illustrating how a French court ruled that a product testing firm did not have to pay more than 3,000 women who had developed “leak-prone breast implants”).

involving breast implants filed in the 21st Century. The history of litigation before that time is covered in the previous section.

A. Capsular Contracture

Capsular contracture occurs when scar tissue forms around the implant and “gradually contracts, deforming or hardening the breast.”⁹⁵ This is an acknowledged risk of this form of cosmetic surgery and it is estimated that around 10% of women with breast implants will develop this painful condition.⁹⁶ Statistically, there is a higher rate of capsular contracture in those who obtain silicone implants as compared to those with saline implants.⁹⁷ Because the condition results from bacteria, it is a common source of breast implant litigation.

In *Maynard v. Sena*, the plaintiff filed a malpractice action against a plastic surgeon claiming that he was negligent in her postoperative care by not wearing surgical gloves when he drained fluid that had developed in the plaintiff’s left breast as the result of a capsular contracture.⁹⁸ She maintained that this failure caused her to develop an infection, which resulted in lengthy and extensive difficulties.⁹⁹ A defense verdict was rendered and the primary issue on appeal was whether the trial judge committed error by allowing the physician to testify as to his custom of always wearing gloves in his office when conducting surgical procedures.¹⁰⁰ Particularly persuasive in the Court’s choice to affirm the judgment was the trial court’s statement that: “Evidence of a habit of a person or the retained practice of an organization is admissible to prove that the conduct of the person or organization on a particular occasion was in conformity of the habit or routine practice.”¹⁰¹

Murphy v. U.S. also involved a non-sterile environment.¹⁰² Murphy had breast augmentation surgery at a military facility and

95. *Toole v. McClintock*, 999 F.2d 1430, 1431 (11th Cir. 1993).

96. *Breast Implants Placement and Likelihood of Capsular Contracture*, REALSELF Q&A BLOG, <https://www.realself.com/question/subfascial-subpectoral-breast-implant-capsular-contraction> (last visited July 22, 2017).

97. Yasser El-Sheikh et al., *Incidence of Capsular Contracture in Silicone versus Saline Cosmetic Augmentation Mammoplasty: A Meta-Analysis*, 16 n. 4 *Can. J. Plastic. Surgery* 211, 211 (2008), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2691025/>.

98. *Maynard v. Sena*, 125 A.3d 541, 544 (Conn. App. Ct. 2015).

99. *Id.*

100. *Id.*

101. *Maynard*, 125 A.3d at 546.

102. *Murphy v. United States*, No. CIV. 06-00304 BMK, 2009 WL 454627 (D. Haw. Feb. 23, 2009).

soon discovered a lump in her breast, which caused increasing pain.¹⁰³ A consultation with another surgeon revealed a four-inch human hair was attached to the left implant which caused a capsular contracture.¹⁰⁴ This condition was described as “a shrinkage of the natural scar tissue that forms around a breast implant and causes the implant to become tight and feel firm and hard.”¹⁰⁵ The primary dispute was whether the strand of hair caused the capsular contracture.¹⁰⁶ The plaintiff’s expert testified that capsular contracture develops in five percent of breast implant patients.¹⁰⁷ While the problem is not fully understood, it is caused by something other than an implant that is left inside the pocket of the breast such as bacterial or a human hair.¹⁰⁸ The government’s expert opined that if the hair found on the implant had caused the capsular contracture, it would have resulted in an inflammatory response and the hair would have been surrounded by a scar.¹⁰⁹ Since the hair was attached to the implant rather than embedded in a scar, the expert noted that the foreign matter did not cause the condition.¹¹⁰ The court found in favor of the plaintiff and determined that the hair was the primary cause or significantly exacerbated her condition.¹¹¹ The experts both agreed that bacteria is the primary culprit in the development of this painful condition, but the court found the explanation provided by claimant’s expert more persuasive.¹¹²

B. Tax Deduction for Breast Implants

One of the more unusual cases involves a claim brought by Cynthia Hess, a/k/a Chesty Love, challenging an Internal Revenue determination that breast implants were not an ordinary and necessary expense in relation to a business.¹¹³ Ms. Hess was a topless dancer whose agent convinced her to have breast implants in order to enlarge

103. *Murphy*, 2009 WL 454627, at *1.

104. *Murphy*, 2009 WL 454627 at *2.

105. *Id.*

106. *Id.*

107. *Id.*

108. *Murphy*, 2009 WL 454627 at *2.

109. *Id.* at *3.

110. *Id.*

111. *Id.*

112. *Murphy*, 2009 WL 454627 at *3.

