

# Women who say they were sickened by breast implant disease demand FDA action

**Patients urge advisory panel to recommend banning some products and mandating disclosure of more risk information.**



U.S. health officials are taking another look at the safety of breast implants, including the silicone breast implants pictured here. (Donna McWilliam/AP)

By **Laurie McGinley**

Women who say they were harmed by breast implants demanded the Food and Drug Administration take new steps to protect consumers, including providing

more information about potential risks and banning devices linked to the most serious complications, including cancer.

Telling searing stories about broken health, disrupted families and lost careers, the women pressed an FDA advisory panel to recommend more long-term research, bans or restrictions on certain products and a beefed-up informed consent process so that women have a clear understanding of the risks and benefits of the devices before they opt for surgery.

"I was not warned" about the risks of implants, Jamee Cook, an advocate and former ER paramedic, told the FDA's expert committee. Cook, who lives near Dallas, said that after getting implants in 1998, she suffered for years from swollen lymph nodes, chronic fatigue, migraines and a low-grade fever. She said she eventually had the devices removed, after which many, but not all, of her symptoms eased.

The FDA said recently it is taking a closer look at implants, which have sparked anger and contention for decades. The agency asked its General and Plastic Surgery Devices Advisory Committee for recommendations on a raft of issues, and Cook's testimony was part of a two-day hearing, which continues Tuesday, on the key issues.

Several plastic surgeons pleaded with the panel to proceed carefully, saying that implants generally are safe and an important option for women who want breast augmentation or reconstruction after breast cancer surgery. They said that women's choices should not be curtailed. About 400,000 women a year get implants, 75 percent for cosmetic reasons and the rest for reconstruction after breast-cancer surgery.

Many of the dozens of patients who attended the meeting at FDA's headquarters in Silver Spring, Md., wore ribbons to graphically state their concern about two types of illnesses they say are linked to implants. Black and white ribbons symbolized what's now called "breast implant illness," a constellation of autoimmune problems that includes joint and muscle pain and allergies and fatigue. Pink and green ribbons signified an uncommon lymphoma that health authorities around the world, including the FDA, link to some implants.

Anastasia Allmendinger, a 53-year-old resident of Newport News, Va., said that she got implants in 2010 and years later was diagnosed with the cancer, called

anaplastic large cell lymphoma, or ALCL. She underwent surgery to remove the implants, chemotherapy and a stem-cell transplant, and is now doing well, but said that manufacturers should be held accountable for the illnesses and women should be better informed. Experts say that many patients can be successfully treated only with surgery.

Many of the advocates who spoke on Monday called for a ban on textured implants -- the kind most strongly linked to the cancer. There is some evidence the problem could be caused by bacterial infections involving the implants, researchers said.

The FDA has identified 457 cases of the lymphoma and nine deaths in the United States. Six hundred cases and 17 deaths have been reported worldwide.

On the other main illness of concern -- the one linked to autoimmune and connective-tissue disease -- the FDA and the patient community have long been at odds.

Thousands of women have complained about autoimmune and connective tissue problems on social media but the FDA has repeatedly said that the "weight of evidence" does not show implants cause "systemic" illness.

That opinion was challenged last September, when researchers at MD Anderson Cancer Center found that silicone implants were linked to higher rates of autoimmune disorders such as scleroderma and rheumatoid arthritis than found in the general population. A leading author, Mark Clemens, said the study didn't prove cause and effect but signaled a reason for concern.

The FDA immediately expressed skepticism, saying the study was flawed. But Binita Ashar, the agency's director of surgical devices at the FDA's Center for Devices and Radiological Health, also said the agency is stepping up its long-term surveillance of implants and using patient registries to track complications from the devices.

That view was repeated in the agency's announcement about the meeting that began Monday. The FDA said that "there is not sufficient evidence to show an association between breast implants and rheumatologic or connective tissue disease diagnoses." But it added, "there are numerous breast implant patients convening on social media to discuss a wide variety of symptoms that they are

experiencing – symptoms which may or may not meet the diagnostic criteria to be categorized as a disease.”

Diana Zuckerman, president of the National Center for Health Research, said in an interview she doesn't understand “why the FDA seems so close-minded” about the scientific evidence that at least some women have developed autoimmune diseases as a result of their breast implants. “We have always said we don't know what the percentage is -- just that for women who are sick, getting them out makes them better,” she said.

Zuckerman presented data on Monday from a study that her group conducted involving more than 400 women who had their implants removed because they were having health problems. In the vast majority of cases, she said, the women's health improved. The study has not been published yet.

The FDA banned most implants in 1992 but lifted that ban in 2005. The agency approved implants made by Allergan and Mentor in 2006, requiring them to conduct long-term studies on the impact on women's health.

Recently, the FDA has stepped up its scrutiny of the devices. Last week, it sent warning letters to two major implant manufacturers, saying they hadn't conducted required long-term safety studies of the devices and warning them the devices could be ordered off the market if the studies aren't completed. The agency also said recently it would take a closer look at how materials used in a range of surgical implants – including those used in hip and knee replacements – could potentially affect health.