COURT FILE NO.: 00-CV-184729CP
DATE: 2007/05/03

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N:	)	
	)	
S. JOYCE ATTIS and A. TESLUK	)	John Legge, Cameron Pallett, Patrick Orr, Yves Lauzon, Kirk Baert and Celeste Poltack for the Plaintiffs
Plaintiffs	)	
	)	
- and -	)	
	)	
HER MAJESTY THE QUEEN IN RIGHT OF CANADA as represented by the MINISTER OF HEALTH, THE ATTORNEY GENERAL FOR CANADA, REGULATORY INSTITUTION 1, REGULATORY INSTITUTION 2, JOHN DOE and JANE ROE	)	C.A.Amerasinghe, Q.C., André Lespérance, James Soldatich and Susan Keenan for the Defendants
Defendants	)	
	)	**HEARD:** February 19, 20 and 21, 2007

Proceeding under the *CLASS PROCEEDINGS ACT, 1992*

WINKLER R.S.J.:

REASONS FOR DECISION

Overview

[1] This proceeding represents one of the final chapters in the protracted, multi-country breast implant litigation. The government defendants are alleged to have failed or refused to properly regulate the use of breast implants manufactured, distributed, imported and sold in Canada by Dow Corning Corporation and its associated, affiliated or subsidiary corporations (collectively "Dow"). Claims against Dow directly have been the subject of settlements in separate litigation. The plaintiffs bring this motion for an order certifying the action against Canada as a class proceeding under the *Class Proceedings Act, 1992*, S.O. 1992, c.6 ("CPA") and appointing them

as the representative plaintiffs in relation to a national class, except for British Columbia, said to include some 29,500 persons.

Background

[2] The plaintiff, Ms. Attis, suffers from Poland's syndrome. As a result, her right breast did not develop. On June 19, 1972, she was implanted with a silicone gel breast implant manufactured by Dow. The type of implant she received was a Dow Corning Cronin 175 cc model.

[3] Sometime after receiving the Dow implant, Attis' right breast hardened and became deformed, eventually necessitating the removal of the implant on February 28, 1992. In her affidavit filed on the motion, Attis describes the state of the implant at the time of removal as either "leaking" or "ruptured". However, the medical records referred to in her affidavit have not yet been provided so as to permit definitive characterization of the actual state of the implant upon being explanted.

[4] Attis claims that following the implantation of her breast implant and the subsequent explantive surgery, she suffered, and continues to suffer from both physical and emotional injuries. These injuries include atypical connective tissue disease, arthralgias, myalgias, alopecia, lymphadenopathy, fibromyalgia, rheumatoid arthritis, edemas, chest pain, hypertension and arthritis. Attis claims that as a result of the implant, she has been diagnosed as 100% disabled.

[5] The plaintiff, Ms. Tesluk, was implanted with bilateral silicone gel breast implants on March 18, 1980. The type of implants Tesluk received were Dow Corning 180 cc low profile implants.

[6] Tesluk contends that her implants hardened and became extremely painful approximately one year after implantation. She deposes that the pain persisted for many years until she underwent a mammogram which showed that her left breast implant had ruptured and was leaking silicone into her body. On March 3, 1994, Tesluk underwent explantive surgery to remove her implants.

[7] Tesluk claims that although her implants have been removed, she continues to suffer from full body pain "due to the slow and steady infusion of toxicity into her body". Tesluk alleges she has been rendered severely disabled and that she suffers from fibromyalgia, osteoarthritis, depression, angina, Hashimoto's thyroiditis, vasculitis, cognitive impairment, arthralgias and myalgia. She also suffers from cysts in both breasts.

[8] Both Attis and Tesluk were members of the class of plaintiffs who sued Dow Corning and other manufacturers in the class proceeding styled as *Bendall v. McGhan Medical Corporation* (1993), 14 O.R. 3d 734 (Gen. Div.). A settlement agreement encompassing that proceeding, embodied in the Dow Corning Breast Implant Litigation Settlement Agreement ("Dow Settlement"), was approved by this court on November 24, 1998. Attis opted out of the *Bendall* action in 1994. Tesluk received compensation pursuant to the terms of the Dow Settlement.