113. Julian Block, *Tax Court Upholds Business-Expense Deduction for Topless Dancer’s Breast Implants*, HUFFPOST (May 9, 2014), http://www.huffingtonpost.com/julian-block/tax-court-upholds-busines_b_5292707.html.

her breast size from a 55FF to a 56 N.¹¹⁴ The Special Trial Judge determined that the surgical procedure was deducible because it enhanced her breasts, was only useful in her line of work, and as such, the breasts were a necessary business prop.¹¹⁵ The judge made the analogy that the implants were similar to business cloths and uniforms.¹¹⁶ As the court noted, "Because petitioner's implants were so extraordinarily large, we find that they were useful only in her business."¹¹⁷

C. Invasion of Privacy

An entity can be held liable for the disclosure of private information about an individual, even if accurate, under the tort of the public disclosure of a private fact.¹¹⁸ This action is defined by the Restatement (Second) of Torts as the dissemination of private information that "(a) would be highly offensive to a reasonable person and (b) is not of legitimate concern to the public."¹¹⁹ Would a woman have a viable cause of action for invasion of privacy if her plastic surgeon accidentally sent pictures of her naked torso to the human resources department of the plaintiff's employer for a pre-surgery coverage determination, instead of to her insurance company?¹²⁰ That is the issue in *Mays v. The Marshall University Board of Governors*.¹²¹ The plaintiff had a mastectomy and reconstructive surgery to her left breast that involved the use of an implant.¹²² A few years later, she became concerned over the appearance of her breast and visited a surgeon about additional surgery.¹²³ During the examination, pictures were taken of her naked breast in order to obtain pre-approval for payment from her insurance carrier.¹²⁴ Unfortunately, the pictures were inadvertently sent to the plaintiff's employer.¹²⁵ The transmittal letter

114. *Hess v. Comm'r of Internal Revenue*, 1994 U.S. Tax Ct. LEXIS 88, at *2-3 (May 4, 1994).

115. *Id.* at *11.

116. *Id.* at *10.

117. *Id.*

118. See Phyllis Karasov et al., *Chapter 13: Privacy*, in *BUSINESS DISPUTES: CLAIMS AND REMEDIES* 13-1 (Edward T. Wahl ed., 2d ed. 2017), http://www.larkinhoffman.com/files/OTHER/Karasov_Privacy_MNCLE.pdf.

119. RESTATEMENT (SECOND) OF TORTS § 652D cmt. a (AM. LAW INST. 1977).

120. *Mays v. Marshall Univ. Bd. of Governors*, No. 14-0788, 2015 WL 6181508 (W. Va. Oct. 20, 2015).

121. *Id.*

122. *Id.* at *1.

123. *Id.*

124. *Mays*, 2015 WL 6181508 at *1.

125. *Id.*

contained the plaintiff's name along with the images.¹²⁶ The envelope was opened by a representative of the Human Resource Department who immediately showed them to her supervisor.¹²⁷ The manager directed that the pictures be forwarded to the plaintiff in a sealed envelope marked confidential.¹²⁸ The court dismissed the lawsuit noting Mays' medical information was not disclosed to the public.¹²⁹ It ruled that tort entails widespread disclosure and it cannot be limited to a small group of people.¹³⁰ In this case, the pictures were only viewed by two people so the plaintiff did not have a viable cause of action.¹³¹

Hetter v. Eight Judicial District Court In and For the County of Clark, involved an invasion of privacy claim by a patient after her plastic surgeon used her before and after breast augmentation pictures in a brochure.¹³² The defendant countered that Hetter had consented to the publication of the pictures in exchange for a reduction in the price of the operation.¹³³ During discovery, the trial judge issued an order directing the doctor to disclose a list of his patients so that counsel for the plaintiff could send a letter asking if the patients had viewed the brochure.¹³⁴ The defense filed a Writ of Mandamus challenging this order on the basis of physician-patient privilege and relevancy.¹³⁵ The court granted the request and prohibited the disclosure of the information.¹³⁶ While disclosing a patient's identity does not always violate the doctor-patient privilege, the revealing of a patient's name in this situation discloses that plastic surgery is implicated.¹³⁷ Most people would consider "breast augmentation as a confidential matter they would not want disclosed."¹³⁸

126. *Mays*, 2015 WL 6181508.

127. *Id.*

128. *Mays*, 2015 WL 6181508 at *1.

129. *Id.*

130. *Id.* at *6-7

131. *Id.* at *7

132. *Hetter v. Eight Judicial Dis. Court of State In & For Cty. of Clark*, 874 P.2d 762 (Nev. 1994).

133. *Id.* at 763.

134. *Id.*

135. *Hetter*, 874 P.2d at 763.

136. *Id.* at 766.

137. *Id.* at 764.

138. *Id.* at 763.

