

**hypochondriac** — A person who experiences imaginary physical ailments. The defense contended that this was actually Charlotte Mahlum's condition.

**neurology** — The scientific study of the human nervous system.

**neuropsychiatry** — A medical specialty that combines neurology and psychiatry.

**paresthesia** — A sensation in the body characterized by numbness, prickling, or burning. Evidence is presented at the trial that Charlotte Mahlum had paresthesia before getting implants.

**plaintiff** — A person who brings a legal action, such as a lawsuit. In Mahlum v. Dow Chemical, the plaintiff was Charlotte Mahlum.

**punitive damages** — Money awarded by a court to a person that is intended to punish the defendant and prevent that person or business from repeating the conduct. Punitive damages are also awarded in order to warn others of the consequences of the action. The punitive damage award in Mahlum v. Dow Chemical was \$10 million (later set aside).

**rheumatology** — The scientific study of various diseases that cause pain or inflammation in muscles, tissues, or joints.

**saline implants** — A type of breast implant that contains sterile salt water. Though presumably safer, many contend that they do not feel and look as natural as gel implants and some say they are more likely to leak.

**silicone** — A synthetic plastic developed in the 1930s. It has been used for various medical purposes (artificial joints, implants, etc.) for over a half-century.

**toxicology** — The study of poisons and their effects.

**U.S. Food and Drug Administration** — An agency of the Public Health Service of the U.S. Department of Health and Human Services. Founded in 1927, one of its main duties is to ensure that drugs are safe and effective. It did not begin regulating medical devices (such as breast implants) until 1976.

#### **Things to Think About**

\* Some people look at plastic surgery as a procedure inspired by vanity but in fact it is often used to correct serious disfigurements caused by birth defects, accidents, surgery, and the like. When do you think plastic surgery is justified and when do you think it can become frivolous?

\* Many women who choose breast implants report that they are not urged to do so by the men in their lives, who say they are satisfied with the way the women look. If that is so, can you still make the case that the women are making a sound decision about their choice? What if women who receive breast implants actually find that because their self-esteem is raised they are helped to achieve certain goals in their lives? Do Americans place too much emphasis on physical appearance, especially for women?

\* The defense lawyers in the Mahlum case raised the possibility that Charlotte Mahlum was a hypochondriac. What do you know about hypochondria? Do you ever exaggerate or worry excessively about your health? Based on what you've learned about Charlotte Mahlum's symptoms, do you think they could be caused by hypochondria?

\* How persuasive do you find the evidence that Dow Chemical either ignored or suppressed evidence that silicone gel could be dangerous? If you were a juror in the case, would you have agreed with the verdict?

\* One of the attorneys in the videotape compared silicone gel breast implants to the Dalkon Shield and Agent Orange. What can you learn about these other two controversial products?

#### **Internet Resources**

<http://www.courtTV.com/casefiles/verdicts/mahlum.html> — A useful summary of the case from Court TV.

<http://www.lectlaw.com/files/cas61.htm> — Text of the jury verdict.

<http://consumerlawpage.com/article/dow.shtml> — From a civil trial lawyer, an article entitled, "Update on Breast Implants: The New Evidence Against Dow Chemical."

<http://www.fjc.gov/BREIMLIT/trials.htm> — A useful list of breast implant cases brought to trial.

[http://www.fda.gov/fdac/features/995\\_implants.html](http://www.fda.gov/fdac/features/995_implants.html) — From the FDA, "A Status Report on Breast Implant Safety."

<http://www.fda.gov/cdrh/breastimplants/> — Also from the FDA, their gateway page to information on breast implants, including the latest information updates.

<http://www.pbs.org/wgbh/pages/frontline/implants/note.html>

The PBS series Frontline covers medical and legal aspects of "Breast Implants on Trial."

<http://www.productsliaw.com> — A site devoted to product liability law, it has a section on "Silicone Breast Implants."

#### **Other Resources**

Angell, Marcia. *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case*. W.W. Norton, 1997.

Bondurant, Stuart, ed. *Safety of Silicone Breast Implants*.

National Academy Press, 2000.

Bruning, Nancy. *Breast Implants: Everything You Need to Know*. Hunter House, 1995.

Byrne, John A. *Informed Consent*. McGraw-Hill, 1997.

Jacobson, Nora. *Cleavage: Technology, Controversy, and the Ironies of the Man-Made Breast*. Rutgers Univ. Press, 2000.

Stewart, Mary White. *Silicone Spills: Breast Implants on Trial*. Praeger, 1998.

Vanderford, Marcia L., and Smith, David H. *The Silicone Breast Implant Story: Communication and Uncertainty*.