History of the Present Litigation

[9] This motion for certification is the culmination of numerous case conferences and preliminary motions. The most significant of these was a motion, and subsequent appeal, brought by Canada under r. 21 of the *Rules of Civil Procedure*, R.R.O. 1990, Reg. 194, for an order dismissing the action based on the release wording of the settlement agreements flowing out of four previous class proceedings against breast implant manufacturers, including the Dow Settlement. At the time Canada moved to dismiss the action, the plaintiffs claimed against the government in respect of breast implants of every manufacturer. (I will refer to the government defendants as either "Canada" or "the government" throughout these Reasons.)

[10] I dismissed the motion at first instance in Reasons released January 27, 2003, (reported at (2003), 29 C.P.C. (5th) 242), on the basis of the reservation of rights clause in the settlement documentation. However, given that the plaintiffs' claims against Canada were only made in relation to Dow products, the claim was narrowed, by striking any allegations in respect of manufacturers other than Dow. In addition, in consideration of the terms of the Dow Settlement, the plaintiffs' entitlement to claim, from a damages perspective, was held to be limited to the several liability of Canada. Accordingly, the plaintiffs were given leave to amend their pleadings to claim only several liability as against Canada and to limit the claim to the products of Dow. That decision was upheld by the Court of Appeal (reported at [2003] O.J. No. 4708) and leave to appeal to the Supreme Court of Canada was denied on July 15, 2004 (see [2004] S.C.C.A. No. 41).

[11] At the conclusion of the appeals, the plaintiffs amended their Statement of Claim, limiting their claim to the several liability of Canada to conform to the reservation of rights clause in the Dow Settlement, and specifically, in relation to Dow products. Canada then delivered a third party claim against Dow Corning seeking both damages and declaratory relief, and alleging, *inter alia*, negligence, negligent misrepresentation and breach of a duty to warn.

[12] Dow Corning indicated its intention to bring a motion to strike the third party claim based on the indemnification clause contained in the Dow Settlement. However, in Reasons released April 12, 2005 (reported at [2005] O.J. No.1337), I determined that, as a matter of principle, the certification motion ought to be the next procedural matter to be heard and determined. Consequently, the plaintiffs bring this motion. The certification motion first came on for hearing before this court on April 24, 2006, but it was clear to me that the record was incomplete. Accordingly, on my own motion, I exercised my discretion under s. 5(5) of the *CPA*, and adjourned the matter to permit the plaintiffs to amend their materials and adduce further evidence.

[13] Canada seeks leave to deliver an Amended Statement of Defence. The plaintiffs resist this motion on the ground that Canada is said to be resiling in the fresh pleading from admissions made in its earlier pleading. I can find no basis for this submission. Accordingly, leave is granted to deliver the Amended Statement of Defence forthwith.

Issues

[14] On this motion the parties have put in issue every element of the test for certification under s. 5(1) of the *CPA*. In particular, the argument regarding the existence of a cause of action consumed substantial time on the motion. It is common ground that the claim is one of regulatory negligence. However, Canada contends that the plaintiffs' pleadings fail to disclose a cause of action on the standard set out in *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959. Canada asserts that it is plain and obvious that the claim suffers from radical defects, namely, that the statutes at its root cannot ground a private law duty of care. Canada also takes the position that apart from the failure of the plaintiffs to state a tenable cause of action, the proceeding does not meet the other criteria necessary for certification under ss. 5(1)(b),(c),(d) and (e) of the *CPA*.

[15] While I do not agree that the criteria for certification under s. 5(1)(b) through (e) cannot be satisfied, I am persuaded by the argument of Canada that there is no cause of action at law based on the allegations pleaded by the plaintiffs.

[16] Following the decisions of the Supreme Court of Canada in *Cooper v. Hobart*, [2001] 3 S.C.R. 537, and *Edwards v. Law Society of Upper Canada*, [2001] 3 S.C.R. 562, it is now settled law that where a governing statute is at issue, and a claim of a private law duty of care is made against a government actor relating to regulatory negligence, the duty of care alleged must be found in the statute.

[17] Here, although the plaintiffs cite several statutes and regulations, they cannot point to any provision that specifically imposes a duty of care of the nature claimed on the government. Instead, the plaintiffs contend that statutory provisions and regulations that are expressly aimed at imposing obligations on manufacturers and distributors of medical devices can be expanded by implication to include a private law duty of care owed by the government to the consumers or users of the devices. On the facts as alleged in the pleadings, I cannot accede to this argument. In sum and substance, the claim of the plaintiffs is not one of a breach of duty but rather one of failure to govern. It is well settled that no action lies for such a claim. My reasons follow.