D. Defamation

A physician filed a defamation action against his patient over negative comments that she posted on a website in *Loftus v. Nazari*.¹³⁹ The facts demonstrate that Nazari had breast implant surgery and a breast lift.¹⁴⁰ She was unhappy with the results and posted her opinion on a website complaining that the doctor had left her with permanent nerve damage, terrible scars and disfigured breasts.¹⁴¹ The defendant then went on to say that she had filed a complaint with the U.S. Attorney and the Ohio Medical Board.¹⁴² The court dismissed the claim finding that the statements concerning her poor surgical results were protected opinion.¹⁴³

In *Smith v. Garber*, the plaintiff had a breast augmentation performed by Dr. Garber.¹⁴⁴ Because the plaintiff believed the surgery was done incorrectly, she sued for malpractice.¹⁴⁵ Subsequently, a magazine ran a story about the notable career of Sal Calabro, M.D., a well-known plastic surgeon, who was affiliated with Dr. Garber.¹⁴⁶ The article stated in part:

Over the years, Calabro has been named in a handful of lawsuits; some were thrown out of court, and his name was removed from others directed at the work of his associate physicians. Dr. Brett Garber, who handles some of Calabro's breast work now, is involved in two suits from patients at Calabro's center 'I'm pissed that I got sued at Sal's, but do I think these are frivolous charges? Yes', he says. 'Was Sal involved in either of them? No. When you're a celebrity, you're going to get kooks.'¹⁴⁷

This article prompted a second lawsuit for defamation in which the claim was dismissed.¹⁴⁸ The court stated that "questionable rhetoric or hyperbole do not constitute defamation."¹⁴⁹ It was reasonable

139. *Loftus v. Nazari*, 21 F. Supp. 3d 849 (E. D. Ky. 2014).

140. *Id.* at 852.

141. *Id.*

142. *Loftus*, 21 F. Supp. At 852.

143. *Id.* at 856.

144. *Smith v. Garber*, No. CIV.A. 03-1424, 2003 WL 21960720, at *1 (E.D. Pa. June 25, 2003).

145. *Id.* at *1.

146. *Id.*

147. *Smith*, 2003 WL 21960720 at *1.

148. *Id.*

149. *Id.* at * 1.

that the plaintiff would take offense to being referred to as a “kook”, but the article was not reasonably capable of a being defamatory.¹⁵⁰

E. Social Security Disability

In *Hays v. Colvin*, the plaintiff applied for social security benefits alleging a variety of ailments, one of which was related to her breast implants.¹⁵¹ The standard for disability is “the inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.”¹⁵² Determination of disability under the Social Security Act requires a five-step analysis:

(1) [the claimant] is unable to engage in substantial gainful activity; (2) has a severe medically determinable physical or mental impairment; (3) has such an impairment that meets or equals a Listing and meets the duration requirements; (4) can perform [her] past relevant work, in light of his residual functional capacity; and (5) can make an adjustment to other work, in light of [her] residual functional capacity, age, education, and work experience.¹⁵³

The plaintiff previously had silicone breast implants, which were found to be leaking.¹⁵⁴ These were eventually replaced with saline implants.¹⁵⁵ The plaintiff had trouble sitting, standing, lifting, bending, and had several epidural blocks.¹⁵⁶ Ultimately, the Administrative Law Judge (“ALJ”) found that the plaintiff did not qualify for disability benefits because she could still perform a full range of light work, and her impairments could reasonably be expected to produce no worse than a moderate degree of pain.¹⁵⁷ The District Court upheld the findings of the ALJ, because absent an abuse of discretion, the District Court will not disturb the ALJ’s findings.¹⁵⁸

150. *Id.* at *2; *see also*, Fowler v. Capital Cities/ABC, Inc., No. CIV.A.3:00-CV-2417-P, 2002 WL 31230802 (N.D. Tex. 2002); Martinez v. Soignier, 570 So.2d 23 (La. Ct. App.1990).

151. *Hays v. Colvin*, No. 2:15-CV-00100-JEO, 2016 WL 1270524, at *1 (N.D. Ala. 2016).

152. *Id.* at *2; 42 U.S.C. § 423(d)(1)(A)(2015); 42 U.S.C. § 416(i)(1)(2004).

153. *Hays*, 2016 WL 1270524 at *2 (quoting Evans v. Comm’r, Soc. Sec. Admin., 551 F. App’x 521, 524 (11th Cir. 2014)).

154. *Id.* at *4.

155. *Id.*

156. *Hays*, 2016 WL 1270524 at *4

157. *Id.* at *3.

158. *Id.* at *6.

F. Preclusion of Expert Testimony

Novel scientific evidence is subject to challenge before the court will allow the testimony.¹⁵⁹ The admissibility of expert testimony in federal and some state courts is governed by four factors set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*¹⁶⁰ The factors are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error in using a particular scientific technique and the existence and maintenance of standards controlling the technique's operation; and (4) whether the theory or technique has been generally accepted in the particular scientific field.¹⁶¹ While these factors are most commonly used, they are neither definitive nor exhaustive.¹⁶²

The Court in *In re Dow Corning Corp.* applied these factors in relation to three expert witnesses for the plaintiff, who elected not to participate in a settlement process as part of a confirmed Chapter 11 plan, and instead brought suit to recover for alleged injuries involving silicone breast implants.¹⁶³

The Court disqualified the first expert, Dr. Jerry Bush, because he did not establish his knowledge or training as it relates to autoimmune disease.¹⁶⁴ While Dr. Bush had knowledge, skill, experience, and education as to internal medicine, he had no specific knowledge as to whether silicone breast implants could cause autoimmune diseases.¹⁶⁵ In his report, Dr. Bush never identified how the silicone implants caused the plaintiff's autoimmune disease.¹⁶⁶ He did not cite to any theory that had been subject to peer review and publication, choosing instead to merely summarize the plaintiff's medical history.¹⁶⁷ Because of these reasons, the Court found Dr. Bush's testimony would not assist the jury in determining causation, and the Court precluded his testimony.¹⁶⁸

159. See generally *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

160. *Id.* at 593-94.

