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Breast Implants Ignite Silicone Furor

By Stuart M. Wise

AS THE uproar over silicone gel-filled breast implants rages, the number of lawsuits against the manufacturers of the devices by the women who received them continues to swell:

- In Minneapolis, lawyer Charles S. Zimmerman of Zimmerman Reid has filed a class action in state court against implant maker Dow Corning, suing for damages equal to the cost of implanting them and removing them.
- A New York state trial judge has refused to dismiss an $8 million suit filed against Cooper Cos. by attorney Denise Dunleavy on behalf of a woman whose silicone breast implants ruptured, despite the manufacturer's alleged guarantee that the devices would "last a lifetime."
- A rash of new suits is expected in California, where state law allows women to seek damages for fraud even if they cannot prove harm from the device.

But breast implants may be only the beginning, as more evidence of the dangers of silicone surfaces. Developed in the 1930s by Dow Corning scientists as a substitute for mortar, silicone was shelved until the 1950s, when it was marketed as Silly Putty. Since then, silicone has been used in numerous medical devices, including tubes and valves, penile prostheses, clips that close fallopian tubes, as well as tubing for blood oxygenators and dialysis machines.

Increasingly, however, data reveal that the silicone in these devices can cause medical problems to users. Breast implants, for example, can rupture, leaking the silicone into the body, which data suggest can result in autoimmune diseases.

Such was the case in California with Mariann Hopkins, who contracted severe immune system disease after a rupture. Last month, a jury awarded her $7.3 million for her injuries, $6 million of that in punitive damages. Two other cases in Atlanta and San Francisco have also resulted in plaintiffs' victories.

Studies have traced other medical problems to the silicone tubing used in treating patients. For example, it was found that dialysis patients who had their blood purified through silicone tubing had a high incidence of liver disease — and in some cases, died. Autopsies on these patients revealed a large presence of silicone particles, which was traced to the tubing. Similarly, heart bypass patients whose physicians used silicone as an antifoam agent in oxygenating patients' blood suffered blocked capillaries, which led to tissue damage.

Another condition traced to silicone is scleroderma, fibrous growths that lead to thickening of skin. The cases studied involved men directly exposed to silica either as miners or sandblasters.

In addition, silicone gel-filled breast implants make it difficult to take mammograms, thus hindering the diagnosis of breast cancer. One study by the Breast Center in Van Nuys, Calif., showed the volume of tumors in women with implants was four to five times greater at the time of diagnosis than in women without implants. And 45 percent of the implanted women had cancer that had spread to the lymph nodes by the time the disease was diagnosed.

Mr. Zimmerman, whose class action is focusing on asymptomatic women who have yet to suffer adverse health effects, says he has handled

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Mr. Wise is the publisher of this newsletter.

Names in the News

Below are some names that have come up in reports on breast implant litigation and surrounding controversy.

PLAINTIFFS' ATTORNEYS

- Bruce Finzen of Minneapolis' Robins, Kaplan, Miller & Ciresi is handling silicone breast and hip prosthesis cases.
- Karen Koskoff of Bridgeport, Conn.'s Koskoff, Koskoff & Bieder, co-chairwoman of the American Trial Lawyers Association's Breast Implant Litigation Group, plans to name plastic surgeons as defendants in implant suits she files.
- Salvador Liccardo of San Jose, Calif.'s Caputo, Liccardo, Rossi, Sturges & McNeil represents women in more than 200 breast implant cases and is handling other silicone-related injury suits involving testicles and chins.
- Kenneth B. Moll of Chicago's McDowell, Moll, Fitzgibbons and Drew represents at least 50 women with breast implant claims.

MEDICAL EXPERTS

- Dr. Nir Kossovsky, a specialist in biomaterials and pathology at the University of California at Los Angeles, has been researching the effects of silica and silicone on the body.
- Marc Lappe, a professor at the University of Illinois College of Medicine, has testified on behalf of breast implant plaintiffs, but a New York plaintiff's verdict recently was reduced because some of Professor Lappe's testimony was deemed inadmissible.
- Dr. Noel R. Rose, professor and chairman of the Department of Immunology at Johns Hopkins School of Hygiene and Public Health, has testified in court on behalf of Dow Corning.
- Dr. Melvin J. Silverstein of the Breast Center in Van Nuys, Calif., has studied the problem of silicone's opacity to X-rays, which makes mammograms to detect early breast cancer very difficult.
- Dr. Frank B. Vasey, a rheumatologist at the University of South Florida College of Medicine, has testified before the FDA on the adverse effects of silicone on the body.
- Dr. Steven Weiner, chief of rheumatology at the UCLA School of Medicine, has treated about 60 women with implants who have scleroderma or other autoimmune disorders.

