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# Breast-implant sales suspended

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

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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.

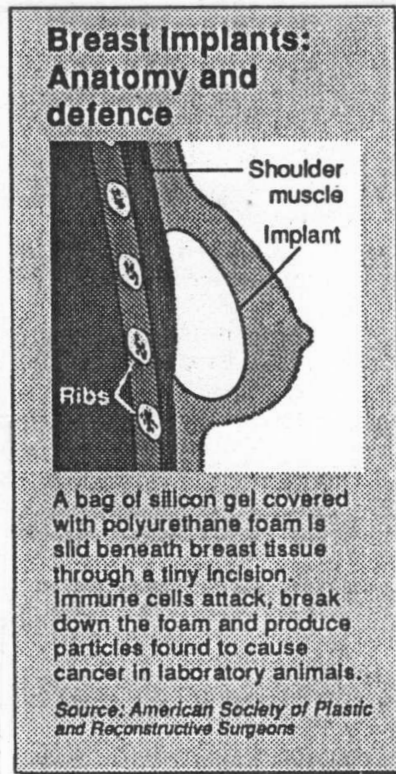
"Just because we have halted sales temporarily, it doesn't mean we believe our product is unsafe," Mr. Simpson said in an interview in Toronto.

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



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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.

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?"

The article EM9202 reprinted above is used in Figure 11.6a of the STAT 221 Course Materials.