Law and Analysis

[18] The plaintiffs assert that Dow Corning implants were imported and distributed into the country with Canada's consent, despite its knowledge that such devices posed serious health dangers. The plaintiffs allege that the government, pursuant to the *Food and Drugs Act,* R.S.C. 1985, c. F.27 ("FDA"), is charged with the mandate of protecting the health and well being of Canadian citizens. That responsibility includes regulating "devices" imported, distributed and manufactured in Canada. Section 19 of the *FDA* expressly prohibits the selling of a "device" which, when used according to its instructions, may cause injury to the health of the purchaser or user.

[19] The plaintiffs' contention is that the duty owed by Canada is further demonstrated by the fact that Medical Devices Regulations ("MDR") were promulgated in 1976 as a means of enforcing s.19 of the *FDA* and specifically, to provide comprehensive inspectorial and

investigative powers to the government for purposes of regulating the manufacture, distribution and sale of medical devices in Canada. Consequently, it is alleged that it was incumbent on the government, as the sole regulator of medical devices imported, sold and employed in Canada, to ensure that Dow Corning breast implants passed a threshold of safety and effectiveness.

[20] The plaintiffs state that they reasonably relied on the government to screen medical devices and remove from distribution any medical devices it knew were available for implantation in Canada, and which had the potential to be harmful. In this respect, the plaintiffs also contend that the government had duty to warn the plaintiffs, and the members of the proposed class, of any danger inherent in the ordinary use of such devices.

[21] The plaintiffs ground their allegation of a duty to warn, and concomitant breach, on factual allegations relating to information in the possession of the government. Specifically, the plaintiffs contend that, from 1962 to the present, the government received information from various organizations that Dow Corning breast implants may cause and/or contribute to serious injury, or may malfunction with the likelihood of causing serious injury. According to the plaintiffs, the government received information in that time period concerning the health dangers posed by breast implants and the unsuitability of prolonged implantation of silicone materials in the body. In fact, the plaintiffs claim that by 1978, staff in the Bureau of Medical Devices recommended that the *MDR* be amended to prohibit the use of silicone gel devices. Upon learning of the potentially harmful effects of silicone breast implants, it is alleged that the government had a duty to warn the class of the dangers associated with the Dow Corning implants. The plaintiffs contend that the failure to so warn has contributed to or caused the damages they, and the members of the proposed class, have suffered.

[22] In paragraphs 32-38 of the Amended Statement of Claim, the plaintiffs identify the statutory and regulatory scheme giving rise to the duty allegedly owed by the government to them and the putative class as follows:

> 32. The *Canada Health Act*, R.S.C. 1985 c. C-6, particularly by its preamble and section 3, establishes a primary health-care policy objective to protect, promote, and restore the physical and mental well-being of Canadian residents.
>
> 33. The Department of Health Act, S.C. 1996, c. 8 and particularly section 4, establishes public duties of the Minister of Health as including:
>
> 1. the promotion and preservation of the physical, mental, and social well-being of the residents of Canada;
>
> 2. the protection of the residents of Canada against risks to health;
>
> 3. investigation and research into public health;
>
> 4. the establishment and control of safety standards and safety information requirements for consumer products; and

5. the collection, analysis, interpretation, publication, and distribution of information relating to public health.

34. The *Food and Drugs Act*, S.C. 1952-53 c. 38 as amended and consolidated to the present establishes and continues a regulatory scheme, administered by the Minister responsible for Health, to:

1. protect the residents of Canada in matters of health, as well as against fraud in the manufacturing, testing and sale of devices;

2. prohibit things that are injurious to health and that are unfit for use; and

3. prevent deception in the manufacture and sale of goods consumed by the public.

35. The *Medical Devices Regulations,* SOR/75-526, as amended and consolidated, and the *Medical Devices Regulations*, SOR/98-282 established a specific regulatory scheme applicable to devices, administered by the Minister responsible for Health, to:

1. protect the residents of Canada against devices injurious to health and unfit for use;

2. ensure that the integrity of devices is maintained so the residents of Canada may rely upon the claims being made for these devices; and

3. protect the residents of Canada from fraud and deception in relation to these devices.

36. Under the Statutes and Regulations pleaded in paragraphs 32 to 35, Her Majesty and the Defendants had a duty to prohibit the use of the devices at issue herein, and to use its other powers to protect residents of Canada including the Plaintiffs once it had or ought to have had a reasonable apprehension that these devices were being used.

