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

Out-of-court deal compensates women

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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.

The article EM9528 reprinted above is used in Figure 11.6b of the STAT 221 Course Materials.