161. *Id.*

162. *Id.*

163. *In re Dow Corning Corp.*, 541 B.R. 643, 649-53 (E.D. Mich. 2015).

164. *In re Dow Corning Corp.*, 541 B.R. at 649.

165. *Id.* at 650.

166. *Id.* at 650.

167. *In re Dow Corning Corp.*, 541 B.R. at 650.

168. *Id.*

Dr. Justus Fiechtner was the plaintiff's second expert.¹⁶⁹ This physician was a rheumatologist, and the Court decided this was enough to establish his expertise in the field.¹⁷⁰ However, the Court found that Dr. Fiechtner's report lacked methodology, reasoning, and analysis as to how the plaintiff was "predisposed" to autoimmune diseases.¹⁷¹ Dr. Fiechtner admitted in a deposition that the probability of silicone implants causing an autoimmune disease was less than fifty percent, but, an expert attempting to establish proximate cause must state his opinion to a more than a fifty percent likelihood.¹⁷² The Court found Dr. Fiechtner's report would not assist the jury so his testimony was also precluded.¹⁷³

The plaintiff's third expert was Pierre Blais, Ph.D.¹⁷⁴ Dr. Blais was a specialist in the field relating to the chemical properties of silicone gel, however, he could not agree that the silicone gel caused the plaintiff's diseases since he was not a medical doctor.¹⁷⁵ Even though Dr. Blais' research would assist the jury in regards to the chemical properties of silicone, his testimony was speculative as to whether the silicone actually caused injuries.¹⁷⁶ Additionally, other courts have held that Dr. Blais' testimony was unreliable. Therefore, this Court excluded his testimony as to the cause of the plaintiff's injuries.¹⁷⁷

Defendants then moved for summary judgment, claiming that the plaintiff could no longer establish causation without any expert reports.¹⁷⁸ The plaintiff asserted that the defendants' renewed motion demonstrated an attempt to discredit the opinions of the proposed experts, and because the plaintiff had already been awarded Social Security benefits, the issue of causation had been determined.¹⁷⁹ The Court disagreed and ruled in favor of the defendants; holding that because all of plaintiff's expert testimony had been excluded, she had no way to prove causation.¹⁸⁰

In *Norris v. Baxter Healthcare Corporation*, the plaintiff received silicone gel breast implants in 1974, manufactured by the

169. *In re Dow Corning Corp.*, 541 B.R. at 651.

170. *Id.* at 651-52.

171. *In re Dow Corning Corp.*, 541 B.R. at 651-52.

172. *Id.* at 652.

173. *Id.*

174. *In re Dow Corning Corp.*, 541 B.R. at 652.

175. *Id.* at 653.

176. *Id.*

177. *Id.* at 653.

178. *In re Dow Corning Corp.*, 541 B.R. at 654.

179. *Id.* 654-55.

180. *Id.* at 654-55.

defendant's predecessor.¹⁸¹ In 1978, her right implant ruptured and the plaintiff had both implants replaced with a set manufactured by Dow Corning.¹⁸² The plaintiff sued Baxter, alleging the ruptured implant in 1978 caused a series of ailments, including one doctor's belief that she had silicone-induced lupus.¹⁸³

In silicone breast implant litigation, plaintiffs must show both general causation, meaning the substance can cause a particular injury, and specific causation, meaning the substance caused a particular individual's injury.¹⁸⁴ The Court concluded that epidemiological studies are the best evidence of general causation in a toxic tort case.¹⁸⁵

The plaintiff presented two experts, Dr. Vasey and Dr. Espinoza.¹⁸⁶ The District Court excluded both experts, using Federal Rule of Evidence 702 and the *Daubert* factors, because the experts were unreliable as they did not use epidemiological studies in their reports.¹⁸⁷ The Court of Appeals agreed that both doctors' testimony should be excluded.¹⁸⁸ Even though the experts are qualified in the field of rheumatology, they ignored or discounted many of the epidemiological studies finding no reliable link between silicone breast implants and systemic disease.¹⁸⁹ The methodology used by both doctors was deemed not medically or scientifically valid.¹⁹⁰ The doctors' reports relied solely on differential diagnosis and case studies to establish a link between silicone implants and systemic disease, however, this directly contradicted all available epidemiological studies.¹⁹¹ The Court held that in such cases of blatant disagreement, summary judgment for the defendant is appropriate.¹⁹²

181. *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 879 (10th Cir. 2005).