37. Her Majesty and the Defendants have failed to fulfill these duties, and continue to fail to fulfill these duties.

38. The Defendants breach of these duties caused or contributed to the damages that the Plaintiffs have and from which they continue to suffer and has also increased the cost of repair, increased the danger and complications of repair, and decreased the likelihood of successful repair.

[23] It is the plaintiffs' position that they have met the threshold, under s. 5(1)(a) of the *CPA*, to establish that there is a cause of action.

[24] In response, Canada, pointing to s. 19 of the *FDA*, argues that it is plain and obvious that it imposes obligations on those in the supply chain but does not create a duty of care to individuals on the part of the government. Section 19 provides:

> 19. No person shall sell any device that, when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof.

[25] Canada further argues that there is no support for the plaintiffs' assertions that a private law duty exists under the regulations that have been promulgated under the *FDA*. In advancing this argument, Canada emphasizes that the regulatory scheme has undergone 5 iterations since 1962, the start of the putative class period described by the plaintiffs. More to the point, Canada contends that it is similarly plain and obvious that none of the various iterations imposed any private law duty owed to individuals by Canada, as the plaintiffs claim in this case. These five regulatory schemes may be summarized as follows:

(i) December 8, 1954 to August 17, 1969:

During this period, the *Food and Drug Regulations of 1954* were in force. These regulations contained provisions empowering analysts and inspectors to obtain samples, examine or detain breast implants from being imported into Canada for reconstructive purposes. However, breast implants for augmentation purposes were not regulated during this period and manufacturers were not required to provide any information regarding the breast implants they sold in Canada.

(ii) August 18, 1969 to February 28, 1974:

During this period, *Part K of the Food and Drug Regulations* was in force. This regulation required that no person sell a device, including a breast implant for reconstruction or augmentation, unless it was labeled as being required by the Regulations. However, the regulation in force did not require the manufacturer to submit any information to the government.

(iii) March 1, 1974 to September 1, 1975:

During this period, part K of the Regulations was expanded to allow the government to request proof of the safety of a device when a safety concern was identified.

(iv) September 2, 1975 to October 7, 1982:

During this period the *Medical Device Regulations* were in force and these *MDR* reiterated the responsibility of manufacturers to conduct safety and efficacy testing prior to marketing medical devices in Canada. Testing was aimed at substantiating the manufacturers' claims of the benefits obtainable through the use

of the device as well as ensuring that the performance characteristics claimed for a device were justified.

From April 1, 1976 onward, manufacturers were required to submit a notice to the government informing it of the proposed sale of a device in Canada. Such a notification contained information about the device including its name, the manufacturer or distributor, the model designation, directions for use and a copy of any label and/or package inserts.

However, manufacturers were not required to submit, as part of the notice of proposed sale, information concerning the tests performed in respect of the safety and effectiveness of their devices. Although the government could require the manufacturer to provide those tests, it would only do so when a safety concern was identified and warranted such a request.

(v) October 8, 1982 to June 30, 1998:

This final regulatory period amended the *MDR* to subject manufacturers of breast implants to Part V of the *MDR*. Part V required manufacturers to submit to the government all of the tests conducted in respect of their products as part of their "pre-market review". Thus, the test results were required prior to the actual sale of a new device. However, the MDR provided that only "new devices" were subject to the pre-market review requirements; it did not add any new requirements for devices already in the marketplace.

[26] The Supreme Court of Canada, in *Cooper* and *Edwards*, two companion decisions released in 2001, set out the approach to be taken in analyzing whether an allegation of a duty of care can be sustained. As stated in *Edwards* at paras. 8 and 9:

> [para8] The companion case of *Cooper* outlines the approach in assessing whether a duty of care will be recognized in a given case. Specifically, Cooper revisits the Anns test and clarifies the express policy components to be considered at each stage.
>
> [para9] At the first stage of the Anns test, the question is whether the circumstances disclose reasonably foreseeable harm and proximity sufficient to establish a prima facie duty of care. The focus at this stage is on factors arising from the relationship between the plaintiff and the defendant, including broad considerations of policy. The starting point for this analysis is to determine whether there are analogous categories of cases in which proximity has previously been recognized. If no such cases exist, the question then becomes whether a new duty of care should be recognized in the circumstances. Mere foreseeability is not enough to establish a prima facie duty of care. The plaintiff must also show proximity -- that the defendant was in a close and direct relationship to him or her such that it is just to impose a duty of care in the circumstances. Factors giving

> rise to proximity must be grounded in the governing statute when there is one, as in the present case. (Emphasis added).