Lawrence Erlbaum, 1996.

Zimmerman, Susan M. *Silicone Survivors: Women's Experience With Breast Implants*. Temple Univ. Press, 1998.

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When we purchase a product or use a service, we have the right to expect that what we buy is safe. And yet defective products and harmful services are common—indeed, most of the cases in the courts today arise out of just such occurrences. And sometimes lawsuits over products and services result in cases that grip the public in a major way. These cases may attract attention because of the huge numbers of people involved, the novel areas of modern life they reflect, or simply the large amounts of money involved. LANDMARK CONSUMER RIGHTS TRIALS examines some of these unforgettable cases.

## **SILICONE IMPLANTS ON TRIAL MAHLUM v. DOW CHEMICAL**

### **The Silicone Controversy**

Silicone is a type of plastic first developed in the 1930s. It combines the element silicon with oxygen, carbon, and hydrogen to produce a versatile substance that can take the form of a fluid, a rubber-like material, or a gel. Very early in silicone's career it began being put to medical uses, and it's been employed with little debate in such things as pacemakers, heart valves, tubes, catheters, and lenses in the eye. In the years after World War II, doctors began to learn that silicone could be injected into the body to smooth out wrinkles and fill out certain body parts, but it was not until the 1960s that silicone breast implants became available. At first, these implants seemed terrific—they looked natural, felt softer, and could be inserted without making large incisions. And then the debate began.



The makers of silicone gel breast implants were aware that these devices could, on rare occasions, leak into the body, but the scientific evidence was that silicone was an inert, harmless substance. But gradually women with implants began to report health problems, and by the 1980s the U.S. Food and Drug Administration (see Vocabulary) had received a great number of complaints. Finally, in 1991, the FDA, under pressure from the U.S. Congress, required manufacturers to submit data on the safety of silicone gel breast implants, and in the following year the FDA severely restricted their use. Mostly to women who wanted them after undergoing breast removal as part of cancer therapy.

By that point, however, the issue had moved into the courtroom. Many women contended that the manufacturers of these devices had either not tested them thoroughly or had suppressed evidence that they could be harmful, and lawsuits began to be filed. One of the most high-profile of these cases was that involving a Nevada woman named Charlotte Mahlum, whose health, she contended, had been destroyed by leaking silicone gel. Her case provided a public arena for the debate of some serious issues: were the silicone manufacturers at fault or had a kind of hysteria, abetted by litigious clients and eager lawyers, overwhelmed the scientific evidence?

#### **The Issue: Vanity, Medical Necessity, and the Law**

The silicone gel breast implant has been called "the most controversial medical device in history." Why would a woman have breast implants? They don't cure disease; they won't save your life. But for many women who have had a breast removed as part of treatment for breast cancer, a breast implant is a chance to feel whole again after a difficult and painful time. It is estimated that about 20 percent of the breast implants used have gone to women who chose them for breast reconstruction after breast cancer. The other 80 percent have gone to women who wanted them for cosmetic reasons. It may be tempting to criticize these patients, but there's not much doubt that our culture places a premium on certain standards of physical attractiveness. If looking good can help a person achieve a fuller life, how wrong can it be? Many women have reported that breast implants give them more self-confidence and a better feeling about themselves. A survey taken of women who have had the implants found that over 90 percent were satisfied with them, and over 80 percent said they would do it again.

The question, however, is one of safety. Once reports of ill health, possibly related to breast implants, began to arise, silicone gel implants began to get a second look. Scientific evidence, which takes time to collect, has been difficult to interpret, and it seems that opinions tend to fall into three categories. First, there are plastic surgeons and other physicians who believe that the implants are safe and that their condemnation is a form of hysteria. Second, there are women who feel that implants are definitely dangerous and that profit-hungry manufacturers either ignored or suppressed evidence to that effect. And in the middle is a group of researchers who believe that there is evidence that silicone gel implants can be harmful, although perhaps not to the extent that is sometimes charged—maybe there are some women who have a rare genetic predisposition that makes them vulnerable to leaky implants.

But when it comes to the law, the issue is the manufacturer's responsibility to ensure the safety of a product. That issue is what brought silicone gel breast implants into the courtroom.

## TIMELINE

**1948** — ADow Corning article reports that silicone is inert and nonreactive in the body.

**1956** — Another Dow Corning study appears to contradict the 1948 report.

**1964** — Dow Corning begins marketing silicone breast implants.

**1976** — Congress gives the U.S. Food and Drug Administration (see Vocabulary) the authority to regulate medical devices (including implants).