182. *Id.* at 880.

183. *Id.*

184. *Norris*, 397 F.3d at 881.

185. *Id.* at 882.

186. *Id.* at 883.

187. *Id.*

188. *Norris*, 397 F.3d at 886.

189. *Id.* at 885.

190. *Id.* at 884.

191. *Id.* at 887.

192. *Id.*

G. Pneumothorax

In *Vernon v. Benson*, the plaintiff sued Dr. Royal Benson for injuries resulting from a breast augmentation procedure.¹⁹³ During this operation, the plaintiff alleged Dr. Benson caused a pneumothorax, which is commonly caused when a needle for local anesthesia is advanced too far or is misplaced and enters the pleural cavity.¹⁹⁴

Dr. William Gorman, the plaintiff's expert, opined that Dr. Benson breached the standard of care by causing Vernon to suffer a pneumothorax.¹⁹⁵ Dr. Gorman opined that the defendant strayed outside of the normal dissection plane and entered the pleural cavity.¹⁹⁶ Combined with the fact that plaintiff showed no signs of a pneumothorax before the procedure, Dr. Gorman concluded the pneumothorax was the fault of the surgeon.¹⁹⁷ In the recovery room, the patient complained of shortness of breath and chest wall pain, but the pneumothorax went undiagnosed for nearly a week.¹⁹⁸ Dr. Gorman stated these symptoms should never be ignored, and that Dr. Benson breached the standard of care for surgical treatment and postoperative care.¹⁹⁹

At trial, Dr. Benson filed a motion to dismiss based on Dr. Gorman's failure to provide a fair summary of the standard of care as well as what the defendant should have done differently to prevent and treat the pneumothorax.²⁰⁰ The trial court, however, found Dr. Gorman's reports discussed the appropriate standard of care with sufficient specificity to fulfill the statutory requirements.²⁰¹ The court of appeals stated Dr. Gorman's reports need only to fulfill two purposes: "(1) inform Dr. Benson of the specific conduct [plaintiff] called into question; and (2) provide a basis for the trial court to conclude that the claims have merit."²⁰² The court of appeals upheld the trial court's decision, noting that "[a]n expert report need not marshal all of the plaintiff's evidence," as long as the required purposes are fulfilled.²⁰³

193. *Vernon v. Benson*, 303 S.W.3d 755, 757 (Tex. App. 2009).

194. *Vernon*, 303 S.W.3d at 758.

195. *Id.*

196. *Id.* at 758.

197. *Id.*

198. *Vernon*, 303 S.W.3d at 758.

199. *Id.*

200. *Id.* at 760.

201. *Id.*

202. *Id.*

203. *Id.*

In *Flannery v. President and Director of Georgetown College*, the plaintiff filed suit after breast enlargement surgery allegedly resulted in a hemopneumothorax, which is essentially blood and air in the lungs.²⁰⁴ The plaintiff claimed this was caused as a result of a local anesthetic procedure called an intercostal nerve block.²⁰⁵ The defendant informed the plaintiff of the risks of the surgery itself, but she was not warned about the dangers associated with the anesthetic procedure.²⁰⁶

The record showed there was no warning about hemopneumothorax; however, the plaintiff must also establish an existing causal relationship between the physician's failure to adequately divulge the risk and the damage to the patient.²⁰⁷ The plaintiff testified that she would have forgone surgery had she known about the risk of a hemopneumothorax, but not if she knew the risk of a pneumothorax.²⁰⁸ She also did not prove that she would have selected general anesthesia as opposed to a local anesthetic had she known the risk of a pneumothorax.²⁰⁹ While the court agreed that a patient should be warned of all material risks, it stated that the claimant failed to establish a causal link between a failure to warn and the injuries she suffered.²¹⁰ Therefore, a directed verdict in favor of defendant was appropriate.²¹¹

H. Cancer

In *In re Silicone Gel Breast Implants Products Liability Litigation*, the plaintiff was the administrator of Toni Cagle's estate, who was diagnosed with breast cancer about fourteen months after receiving breast implants.²¹² The plaintiff alleged the implants caused or accelerated the cancer.²¹³ The plaintiff did not allege that the silicone itself caused or accelerated the cancer, but instead maintained that the polyurethane foam ("PUF"), which coated the implants, broke down *in*

204. *Flannery v. President & Dir. of Georgetown Coll.*, 679 F.2d 960, 961 (D.C. Cir. 1982).

205. *Id.*

206. *Id.*

207. *Flannery*, 679 F.2d at 962.

208. *Id.*

209. *Id.*

210. *Id.* at 962-63.

211. *Id.* at 963.

212. *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 318 F. Supp. 2d 879, 886 (C.D. Cal. 2004).

