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

EM9039: The Globe and Mail, December 14, 1990, pages A1 and A2

Search on for users of faulty heart valves

250 deaths linked to broken device

BY PAUL TAYLOR
Medical Reporter

Officials are trying to locate 23,000 people in Canada and the United States who received artificial heart valves that may be defective.

The manufacturer says that once a valve breaks a patient can die within hours if it is not replaced.

The valves, manufactured by Shiley Inc., a subsidiary of the giant pharmaceutical company Pfizer Inc. of Irvine, Calif., were implanted between 1976 and 1986.

About 250 deaths worldwide have been linked to the device, known as the Bjork-Shiley Convexo-Concave (C-C) heart-valve implant. The company has already faced numerous lawsuits, some of which have been settled out of court for a reported $1-million each.

The company says it wants to get in touch with heart-valve recipients so they will be able to recognize the signs if something goes wrong and seek immediate medical care.

For the search, the manufacturer has recruited the help of Medic Alert Foundation, a non-profit group that has begun a registry of individuals with artificial implants.

Kenneth Harms, Medic Alert president, said that between 1,500 and 2,000 people living in Canada received the implant. About 1,400 of them are already registered with Medic Alert.

"So we have a big leg up on locating these people," he said, adding that many Canadian hospitals encourage patients to register with Medic Alert.

In the United States the job will be much tougher because many hospitals have not maintained current addresses of patients, he said. Nor are a majority of U.S. patients registered with Medic Alert.

Usually, manufacturers send warning notices to physicians and hospitals when they realize something is wrong with one of their devices. It is then left up to the doctors to notify patients. Seldom do manufacturers try to contact all the patients directly.

"We've never been involved in anything like this before," said Mr. Harms, referring to the massive search for implant recipients.

Brian Evans, a lawyer from Whitby, Ont., who has been representing Canadian patients in lawsuits against Pfizer, said the company "will be seen to be doing the right thing" with its notification effort.

"My concern is that it is too little too late. We've been urging them to do this for some time," Mr. Evans said.

Even when the patients are warned of the potential implant defects there is little they can do except wait, because the risk of dying in surgery to replace the valve is greater than the chance of the implant breaking, said Dr. Roger Sachs, a spokesman for Pfizer.

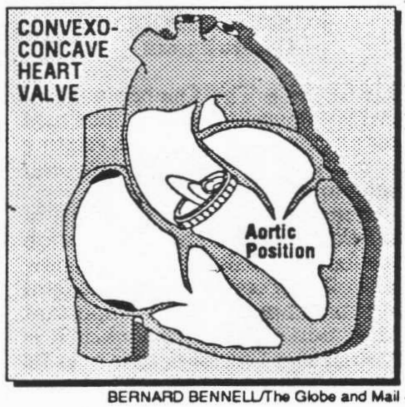
Each year, on average, seven out of every 10,000 implants fail. By contrast, 5 per cent of patients who undergo open-heart surgery die as a result of the operation.

"There is no way to tell in advance if a valve is going to break," he added. So the patients are being urged to watch for the warning signs of a problem and then rush to a hospital when it occurs, Dr. Sachs said. The warning signs can include chest pains, shortness of breath, dizziness and unusual sounds from the device. Some patients may even become unconcious.

Mr. Sachs added that no artificial implant is risk free, and that the artificial heart valves have been responsible for prolonging thousands of lives.

The valves in the heart are designed to keep blood flowing in one direction. In individuals with heart disease, the valves may not open up fully and thereby prevent enough blood from flowing through. Or else they may not close properly, resulting in a backflow of blood.

The artificial valve, which allows the blood to flow normally, was first developed in the 1950s.



BERNARD BENNELL/The Globe and Mail

1 A major theme of the article EM9039 reprinted above is the failure of artificial heart valves *after* they have been implanted in humans, and the serious consequences of such failures. Indicate briefly why it is difficult to ensure the long-term correct functioning of the valves after implantation.

2 The article EM9039 mentions 23,000 people with the particular valve implanted over the period 1976 to 1986, about 250 deaths, and an annual failure rate of 7 per 10,000; show how these figures can be reconciled with each other.

- Find the approximate probability that the implant in a recipient selected equiprobably will *not* fail in 5, in 10, and in 20 years.
  - What *mathematical* assumption underlies the calculation of these three approximate probabilities? Indicate briefly how reasonable the assumption is in this situation.
  - Assess briefly the likley *relative* accuracy of your three approximate probabilities.

3 For the heart valves described above in the article EM9039 and the breast implants discussed overleaf on page 11.30 in the article EM9202, briefly compare and contrast:

- the *difficulties* of producing a device with long-term correct functioning;
- the *consequences* of device failure after implantation.

(*continued overleaf*)

EM9202: The Globe and Mail, January 8, 1995, page A5

Breast-implant sales suspended

Manufacturers bow to U.S. concerns temporarily, but say products are safe

BY PAUL TAYLOR
and ROD MICKLEBURGH
The Globe and Mail

The major manufacturers of silicone breast implants are pulling them off the market in Canada after continuing concerns in the United States about their safety.