[27] No analogous duty of care of the nature alleged in this case that has been recognized previously. The question, therefore, is whether a new duty of care should be recognized in this case.

[28] There is no dispute that the provisions and regulations cited by the plaintiffs establish a general regulatory scheme meant to operate for the benefit of the public at large. The issue is whether the statutory and regulatory scheme creates a private law duty of care owed to plaintiffs individually by the government. In other words, is "proximity" sufficiently "grounded in the governing statute" to create such a private law duty of care? In my view, it is not. The scheme imposes specific duties on manufacturers, distributors or sellers of medical devices. It is plain and obvious, however, that no such obligations are attributed to the government so as to create a private law duty of care.

[29] The flaw in the plaintiffs' theory is readily apparent from a reading of s. 19 of the *FDA*. As stated above, it provides:

> 19. No person shall sell any device that, when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof.

[30] No reasonable interpretation of s. 19 can lead to the conclusion that it imposes a private law duty of care on the government in respect of the sale of medical devices to the public. It is clear that the duty imposed rests with the seller.

[31] In like fashion, I cannot accede to the argument that the regulatory scheme promulgated under the statutes either creates a duty of care or rises to a level that could be regarded as "operational" as opposed to "policy".

[32] At paragraph 131(e) of its Amended Statement of Defence, Canada states:

> (c) as a matter of policy, the regulatory scheme in the Act and Regulations is administered by Health Canada on the basis of voluntary compliance by industry. This approach is reasonable in light of the large and ever increasing number of medical devices on the Canadian market and the prohibitive cost of a fully taxpayer-funded testing system. The Act and Regulations impose responsibility for the safety of devices and medical devices on manufacturers and importers and they are responsible for testing their own products and maintaining evidence of their safety and effectiveness. Health Canada monitors compliance with the Act and the Regulations on the basis of information provided by manufacturers, importers and others.

[33] The plaintiffs, relying on the line of cases that draw a distinction between the "operational" decisions of government bodies, for which liability may attach, and their "policy-making" functions, which are immune from private suit, argue that the regulatory scheme in issue is

operational in nature. I disagree. While I make no finding on whether the "approach" taken is "reasonable", in my view, paragraph 131(e) accurately describes the thrust of the regulatory scheme. It is plain and obvious that it is an exercise in policy-making. The obligations to inform individuals, to provide information and to ensure that devices are safe, rest with the manufacturer, importers and sellers of the devices rather than the government. Neither the statutes nor the regulations relied upon by the plaintiffs establish a duty on the part of the government either to ensure absolute safety of the devices or to insure individuals against loss or damage caused by their use.

[34] In support of their argument regarding the "operational" and "policy" distinction, the plaintiffs relied heavily on *Finney v. Barreau du Quebec*, [2004] 2 S.C.R. 17, a case decided by the Supreme Court of Canada subsequent to *Cooper* and *Edwards*. However, the facts of *Finney* are materially different from the claims advanced in this case.

[35] *Finney* concerned a claim against the Barreau, the professional body charged with oversight of the conduct of lawyers in Quebec, in relation to its failure to properly deal with a specific complaint made against a specific lawyer. The failure of the Barreau to act appropriately and in a timely manner was found to have breached a duty owed to the claimant. However, the individual duty of care that was breached arose with the actual complaint. Upon the making of the complaint, the plaintiff had engaged the operational functions of the Barreau. This situation is to be distinguished from the present circumstances, where there are no allegations of either specific complaints or a specific regime to be engaged by such complaints.

[36] The plaintiffs also relied on the decision of the Federal Court of Appeal in *Swanson Estate v. R.* (1991) 80 D.L.R. (4th) 741 (F.C.A.), a case involving fatalities resulting from a crash of a plane operated by a small commercial passenger airline. This case is also distinguishable on its facts. A claim was advanced against the Minister of Transport, among others, after a plane crash left six passengers dead. The airline operating the plane had been the subject of numerous complaints, by its own pilots, to the Aviation Regulation Branch of Transport Canada. However, the Transport Canada inspectors, despite verifying the complaints as accurate, did nothing more than obtain undertakings from the airline to correct the deficiencies. The inspectors did not follow up to ensure that the undertakings were complied with, despite the obvious dangers presented by the deficiencies. The airline failed to comply and, as a result of inadequate pilot training and faulty equipment, a plane carrying nine people crashed into the side of a mountain, killing six of them.