213. *Id.* at 886.

vivo into 2,4-toluene diamine (“TDA”), which he claimed was carcinogenic.²¹⁴

The defendants filed four motions in limine to exclude the testimony of the plaintiff’s four causation experts: (1) Dr. Neugebauer (an epidemiologist), (2) Dr. Batich (a polymer chemist), (3) Dr. Lappe (a toxicologist), and (4) Dr. Shanklin (a pathologist).²¹⁵ The plaintiff’s causation theory, which relied heavily on expert reports, was as follows:

One epidemiological study provided “suggestive evidence” of a causal link between PUF-coated implants and cancer; the PUF coating biodegrades after implantation in humans; the degradation products of the PUF-coating include TDA; TDA is known to be carcinogenic in animals and is a “probable” human carcinogen; and the amount of TDA likely to be released from Cagle’s implants, Cagle’s pregnancy (which began almost immediately after implantation) and the rare type of breast cancer Cagle suffered renders it more likely than not that her tumor was caused by or its growth accelerated by TDA released from her implants.²¹⁶

The court ruled that the plaintiff was unable to offer scientifically reliable evidence to support the last proposition, and therefore, even assuming the first four theories were admissible, summary judgment was appropriate because the plaintiff could not establish the breast implants caused the decedent’s cancer.²¹⁷

In *Enholm v. Cohen*, the plaintiff employed Dr. Steven Cohen to replace breast implants she had received in 1978.²¹⁸ This procedure also involved injecting fat cells in her chest wall to produce softer breasts.²¹⁹ Five months after the surgery, the plaintiff was diagnosed with uterine cancer, which she attributed to the fat cell injections.²²⁰ She sued Dr. Cohen, alleging he failed to obtain her informed consent, the physician committed fraud, and the fat cell injections violated FDA regulations.²²¹

The fat injection procedure, called cell-enhanced fat transfer (“CEFT”), involves removing fat by liposuction from one area of the pa-

214. *In re Prods. Liab. Litig.*, 318 F. Supp. 2d at 887.

215. *In re Prods. Liab. Litig.*, 318 F. Supp. 2d at 887.

216. *Id.* (alteration in original).

217. *Id.*

218. *Enholm v. Cohen*, No. D067252, 2016 WL 142297, at *1 (Cal. Ct. App. Jan. 12, 2016), as modified on denial of reh’g (Jan. 29, 2016).

219. *Id.*

220. *Id.*

221. *Id.*

tient's body and re-introducing it into the patient's breasts.²²² The patient asserted that Dr. Cohen did not inform her of the risks, and that the procedure was not FDA-approved.²²³ Additionally, had she known about the risks, the plaintiff maintained that she would not have had the surgery.²²⁴

Defendant's expert stated Dr. Cohen's "pre-operative care, consent discussions, and information provided to the patient on the CEFT procedure and study were at all times within the appropriate standard of care."²²⁵ The plaintiff admitted at her deposition that "(1) she had no complaints about the surgical results, (2) no physician had attributed her ovarian cancer to the surgery, and (3) she sustained no physical injury from the surgery . . ."²²⁶ Based upon this testimony, as well as other evidence, the court granted summary judgment in favor of Dr. Cohen.²²⁷

The Court of Appeals upheld the granting of summary judgment.²²⁸ The Court noted the plaintiff submitted no expert testimony to refute the defendant's expert, nor did she present any evidence of actual damages.²²⁹ Even though the patient tried to present newly-discovered evidence on appeal, the facts were still overwhelmingly in favor of Dr. Cohen.²³⁰

I. Temporary Restraining Order

In *Baker v. Patterson*, the plaintiffs filed a Motion for Temporary Restraining Order asking the court to force Dr. Patterson to disclose all information available to him regarding the source of the breast implants he placed in plaintiffs' breasts.²³¹ The claimants alleged that Dr. Patterson used non-FDA approved implants manufactured in China when he performed their surgeries.²³²

In order to obtain a temporary restraining order ("TRO"), the moving party must show: "(1) a likelihood of success on the merits; (2) a

222. *Cohen*, 2016 WL 142297, at *1.

223. *Id.*

224. *Id.* at *5.

225. *Id.* at *9.

226. *Cohen*, 2016 WL 142297, at *4.

227. *Id.* at *14.

228. *Id.*

229. *Id.*

230. *Id.*

231. *Baker v. Patterson*, No. 4:16-CV-00181-MWB, 2016 WL 3024017, at *1 (D. Idaho May 25, 2016).