**1984** — Charlotte Mahlum discovers a lump in her breast; the subsequent treatment eventually leads her to choose breast implants.

**1991** — The FDA requires manufacturers to submit data on the safety of silicone gel breast implants.

**November 1991** — A jury in California awards \$7.3 million to Mariann Hopkins, a woman who suffered immune system problems she contended were due to breast implants.

**April 16, 1992** — The FDA severely restricts the use of silicone gel-filled implants.

**1992** — A class action suit against manufacturers of silicone breast implants is organized. The manufacturers offer a \$4.23 billion settlement, but the agreement falls through.

**July 1993** — After suffering various health problems, Charlotte Mahlum has her breast implants removed. She subsequently files a lawsuit against Dow Chemical.

**1993** — Dow Corning, the leading manufacturer of silicone breast implants, declares bankruptcy. The action severs the company from the Mahlum case.

**February 1994** — Charlotte Mahlum begins suffering full-body seizures.

**September 1995** — A judge rules that the case against Dow can proceed despite its bankruptcy protection.

**October 29, 1995** — The jury finds for Charlotte Mahlum in Mahlum v. Dow Chemical. She is awarded \$4 million compensatory damages and \$10 million punitive damages.

**August 1997** — In a class-action lawsuit involving 1,800 Louisiana women, a New Orleans jury finds that Dow Chemical negligently conducted research on silicone and misrepresented the safety of silicone that later went into breast implants manufactured by Dow Corning Corp., a company half-owned by Dow Chemical.

**December 31, 1998** — By divided votes, the Nevada Supreme Court affirms the Mahlum jury verdict awarding compensatory damages but sets aside the verdict awarding punitive damages.

#### **Important People**

**Angell, Marcia** — Physician who studied the evidence regarding silicone breast implants; she concludes that the overwhelming evidence is that they do not cause connective tissue disease.

**Blackburn, Warren** — Rheumatologist (see Vocabulary) who testifies on Dow's behalf that he sees no association between silicone breast implants and the development of rheumatic diseases. He says he examined Charlotte Mahlum and diagnosed fibromyalgia (see Vocabulary).

**Burchiel, Scott** — Toxicologist (see Vocabulary) who testifies that Dow's studies on silicone safety were done only for worker safety and that the majority had nothing to do with breast implants.

**Cargill, Thomas** — Economics professor who testifies in the damages portion of the trial that Dow Chemical's net worth ranges between eight and nine billion dollars.

**Delaney, Don** — Defense attorney in Mahlum v. Dow Chemical.

**Delis, Dean** — Neuropsychiatrist (see Vocabulary) who testifies that he believes Charlotte Mahlum is exaggerating her mental and physical symptoms.

**Eaton, John** — Charlotte Mahlum's neurologist who testifies about her symptoms.

**Ellis, Rick** — Attorney for Charlotte Mahlum.

**Gershwin, Eric** — Physician who testifies on the dangers of silicone on behalf of the plaintiff.

**Heinkle, Joseph** — Accountant who testifies in the damages portion of the trial that Dow's records show that the company made no money.

**Hornsby, Ernie** — Attorney for Charlotte Mahlum.

**Kessler, David** — Commissioner of the U.S. Food and Drug Administration (see Vocabulary) when silicone gel breast implants are banned.

**Lappe, Mar c** — FDA consultant who testifies on behalf of the plaintiffs that Dow suppressed evidence that silicone was not safe.

**Mahlum, Charlotte** — Plaintiff in Mahlum v. Dow Chemical. She sued for health problems she contended were due to breast implants.

**Mahlum, Marvin** — Charlotte Mahlum's husband.

**McCollister, Donald** — Retired toxicologist and the official Dow Chemical representative in the trial.

**Musser, John** — Spokesman for Dow Chemical.

**Nomura, Don** — Defense attorney in Mahlum v. Dow Chemical.

**Pyle, Don** — Defense attorney in Mahlum v. Dow Chemical.

**Rosenberg, Neil** — Neurologist (see Vocabulary) who testifies on behalf of Dow that he did not believe that Charlotte Mahlum had a neurological disease.

**Rowe, V.K.** — Retired Dow Chemical scientist and author of a 1948 report that said that silicone is inert and nonreactive in the body. Witness for the plaintiffs.

**White, Geoff** — Attorney for Charlotte Mahlum.

#### **Vocabulary**

**bioreactivity** — The interaction of the body and a foreign substance.  
**connective tissue disease** — A chronic inflammatory disease that involves a disorder of the body's connective tissues.

**fibromyalgia** — A condition characterized by aching and pain in muscles, tendons, and joints all over the body, especially along the spine.