Trans-national implications of the breast prosthesis crisis

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Due to its proximity to the United States, Canada has inevitably seen its social, cultural, economic and medical standards heavily influenced by its southern neighbour. Fortunately for Canada, this reality stops short of the way in which medical malpractice disputes are resolved in the US. The differences between the US and Canada certainly bodes well for Canada. No matter how critical the breast implant prosthesis crisis becomes in the US, it can never be as bad in Canada, if only because of the differences in American and Canadian legal systems, the relations between doctors and lawyers, and differing public attitudes. Nonetheless, because of our proximity, much of this is inevitably bound to affect Canada's plastic surgery community.

It is virtually impossible for someone who has not lived in the US to comprehend how any legal judicial system in a civilized society can hold medical malpractice to an absolute standard in which there is virtually no room for error. Time and space do not permit a detailed review. The present critical situation in which your American colleagues find themselves is a witches' brew of an extremely powerful, politically dominant trial lawyers' association, a judicial system in which most of the judges are themselves ex-plaintiffs' attorneys, a panting media corps which is virtually out of control, a group of implant manufacturers who turn out to have been less than candid with our specialty, and a small group of physicians of various specialties who have been very entrepreneurial in selling the procedure and/or eager to volunteer as plaintiff's witnesses. Regrettably, the latter group seem to see this as a unique opportunity to convert anecdotal data and junk science into gold.

It should be clearly understood that all of this has little to do with truth, justice, equity, fairness or scientific intelligence. Like cocaine, this is about money; lots of it. It is generally agreed that before this is over, probably within the next five years, we can anticipate about 15 thousand cases to be filed in the US. Between defence costs settlements and indemnity, somewhere between \$1.5 billion to \$2 billion will have changed hands. Of this amount, roughly 60% will stay in the legal community and 40% will have to be divided among thousands of 'class action' plaintiffs, thereby assuring maximum profit to the trial bar and minimum benefit for those who claim injury. (It is an interesting commentary on the American judicial system that the larger the 'class action' group, the larger the share of profits for the lawyer and the smaller the compensation for the insured patient). We estimate that roughly 75% of that will come from the manufacturers and the rest will probably come from the other sources. We anticipate that the great bulk of these cases will conclude with global settlements after a few dozen trials sometime within the next 18 months or so. To do otherwise would clog the judicial calendar completely and that simply cannot be tolerated. The vast majority of these cases will be either settled or tried in the US Federal court system rather than in the regional courts. We feel reasonably confident that, with few exceptions, the overwhelming majority of these suits will be against the manufacturers alone (product failure) although inevitably some will include the surgeon. Up to the end of June 1993, of approximately 14 cases, six involved the surgeon. With no exceptions, the surgeon has been dismissed from all six cases. (In two others the surgeon's carrier settled because extraneous and exceptional circumstances made defence virtually impossible.) Most liability carriers understand they must make an all out effort to win the first few cases; the alternative is to open up a little barred window and start handing out money, regardless of merit. Under American law, it is much easier to win a case of product liability than to prove departure from the standard of care against a surgeon.

It is impossible to compare the American experience against what will predictably happen in Canada. In the US the existing dispute settlement mechanism is essentially an open lottery and an invitation to anyone who wishes to file a suit against virtually anyone else by investing a few dollars in the filing fee. Under the 'contingency fee' system the attorney pays all of the costs; if he/she wins, he/she keeps one-third to one-half of the settlement after court costs. This system exists only in the US. In any other country, the loser pays costs which discourages non-meritorious law suits; not so in the US.

Regardless of the legal systems, any lawsuit involving breast implants will have roughly the same causes of action:

- What did we know and when did we know it?
- What disclosures were made to the patient before the operation?
- What, if any, part did closed capsulotomy play in the alleged problems?
- What, if any, actual relationship exists between autoimmune diseases and silicone gel?

