

Is Rare Breast Implant Risk Cancer, or 'Condition?'

Small Numbers, Big Concerns as FDA, Scientists Study Rare Cancer

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You might call it a scrap over semantics, but the stakes go far beyond words.

As the Food and Drug Administration continues exploring the incidence of a very rare cancer among a small group of women with breast implants, a longtime critic of the devices charged in a letter to the agency that leaders of two plastic surgery groups were encouraging their members to mislead American women by recasting the malignancy as a "condition" that could easily be remedied with surgery, and asked that the regulators stop them.

Dr. Sidney M. Wolfe, director of [Public Citizen's Health Research Group](#), and Dr. Michael Carome, the group's deputy director, sent a letter to the FDA on Thursday in which they passed along information that a concerned reconstructive surgeon shared from a Feb. 3 webinar for the [American Society of Plastic Surgeons](#) and the [American Society of Aesthetic Plastic Surgery](#).

Citing a transcript the surgeon provided, they wrote that the president of ASPS, Dr. Phil Haeck of Seattle, suggested in the members-only talk that surgeons respond to patients' questions using the term "condition," so as not to "disturb them by saying this is a cancer, this is a malignancy." In fact, Wolfe said in an interview shortly after releasing the letter, anaplastic large cell lymphoma (ALCL) is a type of cancer known as non-Hodgkin's lymphoma and is typically aggressive.

In a response released later in the day, ASPS said the partial transcript Public Citizen released took Haeck's "extemporaneous" remarks "out of context." ASPS said Haeck never meant to "trivialize or minimize" the issue and noted that the two societies had commissioned an independent scientific panel and an independent review through RAND, a think-tank in Santa Monica, Calif., and Washington, D.C., which soon will publish its findings.

The [FDA's review of scientific literature from 1997 through May 2010](#) has identified 34 cases of ALCL among the estimated 10 million women worldwide whose breasts were surgically enlarged with silicone-filled or saline-filled implants; the cases were diagnosed when women sought treatment for pain, lumps, swelling or asymmetry after fully healing from the implant surgeries. The FDA said it was aware of about 60 cases worldwide among women with implants, but there could be duplication among the published and unpublished cases

Cases Prompt Further Study by Breast Surgeons, Epidemiologists

Whether the figure is 34 or 60, it has prompted some highly experienced breast surgeons and epidemiologists to conduct further study into what pathologists called ALCL in the capsules of scar tissue that frequently form around implants.

Among them is [Dr. Steven Teitelbaum, a plastic surgeon in Santa Monica, Calif.](#), and assistant clinical professor of plastic surgery at the David Geffen School of Medicine at UCLA. In an interview Thursday, he said that after poring through "all the raw data" from the reported cases, which included only two reported deaths, he concluded that the ALCL diagnosed in women with implants is a more benign, locally contained phenomenon than what's typically seen with ALCL.

"It is a disorder of the capsule that probably represents some kind of an inflammatory process, a reaction to the implant probably – we don't know for sure – and under the microscope, it looks like a lymphoma, but clinically it behaves like an inflammation of the capsule," Teitelbaum said. Even though it has an "oma" in it, it does not behave like an "oma," he said. "This entity we're calling ALCL is really not ALCL. We don't yet know what to call it."

Two years ago, Teitelbaum said, "I was really worried; now I'm not. I was scared for patients that it was very underreported. What sounded like 34 cases could have been 34,000 cases because you didn't know." However, as implant manufacturers pooled data, and as plastic surgeons reported on cases they'd reviewed and federal health statistics were compiled, "it became clear we were still talking about a number that's very small."

ALCL is by definition a cancer, occurring in lymphatic cells of the immune system. Although these ALCL cases are occurring in scar tissue that's forming around breast implants, they are not breast cancers, which typically occur in the milk ducts and glands of the breast. According to the ASPS, evidence collected so far suggests the disease can be treated with "surgical removal of the implant" as well as the capsule of scar tissue that surrounds it, sparing women unnecessary chemotherapy and radiation. Many patients have fared well with surgery alone, as have patients aggressively treated with chemotherapy and radiation, Teitelbaum said, "whereas even treated patients with real ALCL usually die soon."

Is It Really ALCL?

Breast implant recipients who have been told they have ALCL "are doing much better than you'd expect for ALCL," said epidemiologist [Dennis Deapen](#), a University of Southern California professor of preventive medicine who has pioneered studies of health risks from implants.

In 1977, he began a landmark study that found "breast implants not only don't cause breast cancer, but breast cancer patients get about 30 percent less breast cancer than would be expected." To this day, no one knows just why. He's currently collaborating with Dr. Garry S. Brody, a USC professor of plastic and reconstructive surgery, on a database to determine what's known and not known about each of the reported ALCL cases.

Even with limitations of the data, he said, he was able to observe that patients whose cases were studied were "living longer, they're not dying as frequently as history would suggest. That causes me as an epidemiologist to step back and say, 'Whoa, are these patients really ALCL patients, or do they have something else similar to ALCL?'"

Deapen said oncologists are caught in "in a very difficult situation. They don't want to over-treat should this prove to be something that didn't need treatment more severe than the disease. On the other hand, they don't want to under-treat."

Wolfe told the FDA that his detailed review found that in 17 of the 34 cases, women received chemotherapy, radiation or a combination of both; cancer returned in three of those cases; and two other patients had recurrences after unspecified therapy and only became disease-free after stem cell transplants.

Several doctors interviewed about the findings countered that just because the patients were aggressively treated doesn't mean the powerful treatments were necessary, noting that several of the cases arose in breast cancer

survivors previously treated with types of chemotherapy known for their potential to produce cancers of the lymph system years later.

Still, the very presence of this apparent disease in these women worries some doctors. [Dr. Kristi M. Funk, the Beverly Hills breast surgeon](#) who diagnosed singer Sheryl Crow's breast cancer in 2006, said she'd never seen a case of ALCL, but that any pain, swelling or change in the breast "has to be evaluated. If it's present, it requires treatment of some sort. That in and of itself makes it more than benign. Whether it turns out to be ALCL is inconsequential."

Funk termed it "inappropriate to try to pretend it's not a tumor or a disease or not a malignancy. Calling it some kind of implant capsule reaction that's benign is misleading." She said that in the general population, only 3 out of 100 million women without implants get ALCL in the breast area, compared with a reported 34 of 10 million women with breast implants. "That does raise eyebrows. That's a very significant increase between women with implants and women without implants."

Because the case reports involve both silicone and saline implants, the FDA has refrained from saying one type is more responsible than another. Funk however, noted that of 34 reported cases, seven were saline, 24 were silicone. She hypothesized that there could be something "a little bit more immune-stimulating in the silicone group." Combined with her observations of intact silicone gel implants "sweating to the lymphatic system" where she can sometimes see silicone in the lymph nodes of the armpit, she said that it's possible that in some genetically predisposed people, implants may cause "their body to create these immune responses prematurely."

FDA Needs More Data; Asks Doctors to Report All Confirmed Cases

The FDA, which on Jan. 26 released preliminary findings and analyses of published case reports of ALCL among women with breast implants, issued a statement Thursday acknowledging receipt of Public Citizen's letter and saying it would respond "directly to the group."

The agency has said "additional data are needed to fully understand the possible relationship between ALCL and breast implants" and has asked doctors to report all confirmed cases. In addition, the FDA called for establishment of a registry of cases, while maintaining its official position that "FDA-approved breast implants are safe and effective when used as labeled."