232. *Id.*

likelihood of irreparable harm to the moving party in the absence of preliminary relief; (3) that the balance of equities tips in favor of the moving party; and (4) that an injunction is in the public interest.”²³³ The District Court granted the TRO for only one plaintiff, Camille Adams, because her allegations indicated a likelihood of irreparable harm for the potential physical and emotional damage from non-FDA approved implants and the potential removal of the breast implants.²³⁴ Additionally, the balance of equities tipped strongly in her favor in light of the potential harm, and the absence of any cognizable hardship to Dr. Patterson from disclosing the information.²³⁵ Further, public policy was in favor of granting the TRO because it reflects the general interest in the safety of medical devices.²³⁶

J. Medical Malpractice

Aills v. Boemi involves one of the more substantial verdicts involving breast augmentation surgery.²³⁷ The defendant removed several hundred grams of tissue from each breast and inserted saline implants enlarged to their maximum capacity.²³⁸ These actions interfered with the circulation of the blood causing necrosis to the remaining breast tissue, skin, and nipples.²³⁹ This caused her to undergo thirteen corrective surgeries.²⁴⁰ The plaintiff alleged negligence and lack of informed consent in that the doctor failed to tell her that a breast augmentation could result in harm to her body.²⁴¹ A verdict of \$8,250,000 was rendered by the jury.²⁴²

In *Froneberger v. Owens*, the plaintiff appealed from the granting of defendant’s motion for summary judgment.²⁴³ In 2008, Froneberger was diagnosed with an aggressive form of breast cancer, and underwent a mastectomy on her left breast.²⁴⁴ Dr. Owens was pre-

233. *Baker*, 2016 WL 3024017 (quoting *Idaho v. Coeur d’Alene Tribe*, 49 F. Supp. 3d 751, 762 (D. Idaho 2014)).

234. *Id.*

235. *Baker*, 2016 WL 3024017, at *2.

236. *Id.*

237. *Aills v. Boemi*, No. 06 FJVR 12-23, 2006 WL 3960234, at *1 (Fla. Cir. Ct. Aug. 22, 2006) (Verdict).

238. *Id.*

239. *Id.*

240. *Id.*

241. *Aills*, 2006 WL 3960234, at *1

242. *Id.*

243. *Froneberger v. Owens*, No. 1326, 2016 WL 770003, at *1 (Md. Ct. Spec. App. Feb. 29, 2016).

244. *Id.* at *2.

sent in the operating room to create a “pocket” by placing an expander under her skin to allow for the eventual placement of a gel-based implant.²⁴⁵ Dr. Owens performed the implant surgery in August 2010, and about two and a half weeks later, the plaintiff complained of pain and swelling in her breast.²⁴⁶ After a visit to the hospital, it was decided the implant needed to be removed so the pocket could be cleared of infection, which Dr. Owens subsequently did.²⁴⁷ The patient sued Dr. Owens alleging medical negligence.²⁴⁸

The plaintiff presented one expert, Dr. Kraus, whose deposition surprisingly provided the basis for the granting of summary judgment in favor of the defendant.²⁴⁹ Dr. Kraus initially testified that Dr. Owens departed from the standard of care by not having a variety of sizes and shapes of implants available when she performed the implant surgery, and that the implant used was either too large or not the proper shape, leading to the infection.²⁵⁰ However, later in the deposition, Dr. Kraus stated the implant itself could not have caused the infection to a reasonable degree of medical certainty.²⁵¹ The trial court granted the defendant’s motion for summary judgment because the expert’s testimony did not “[offer] any of the factual underpinnings in the chain of causation.”²⁵² Finding no abuse of discretion on the part of the trial court, the Court of Appeals upheld the ruling.²⁵³

In *Ditto v. McCurdy*, the plaintiff sued Dr. McCurdy, an ear, nose, and throat specialist and cosmetic surgeon, alleging negligence and fraud stemming from a breast augmentation procedure.²⁵⁴ The patient needed seven surgical procedures, some of which were performed without anesthesia, until the implants were removed.²⁵⁵ The jury awarded \$3,500 in special damages, \$1,000,000 in general damages, \$400,000 in damages for fraud, and \$600,000 in punitive damages.²⁵⁶

245. *Froneberger*, 2016 WL 770003.

246. *Id.*

247. *Owens*, 2016 WL 770003, at *2.

248. *Id.*

249. *Id.* at *3.

250. *Id.*

251. *Id.* at *3-4.

252. *Owens*, 2016 WL 770003, at *6.

253. *Id.* at *11.

254. *Ditto v. McCurdy*, 947 P.2d 952, 954 (Haw. 1997) (hereinafter *Ditto II*).

255. *Ditto v. McCurdy*, 947 P.2d 961, 969-71 (Haw. Ct. App.), *as amended* (June 20, 1997), *aff'd in part, rev'd in part*, 947 P.2d 952 (1997).

256. *Ditto II*, 947 P.2d at 954.

