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SILICONE VALLEY / *On one side, researchers insist implants are 'safe.' On the other, women insist they're not – and the courts agree*

Why, to science, the law's an ass

BY GINA KOLATA
New York Times Service

WHEN it comes to the safety of silicone breast implants, science and the courts have taken strikingly dissimilar stands.

The courts have handed down multi-million-dollar awards based on the presumption that the implants pose a health hazard. So many women have filed suit that implant manufacturer Dow Corning Corp. declared bankruptcy on Monday.

Meanwhile, heavy-duty scientific studies have drawn just the opposite conclusion.

This clash of cultures is due in part to the fact that the legal world looks at individual cases of illness, but science holds that studies of whole populations are truth's only sure touchstone.

The cases that have persuaded the courts concern women who complain of debilitating and mysterious maladies that they attribute to silicone leaking from their implants.

Several years ago, those individual cases, typically described as "anecdotes" by scientists, prompted several epidemiological studies to identify any statistically valid links between implants and disease. So far, seven large studies have reported – and found no such link.

"I don't know a single, high-quality immunologist who is convinced that there is a definable disease related to implants," said Dr. John Sergeant, a professor of medicine at Vanderbilt University in Nashville and a former president of the American College of Rheumatology.

Health officials in other countries agree. France allowed implants back on the market in February, and Britain never stopped their sale.

IN the United States, the beginning of the end for breast implants came in 1992, when David Kessler, the head of the Food and Drug Administration, announced that his agency was calling a voluntary moratorium on their use.

Lawsuits by women claiming injury then began to snowball. Many were based on the theory that, although silicone is an inert substance, the chemical or its breakdown products nonetheless had deranged the immune system, causing a variety of otherwise inexplicable maladies. (Canada also imposed a moratorium early in 1992, by which time an estimated 150,000 Canadian women had received implants. Many thousands of them are taking part in class-action suits against various manufacturers.)

Medical experts summoned by the plaintiffs cited experiments showing that silicone can harm the immune systems of mice. This, according to Dr. Nir Kossovsky, a materials scientist at the University of California at Los Angeles who runs an implant-testing laboratory, "means that silicone can account for many of the symptoms reported by breast-implant patients."

These medical experts also have criticized the epidemiological studies, saying that, had they gone longer or examined more women, they would have found the illnesses that afflicted the plaintiffs.

But scientists persuaded by the studies accuse the courts of mishandling the issue and regard the plaintiffs' medical experts as hired guns.

Dr. Shaun Ruddy, president of the American College of Rheumatology and a specialist in connective-tissue diseases like those being claimed by women with implants, said that so much money was at stake that "it is very easy for people to lose their objectivity." He said he knows of academic doctors who started filling out forms for lawyers at 1,000 bucks a pop.

"I'm tremendously bothered," said Dr. Elizabeth Connell, a professor of gynecology and obstetrics at Emory University's school of medicine in Atlanta. She led an FDA advisory panel that concluded in 1991 that implants fulfilled a public-health need and should remain on the market pending further study.

Dr. Bernadine Healy, a former director of the National Institutes of Health, described women as the pawns and the losers in a

trial lawyers' game she finds "hideous."

Scientists who have produced evidence or spoken against the link between implants and illness have accused plaintiffs' lawyers of harassment.

One of the more influential papers that criticized the link appeared last June in *The New England Journal of Medicine*. It was based on a study by Dr. Sherine Gabriel and her colleagues at the Mayo Clinic in Rochester, Minn., who examined the medical records of every resident in a nearby county from 1964 to 1991.

The team investigated a long list of medical problems, but concluded that none of 749 women with implants had suffered because of them.

DR. Gabriel said she knew her paper would infuriate the lawyers, particularly because it was financed in part by the Plastic Surgery Educational Foundation, the educational arm of the American Society of Plastic and Reconstructive Surgeons. But because the study had been under way for several months before receiving the grant, she did not think anyone would seriously accuse her of being biased.

Still, as soon as the paper appeared, lawyers charged that it was tainted. Charles Houssiere, a Houston lawyer who says he represents 2,000 to 3,000 women suing implant manufacturers, demanded that Dr. Gabriel produce supporting documents.

"The magnitude of the demands is staggering, the burden is staggering," she said. "They want over 800 manuscripts from researchers that were here, they want hundreds of databases, dozens of file cabinets and the entire medical records of the county." This has "been extremely stressful. It has severely compromised my ability to do research." And, she said, it has had a chilling effect on implant research in general.

Dr. Sergeant of the American College of Rheumatology described the lawyers' tactics and \$4-billion in claims at stake as "a sad commentary. We're such a litigious society in every way. And there are so few curbs on this sort of behaviour."

REFERENCE: Gabriel, S.E., O'Fallon, W.M., Kurkland, L.T., Beard, C.M., Woods, J.E. and L.J. Melton: Risk of connective-tissue diseases and other disorders after breast implantation. *New Engl. J. Med.* **330**(#24): 1697-1702 (1994); see also the editorial on pages 1748-1749: Angell, M.: Do breast implants cause systemic disease? Science in the courtroom. [DC Library call number: PER R11.B7]

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