[37] Another case referred to by the plaintiffs was the decision of Madam Justice Pierce in *Baric v. Tomalk*, [2006] O.J. No. 890 (S.C.J.). Although there is some superficial similarity to the present case in that the subject matter was a medical device, it too is distinguishable on its facts. The medical device in issue in *Baric* was an artificial jaw, or TMJ, implant. However, the factual allegations set out by Pierce J. reveal that the central figure in the case was the corporation subject to regulation. It had committed specific and identified breaches of the regulatory provisions, including some which had come to the attention of an inspector, who had ordered the corporation to take corrective measures, but the Health Canada field staff did not follow up to ensure compliance.

[38] The facts of *Swanson*, *Finney* and *Baric* highlight the manifest differences between the claims made in those cases and the claims made by the plaintiffs here. In *Swanson* and *Finney* specific regulatory processes meant to deal with individuals and corporations breaching regulations had been invoked in respect of specific incidents. The regulatory mechanism already in place had been engaged. The courts found that the persons charged with administering those mechanisms in the context of the complaints made failed to discharge their responsibilities under the regulatory scheme in place.

[39] Unlike the decisions in *Swanson* and *Finney*, which were the conclusion of trial processes, the decision in *Baric* was made on the pleadings alone in the context of a motion to dismiss for want of a cause of action. Nonetheless, looking only to the recitation of the pleadings that were before the court, there were obvious differences in the allegations made in that case as opposed to those before the court here. In *Baric*, the corporation subject to regulation was alleged to have breached the regulations on a number of occasions. It had been noted as being in breach by inspectors and field personnel of Health Canada. No remedies or sanctions had been applied to the company despite the investigations and findings of the inspectors. In the context of these factual allegations, Pierce J. found that it was not plain and obvious that a cause of action could not exist. However, Pierce J. also declined to make her judgment applicable to a broad range of similar litigation involving the same medical devices, instead holding that each case should be examined on its facts to determine whether a cause of action existed.

[40] In contrast, when the pleadings are examined in this case, no such allegations of the nature of those made in *Swanson*, *Finney* and *Baric* are made by the plaintiffs. Here, where the plaintiffs make allegations of complaints to the government, they are of a general nature relating to information about the devices and the allegation of breach of duty relates to a failure to amend regulations.

[41] Indeed, in paragraph 36 of the Amended Statement of Claim, the plaintiffs have succinctly reduced the claim to its essence stating:

> 36. Under the Statutes and Regulations pleaded in paragraphs 32 to 35, Her Majesty and the Defendants had a duty to prohibit the use of the devices at issue herein, and to use its other powers to protect residents of Canada including the Plaintiffs once it had or ought to have had a reasonable apprehension that these devices were being used. (Emphasis added.)

[42] An allegation that there was a "duty to prohibit" is akin to an allegation that there is a duty to govern in a certain way. By extension that renders the plaintiffs' claim one of failure to regulate *simpliciter* or, in other words, a failure to govern. That is a manifest policy decision and it is well-settled that, as such, it is immune from civil liability. The underlying reasons for such immunity are well-stated by Hugessen J. in *A.O. Farms Inc. v. Canada*, [2000] F.C.J. No. 1771 at para. 11:

> ...The relationship between the government and the governed is not one of individual proximity. Any, perhaps most, government actions are likely to cause harm to some members of the public. That is why government is not an easy

> matter. Of course, the government owes a duty to the public but it is a duty owed to the public collectively and not individually. The remedy for those who think that duty has not been fulfilled is at the polls and not before the Courts.

[43] Further, I am unable to accept the plaintiffs' proposition that *Finney* has in any way varied the principles set out in *Cooper* or *Edwards*. Although *Finney* was decided in the Quebec Civil Code context, as Lebel J. stated at para. 46:

> [para46] One other comment seems timely here, regarding an aspect of the arguments made by the Barreau regarding the analysis of its civil liability. In the appellant's submission, the common law principles that apply to public bodies preclude liability in its case. As the respondent pointed out, in common law, the Barreau would have been no less liable in the circumstances of this case if the analysis adopted by this Court in *Edwards v. Law Society of Upper Canada*, [2001] 3 S.C.R. 562, 2001 CSC 80, and *Cooper v. Hobart*, [2001] 3 S.C.R. 537, 2001 CSC 79, had been applied. The decisions made by the Barreau were operational decisions and were made in a relationship of proximity with a clearly identified complainant, where the harm was foreseeable. The common law would have been no less exacting than Quebec law on this point.