The Supreme Court of Hawaii reversed the finding of liability with respect to the fraud count and vacated the award of punitive damages.²⁵⁷

The plaintiff's claim for fraud was premised on the fact that McCurdy had a duty to disclose that he was not a board certified plastic surgeon; this fact was material to her decision to allow the defendant to perform the surgery.²⁵⁸ Dr. McCurdy rebutted this allegation with two experts, who claimed that there is confusion relating to two different certifying boards, and that Dr. McCurdy is a member of one of them.²⁵⁹ Additionally, the surgeon argued that, a physician does not have an affirmative duty to disclose his qualifications to a patient prior to providing treatment.²⁶⁰ The Court agreed and stated that the doctrine of informed consent merely means that a doctor has an affirmative duty to disclose the types of risks and alternatives to a proposed treatment or surgery.²⁶¹ The Court reasoned that Dr. McCurdy was certified as an otolaryngologist, facial surgeon, and cosmetic surgeon, and always held himself out to be so.²⁶² Further, this is a matter for the legislature and the board of medical examiners, and not the courts.²⁶³ Accordingly, because Dr. McCurdy did not have an affirmative duty to disclose his qualifications, he cannot be found liable for fraud.²⁶⁴

K. Emotional Distress

In *Maurer v. Heyer-Schulte Corporation*, the plaintiff claimed that she developed a fear of cancer after breast augmentation surgery, alleging, inter alia, deformation, scarring, several auto-immune diseases, mental pain and suffering, and the physical injury of having a carcinogen placed in her body.²⁶⁵ In order to prevail on a fear of cancer claim, the plaintiff's fear must be reasonable and causally related to the defendant's negligence.²⁶⁶ The plaintiff does not need to prove the implants will lead to cancer, but must show that there is "any possibil-

257. *Id.*

258. *Ditto II*, 947 P.2d at 955.

259. *Id.* at 955-56.

260. *Ditto II*, 947 P.2d at 958.

261. *Id.*

262. *Ditto II*, 947 P.2d at 958.

263. *Id.* at 958-59.

264. *Id.* at 959.

265. *Maurer v. Heyer-Schulte Corp.*, No. CIV.A. 92-3485, 2002 WL 31819160, at *1 (E.D. La. Dec.13, 2002).

266. *Id.* at *3.

ity of acquiring a disease, no matter how remote.”²⁶⁷ However, the patient has to produce at least some reliable scientific evidence that breast implants can cause cancer.²⁶⁸

The surgeon produced two scientific reports which found that there is no association between breast implants and cancer, as well as voluminous epidemiological studies showing no causal link between breast implants and cancer.²⁶⁹ The Court concluded, based on the large amount of evidence produced by the surgeon, that the defendant had met his burden in showing that the plaintiff’s fear of developing cancer was unreasonable as a matter of law.²⁷⁰ The patient merely submitted a handwritten memorandum and a committee staff report in support of her position, neither of which can be considered conclusive scientific evidence.²⁷¹

CONCLUSION

Breast augmentation is one of the most popular forms of plastic surgery. This growth is a reflection of the number of physicians performing the techniques, reduced costs, and the less-invasive nature of the modifications. After all, the procedure offers instant gratification but it is not without risk. Complications range from an infection to permanent nerve damage and even death.

Breast augmentation uses different substances, such as saline or fat to enlarge breast size, to reestablish breast dimension or to reconstruct the chest area after a mastectomy or injury. Common difficulties associated with implants are capsular contracture, additional surgery, implant removal, rupture or deflation of the implant, and bleeding. Occasionally, patients are not pleased with the aesthetics of the implants, claiming that they are malpositioned, asymmetrical, too large or too small, fake in appearance, or their scars are too wide or thick.

Breast implant litigation enjoys a robust, but controversial history. The first successful lawsuit over ruptured breast implants occurred in 1977 and million dollar verdicts became common place. The media’s coverage over silicone breast implants exploded in 1991 as the result of a \$25 million verdict against a manufacturer. This verdict was roundly criticized in the American Medical Association’s Journal of

267. *Id.*

268. *Maurer*, 2002 WL 31819160.

269. *Id.* at *1.

270. *Id.* at *4.

271. *Maurer*, 2002 WL 31819160, at *4.

Ethics and it was claimed that the plaintiff's lawyer generated a great deal of sympathy for his client by hiring a public relations firm that obtained interviews with a variety of television shows. Contemporaneously, the FDA ordered manufacturers of silicone gel breast implants to provide additional studies. They noted that the existing research was insufficient to prove the safety of the devices.

These developments caused several manufacturers to withdraw from the breast implant business. Likewise, more women with breast implants have stepped forward asserting a multitude of issues, and a small group of experts continue to link breast implants to the development of autoimmune disease without any real scientific basis to support their conclusions.

The wheels come off the wagon in the plaintiffs' successful run of breast implant litigation in 1994 as the result of a study conducted by the Mayo Clinic. The 30-year study published in the *New England Journal of Medicine* found no connection between breast implants, connective-tissue diseases and other disorders. This was followed by pronouncements from a variety of other groups who also found no connections between breast implants and disease. Even the FDA ended up reversing its position.

From a litigation point of view, the dockets contain thousands of lawsuits involving breast implants. The volume of cases, however, is much less than it was 40 years ago, during the frenzy over the safety of the devices. Nevertheless, breast augmentation is still a surgical procedure with its attendant complications and unfulfilled expectations by some patients. The types of lawsuits and theories of liability run the gamut like any other surgical procedure, but at least they no longer attempt to link the implants to a variety of diseases based upon flawed scientific studies.