"We have been advised to suspend sales temporarily," said David Simpson, a spokesman for Dow Corning Canada Inc.

He added the decision was made by the company's U.S. parent late Monday after the U.S. Food and Drug Administration called on all doctors to stop putting breast-enlarging silicone implants in patients.

Other silicone implant producers – including Mentor Corp. of Santa Barbara, Calif. – are also halting worldwide sales until the FDA completes its safety review.

But all the firms continued to insist yesterday that nothing is wrong with their products, and plastic surgeons in Canada said they have no evidence that implants are dangerous.

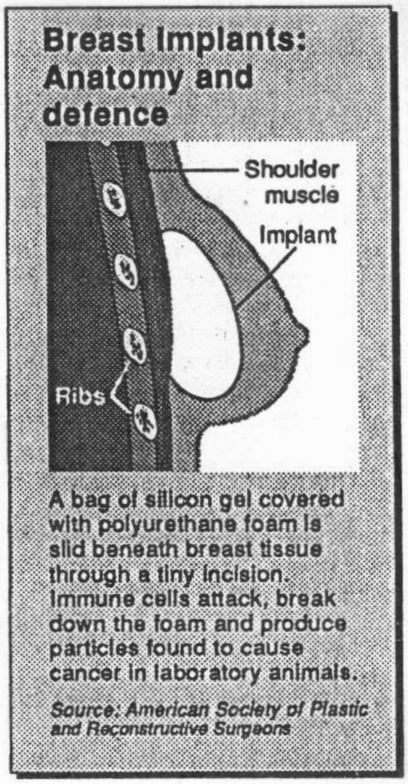
"Just because we have halted sales temporarily, it doesn't mean we believe our product is unsafe," Mr. Simpson said in an interview in Toronto.

The FDA in the United States has received reports the implants can break down, causing pain and other complications in patients. Some critics have suggested that the implants could trigger a variety of different illnesses.

Meanwhile, the Canadian government is being attacked for not doing enough to investigate concerns about breast implants. Instead, critics charge it is sitting idly by as events unfold south of the border.

"Everyone around the government is acting, but the government isn't acting," said Joy Langan, a New Democratic MP who had an implant operation after suffering from breast cancer more than six years ago.

"We have been after the federal government for well over a year to do some proper research into safety. The minister said he was not interested in anecdotal evidence and was waiting to see what the FDA would do," she said.



N.Y. Times News Service

When the FDA called for its moratorium on Monday, a spokesman for Health and Welfare Canada said that it was not taking any immediate action but has asked the U.S. agency for all the information on which it based its decision.

Pierre Blais, a former health-and-welfare employee who has done extensive research into the safety of breast implants, charged that the department's health-protection branch "tries to create the illusion that its role is to protect the consumer, but it is really more interested in maintaining smooth relations with industry."

He said Monday's announcement by the FDA was "remarkable. It was unique. A formal statement from the FDA that the type of abuse by plastic surgeons that has gone on for 35 years is not to go on."

Dr. Blais, now the president of an Ottawa-based consulting firm, said the track record of some breast implants is atrocious and that, overall, "there is one chance in two that someone receiving one will be back in surgery within five years."

Dr. Blais said health and welfare "has put itself in a position of low credibility" over the breast-implant controversy. But Toronto plastic surgeon Michael Bederman, who has performed about 4,000 breast augmentation operations over the past 16 years, says he will continue to do breast implants despite the controversy.

"I believe it is an operation that is extremely safe and relatively risk-free. Two million women in the United States have had breast implants and, to date, there is still no hard evidence that the implants cause anything wrong," Dr. Bederman said.

Studies indicate that about 80 per cent of all breast enhancement operations are performed for cosmetic reasons, rather than for reconstruction after breast surgery.

Phyllis Rittenhouse, who provides post-operative care and consultation for women undergoing plastic surgery, said she believes fewer breast implants are being performed these days.

"It's the controversy and a new feminist attitude that you should like yourself the way you are," Mrs. Rittenhouse said. "In a way, it's a sad commentary that a lot of women have felt brainwashed to think that large breasts were part of our sex appeal. I know of one woman who came back three times for breast augmentation because each time her husband said he wanted her breasts bigger. Isn't that sick?

4 In the first paragraph of the middle column of the article EM9202 reprinted above, Ms. Joy Langan states that: *The minister said he was not interested in anecdotal evidence .....*

- Explain briefly what is meant by *anecdotal evidence* in this context, and suggest why it would be inadequate.
- Outline the type(s) of evidence that would normally be considered *adequate* in the context of the article EM9202.

5 In successive paragraphs of the right-hand column of the article EM9202 reprinted above, Drs. Blais and Bederman give greatly differing assessments of the safety of silicone breast implants; outline possible reason(s) for this level of disagreement.