[44] The Reasons of Lebel J. in *Finney* are express on the point that past operational decisions, rather than policy functions, were at issue. Accordingly, and as adverted to by Lebel J., *Finney* neither overrules nor modifies the holdings in *Cooper* and *Edwards*.

[45] In like fashion, the more recent Ontario appellate decisions involving allegations of a private law duty of care on the part of government, in *Klein v. American Medical Systems, Inc.*, [2006] O.J. No. 5181 (Div. Ct.) and *Eliopoulos v. Ontario (Minister of Health and Long Term Care)*, [2006] O.J. No. 4400 (C.A.) are consistent with past jurisprudence regarding the distinction between policy and operational decisions, and the inability to ground a private law duty of care cause of action on a policy decision. Both *Klein* and *Eliopoulos* uphold the right of the government to govern in the general public interest without being subject to the threat of suit. As stated by Sharpe J.A. in *Eliopoulos* at para 33:

> Public health priorities should be based on the general public interest. Public health authorities should be left to decide where to focus their attention and resources without the fear or threat of lawsuits

[46] Since I have found that the plaintiffs' claim fails on what is regarded as the first part of the two part test enunciated in *Anns*, and as clarified in *Cooper* and *Edwards*, it is unnecessary to consider whether residual policy issues, the second stage of the *Anns* test, would negate the finding of a duty of care.

[47] For the reasons set out above, the plaintiffs are unable to satisfy the first criterion for certification under s. 5(1) of the *CPA*. Accordingly, the motion is dismissed. Submissions were made at the hearing of this matter that the parties have entered into an agreement to have the determination made on this motion have a binding effect in respect of a similar proceeding in Quebec (*Solange Roy v. The Minister of Health of Canada and the Attorney General of Canada*).

I would ask counsel to attend at a case conference to speak to that issue prior to settling the order flowing from these Reasons.

Certification Issues Under ss. 5(1)(b)-(e) of the *CPA*

[48] In the interests of expediency, and given the fully developed record before the court, I consider it appropriate to address the remaining elements in the test for certification, notwithstanding the dismissal of the motion on the s. 5(1)(a) criterion under the *CPA*.

[49] As stated above, I am not persuaded that the remaining criteria could not be met in the action as framed.

[50] I turn first to the issue of whether there is an identifiable class. The plaintiffs are seeking certification of a national class with the exception of British Columbia residents. The plaintiffs estimate the number of class members at approximately 29,500 individuals. The following class description has been proposed for certification in the Notice of Motion:

> "All persons resident in Canada, except those residing in British Columbia when implanted, who were implanted between January 1, 1962 and December 31, 1992, inclusive, with various devices in Canada variously known as breast implants manufactured, imported, distributed or sold by Dow Corning Corporation, Dow Corning Wright, Dow Corning Canada Inc., and/or their associated, affiliated or subsidiary corporations or entities ("Dow Corning breast implants") which include, but are not limited to, the following:
>
> a. silicone oil for injection into human breasts;
>
> b. silicone oil in a polymer or other alloplastic shell;
>
> c. adulterated silicone oil known as silicone gel in a polymer or other alloplastic shell;
>
> d. saline solution in a polymer or other alloplastic shell;
>
> e. urethane or other alloplastic foam in a polymer or other alloplastic shell;
>
> f. one of the foregoing shelled implants with a urethane or other alloplastic foam coating on the exterior surface of the polymer or other alloplastic shell;
>
> g. urethane or other alloplastic foam without a shell; or
>
> h. further and other alloplastic devices, full particulars of which are or were known to the defendant but for which the defendant has or have destroyed, altered, or hidden the relevant records or documentation."

[51] Canada contends that the class definition is "unnecessarily broad" and that there is no rational "connection between a class member who did not suffer any injury or damages and negligence by [Canada]". I do not agree.