DEFENSE ATTORNEYS

- Robert S. Niemann of San Francisco's Lynch, Loofbourro, Helmenstine, Gilardi & Grummer P.C., represented Surgitek, a Bristol-Myers subsidiary, in litigation involving its polyurethane-coated breast implants.
- Dr. Frank Woodside of Cincinatti's Dinsmore & Shohl is coordinating Dow Corning's defense nationwide.

Recall Planning Should Start

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some instances, the product must be discarded and destroyed — as in the case of contaminated foods and medicines. In others, the product needs to be returned and repaired or retrofitted. In still others, the remedy may consist of new warnings or instructions alerting users to a product danger they might not otherwise appreciate. No two recalls are exactly the same and each remedy has different dimensions.

Preparing for a product recall begins with a detailed action plan. Among the principal steps are:

Establishing Accident Causality. Recall planners must be prepared to positively establish a link between the accident circumstances and the use of the product. An investigative format and policy that will allow company planners to know the exact details of a product-related accident must be in place. Without such information, the company will not be able to determine whether the accident was an idiosyncratic event, or whether it may represent the start of a series of accidents directly related to the product. If a company lacks the personnel resources to conduct field investigations of product accidents, it might consider using commercial sources that supply such services.

Bracketing the Affected Product Population. No company wants to recall products that are safe and represent no hazard. But a firm may find itself in that situation if it is not able to satisfactorily isolate the product defect to a particular lot, model, period of manufacture, etc. Bracketing begins by satisfactorily marketing the product — and its components — so that the affected products can be readily identified.

This does not mean that every product must contain a unique serial number identification (although this is advisable for many products). It does mean that by making slight changes in design, materials, etc., it becomes possible to identify and isolate a batch of products from a company's total output of that product over a defined time period.

The extent of the "bracket overhang" — the number of products beyond the actual affected ones that may need to be recalled.— must also be established. In some recalls, the bracket boundaries are well defined — e.g., all models of a particular design or that use a selected component may need to be recalled. But in other cases, because of gradual changes in production, etc., the boundaries will be less clear. The company must be prepared to extend the bracket boundaries so it can be certain that all affected products can be recovered.

Planning for Required Recall Components. Many recalls require the addition or replacement of a part, the addition of new warning signs, etc. While companies must plan for the rapid acquisition of these components, in some recalls, firms have taken years to acquire the retrofit parts needed. In such situations, affected product holders are notified that their products have been recalled but are then unable to have the

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several suits over TMJ jaw devices manufactured by Vitek and Dupont. These devices, which use silicone, have been blamed for bone degeneration and infection. Mr. Zimmerman says "a lot" of those suits have been settled.

As for the breast-implant class action, he says, "The companies knew the implants exposed people to an unreasonable risk of harm and did not disclose information, and the result is we have a major health risk on our hands brought on by the failure to disclose information."

What to Look for

In handling these cases, Mr. Zimmerman says it's important that potential plaintiffs monitor themselves. He refers them to doctors and asks the women to keep a diary of their conditions. To determine their validity as class members, he has each woman fill out a questionnaire and provides her with a sheet of information.

"We have compiled a lot of information on what they should do, such as have mammograms," he says.

Mr. Zimmerman notes that "we're not trying to create a personal injury class action. We're dealing with people who have [the implants] but don't know what to do. They walk around with concerns." Cases involving women already allegedly injured by the implants are being handled in "private, one-on-one litigation," he says.

Bruce Finzen of Minneapolis' Robins, Kaplan, Miller & Ciresi, who represents several women in breast-implant cases, agrees that lawyers should make sure their clients go for a medical work-up. He says it is important for a rheumatologist to determine if the symptoms — such as joint pain and general fatigue — are consistent with a condition blamed on the silicone implants.

At this point, Mr. Finzen's cases, as well as Mr. Zimmerman's, are in "very preliminary" stages. But as the use of silicone surfaces in more and more products and users suffer adverse effects in increasing numbers, silicone may become, as one lawyer put it, "the asbestos of the '90s."

"There's powerful scientific evidence to show the relationship between silicone and autoimmune disease," says Salvador Liccardo of San Jose, Calif.'s Caputo, Liccardo, Rossi, Sturges & McNeil. "It involves immunology, which is a very complex field. Any lawyer handling these cases better be familiar with it, or find someone who is — or raise his malpractice insurance."