Figure 11.6b. COSTS OF POOR QUALITY AND PRODUCTIVITY: Medical Prosthetic Devices

EM9516: The Globe and Mail, May 17, 1995, page A10

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 Sergent, 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 Univerity'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. Sergent 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]

(*continued overleaf*)

EM9523: The Globe and Mail, June 21, 1995, page A3

U.S. firm to pay $28-million for implants

Out-of-court deal compensates women

BY JANE COUTTS
Health Policy Reporter

In a landmark deal, a U.S. pharmaceutical giant has agreed to pay $28-million in compensation to women in Ontario and Quebec who say they have health problems because of breast implants the company manufactured.

In the first class-action settlement reached by a U.S. implant manufacturer outside the United States, Bristol-Myers Squibb negotiated the out-of-court deal in response to suits brought by women who blame the silicone-gel implants for problems ranging from hardening of the breasts to autoimmune diseases.

Only women in Ontario and Quebec are eligible for the settlement because only those two provinces have class-action legislation, one of the lawyers involved said.

However, Michael Eizenga said the settlement could benefit women in other provinces who are contemplating legal action. He also suggested the deal might encourage other manufacturers of breast implants to settle.

Although no one at the news conference held to announce the settlement was prepared to say how many women might benefit from the fund, Jane Bloomfield, who co-chairs a support group for breast-implant users, said even those like her who are not included in the deal will benefit psychologically.

"Someone has taken responsibility and acknowledged they may be ill because of their implants", Ms. Bloomfield said.

The London, Ont., nurse had an implant when she was 18 to augment a breast that never developed, and has had continuing problems with skin infections and breast abscesses. Now 32, she had three inserts before giving up, and has undergone more than 20 operations in the last four years. Because her implants were not manufactured by Bristol-Myers Squibb, she is not eligible for money from this settlement.

Under the terms of the settlement, which has yet to receive final approval from the court, the $28-million will be put into a special fund for 12 years, likely to be administered by an insurance company.

Widespread advertising will inform women not involved in the original litigation that they may be eligible for compensation if they suffer from any of the illnesses commonly attributed to breast implants and if their implant was manufactured by Medical Engineering Corporation MEC, a wholly owned subsidiary of Bristol-Myers Squibb.

Women who meet the criteria set out in the deal will be assessed and their share of the $28-million will be based on the severity of their illness, their age and the total number of claimants.

Mr. Eizenga would not guess at what individual settlements might amount to, since no one knows how many women might apply.

He did say that of an estimated 100,000 implants in Canada, Bristol-Myers Squibb is thought to have had between 20 and 25 per cent of the total market.

The settlement was reached despite continuing controversy over the issue of implant-related health problems. Several scientific studies have failed to find a link between implants and the systemic health problems some have attributed to them, which include atypical neurological disease syndrome, systemic lupus and connective tissue disease.

There have been complaints that the issue was fed by U.S. judges and juries, swayed by anecdotal accounts of suffering that were unsupported by scientific data.

More localized problems, such as ruptures, infections and painful hardening of the breasts, caused when scars develop around the implants, are more clearly attributed to the products, which were banned in the U.S. and Canada in 1992.

France decided in February to permit their sale again. They were never taken off the British market.

Silicone-gel breast implants were the subject of a huge product-liability settlement in February of 1994, when Bristol-Myers Squibb, Dow Corning and Baxter International Inc. agreed to set up a $4.2-billion fund to compensate women claiming they were adversely affected by the implants.

Because only a little more than 3 per cent of that sum was allotted to women outside the United States, Mr. Eizenga said, the Bristol-Myers deal is a particular boon to Canadian women who would have otherwise had to compete with women all over the world for a share of the 1994 settlement.

1 Describe concisely the *Question* that is the primary matter of concern in the two articles EM9516 and EM9523 reprinted in this Figure 11.6b.

- Identify the *response* variates mentioned in the articles and the primary *explanatory* variate.

2 Explain briefly whether the human data described in the articles EM9516 and EM9523 come from investigations with *experimental* or *observational* Plans, and indicate what *statistical* issue is raised by this matter in the Question context.

- Comment briefly on the inference that implants *cause* the various systemic diseases.

3 Discuss, from a *statistical* perspective, the statement in the fourth paragraph of the article EM9516 reprinted overleaf on page 11.31: .... *the legal world looks at individual cases of illness, but science holds that studies of whole populations are truth's only sure touchstone.*

- Compare and contrast what the two articles describe in the case of breast implants with what has happened in regard to the health consequences of smoking.

The articles EM9516 and EM9523 reprinted overleaf on page 11.31 and above are also used in Statistical Highlight #102.