[52] The basic claim of the plaintiffs is that the breast implants, or medical devices, at issue were unsafe for their intended use and, therefore, should not have been permitted to be sold or used in Canada. It logically follows that there is a rational connection among all individuals who were implanted with the devices and the claim made. The fact that some of the individual class members may not have suffered harm, or not yet suffered harm, does not alter the fact that they were exposed to an allegedly defective device. While any particular class member's claim may prove to be unsuccessful, one purpose of class action litigation is to achieve judicial economy by resolving all potential claims. As stated in *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158 at para 21:

> The representative need not show that everyone in the class shares the same interest in the resolution of the asserted common issue. There must be some showing, however, that the class is not unnecessarily broad -- that is, that the class could not be defined more narrowly without arbitrarily excluding some people who share the same interest in the resolution of the common issue. Where the class could be defined more narrowly, the court should either disallow certification or allow certification on condition that the definition of the class be amended...

[53] In consideration of an allegation that a given product is unsafe for use, it is difficult to accept the proposition that all users would not have some interest in the outcome of the litigation. Conversely, it is equally difficult to accept a proposition that the defendant subject to the allegation would not want to ensure that all potential claims are resolved and all potential claimants bound by the result, including those claims that may fail.

[54] Notwithstanding my view that the class description is not overly broad in the context of the claim made by the plaintiffs, as the Supreme Court noted in *Hollick*, it would be within the court's discretion to amend the class description in any event. One approach to limiting classes, which is becoming a common practice among plaintiffs to circumvent arguments regarding over-inclusive class descriptions, would effectively meet the argument advanced by Canada. That approach is to include a limiting phrase in the class description to the effect of "all those persons who claim" in respect of the alleged harm, or some variation thereof.

[55] A definition based on a "claims made" limitation was utilized in *Rumley v. British Columbia*, [2001] 3 S.C.R. 184. By the time the *Rumley* case reached the Supreme Court, the parties to the litigation were not contesting the class definition and thus the Court did not comment expressly on the class description. However, the Court was required to consider the uncontested class definition as set out by the British Columbia Court of Appeal in the context of its determination of the live dispute relating to common issues. Given the number of times the Court had reference to the class definition during its discussion on common issues, it must be assumed that the definition, if not expressly approved, was, at a minimum, implicitly so.

[56] The use of "claims made" limiters has not been universally accepted. Some courts have characterized them as verging into an impermissible "merits-based" definition. I do not share this view. If membership in a class is defined as those who make claims in respect of a particular event or alleged wrong, no determination of the merits of any particular claim is necessary prior to making a determination as to whether the claimant is a member of the class. Similarly, if a person's claim fails, it does not eliminate the person from the class, rather it demarks the claimant as a class member whose claim has been determined through a binding process. It is not the purpose of class proceedings, or class definitions, to bind only successful claimants. All those who may bring claims in respect of a particular event or allegation should be bound if possible, subject of course to the legislated exception of those putative class members who exercise the right to opt out of the class proceeding.

[57] Another criticism of a "claims made" limiter on class description is that it does not provide the necessary certainty of identifying those who are bound by the class definition. In my view, this criticism is founded on too narrow an interpretation of both the class definition and the functions of a court supervising a class proceeding. Defining a class as those persons "who claim" includes those persons who may come forward in the future to make a claim. A defendant and, for that matter, the court, will be in a position to ascertain whether a particular person is included in the class and bound by the resolution of the common issues. In this respect, it is trite that class members need not be identified individually at the time the class is certified. Accordingly, utilizing a "claims made" in the appropriate case leaves the defendant in no different position vis à vis knowledge of the class membership than would be otherwise the case. As for the potential class members, the court can ensure that the notice adequately conveys the effect of the class definition and the fact that claims in the future may be barred as a result of the resolution of the proceeding.

[58] I do not wish to have any of the foregoing construed as a departure from the prohibition against merits based class descriptions. Thus, to combine a merits based determiner with a "claims made" limitation would run afoul of the settled principles regarding class descriptions.

[59] Here, I do not find it necessary to insert a "claims made" limiter in that the class description proposed by the plaintiffs is not overly broad. However, in my view, such an amendment would entirely meet the objection to the class description advanced by Canada.

[60] The next criterion to be considered is whether the claim raises common issues. The plaintiffs have proposed 15 common issues which they allege are determinable without regard to the individual circumstances of any class member. The plaintiffs assert that resolution of these common issues will significantly advance the litigation as they would be dispositive of key elements of liability of Canada in relation to the class.

[61] Canada argues that resolution of the proposed common issues will not be sufficient to establish liability and each claim will have to be individually evaluated to determine causation. Accordingly, it is asserted that the common issues advanced do not address the issue of fitness of the devices for their intended use. Moreover, there is no evidence that all of the models of Dow Corning implants shared common characteristics so as to address the general fitness of these implants.