On this basis we doubt that any cases dating from before 1988 should involve the surgeon. Between that date and now, however, the outcome of these suits is still an open question, since it is presumed that between around 1988 and the present, the plastic surgery community was, or should have been, aware of the problems attributed to silicone gel. It is probably unrealistic to issue blanket denials of any relationship. There is increasing experimental evidence that there is some as yet poorly understood relationship between the gel and autoimmune symptoms in a very small minority of patients. The plastic surgery community should concentrate much more intensively in pointing out that: statistically, the incidence of real, identifiable complaints is still running somewhere in the neighbourhood of 1 to 2% of all implanted patients; until very recently all reports of autoimmune phenomena were anecdotal reports without true statistical validity; any alleged tampering with experimental evidence by manufacturers was unknown to the plastic surgical community until very recently.

Additionally, it should be pointed out repeatedly that the disproportionate hysteria caused by the media has created a climate of acute anxiety for well over 95% of implant recipients without symptoms. They must now learn to live with a sword of Damocles over their head for the rest of their lives.

In March of this year the Chief Medical Officer for the British Ministry of Health issued a proclamation whose key statement says, "The Independent Expert Advisory Group, convened to examine all relevant data of the evidence relating to silicone gel breast implants and connective tissue disease, concluded that there is no evidence of an increased risk of connective tissue disease in patients who have undergone silicone gel breast implants and therefore no scientific case for changing practice or policy in the UK with respect to breast implantation".

I need not point out that this is the official position of Her Majesty's government and not a third world country. My British correspondent attached a note saying, "one of our countries is dead wrong!" It is also interesting to note that virtually all of the ministries of health in Europe have followed the British viewpoint rather than the American one. We are puzzled by the Canadian government's position on breast implants in view of Canada's traditional cultural ties to the United Kingdom.

Regardless of outcome, the secondary effects of this crisis are now becoming evident and the future ones predictable. The American silicone devices industry has suffered a mortal blow from which it is not likely to recover. All of the major players, with two exceptions, have stopped making breast prosthesis. The two remaining ones are reasonably small corporations. It is unclear whether they will be able to withstand the onslaught of the American legal juggernaut. If you were the manufacturer of a device which produces a very small margin of profit but suffocating financial consequences, what would you do? The 'spin off' effect is likely to affect all other implantable devices made up of silicone and set surgery back about 30 years. It is entirely likely that foreign manufacturers producing devices (France, Japan and Brazil) will see their business boom. It is likely that there will be an increased demand for augmentation surgery by surgeons in countries other than the US or Canada with a predictable rise in morbidity. It is likely that there will be significant increases in advertising by unqualified surgeons all over the world who will wish to profit from the loss of the American case load. It is likely that all of this will bring a significant increase in malpractice insurance costs to the surgeons of the European community. Undoubtedly there will be increased interest and activity by plaintiffs' attorneys in Canada who will see in all of this the same opportunity for profit as their American colleagues.

RECOMMENDATIONS

- The Canadian societies should make vigorous representations to the Ministry of Health regarding the utterly conflicting conclusions of the British and European Community and the American Food and Drug Administration.
- The Canadian societies should establish an active legislature liaison committee, if one does not exist already.
- The Canadian societies should establish and maintain a 'key contact' registry. Many members of your societies have, as patients, individuals who might be influential in the adoptions of laws and regulations in your country. Their names should be available.
- Your societies should establish and promulgate to Parliament the minimum standards or qualifications for expert witnesses to minimize the exposure to 'junk science'.
- Where government-sponsored medical reimbursement schemes predominate, medical societies should explore the establishment of a fund for compensation of victims of medical maloccurrence to be maintained jointly by the government, the defence union and the medical device and pharmaceutical industry.
- The concept of screening panels and/or arbitration should be vigorously pursued.

Lastly, all plastic surgery organizations, regardless of nationality, should never underestimate the imagination and ability of plaintiffs' attorneys to come up with new and potentially profitable methods of assault. Beyond the present breast prostheses crisis, surgeons in the US are now faced with a 'second generation' group of cases in which it is alleged that children who breast fed from mothers who had previously had silicone gel breast implants are now suffering from a variety of diseases as a result of having ingested contaminated mother's breast milk. Caveat Emptor!