

**ONTARIO
SUPERIOR COURT OF JUSTICE**

BETWEEN:

KATHRYN ANNE TAYLOR

Plaintiff

- and -

HER MAJESTY THE QUEEN IN RIGHT OF CANADA
as represented by the MINISTER OF HEALTH,
THE ATTORNEY GENERAL FOR CANADA

Defendant

Proceeding under the *Class Proceedings Act, 1992*

**FRESH AS AMENDED
REPLY**

1. Except where expressly admitted herein, the Plaintiff denies each and every allegation of fact contained in the Fresh as Amended Defence ("Defence") herein and put the Defendant to the strict proof thereof.
2. The Minister of Health has specific and direct non-delegable obligations and duties under:
 - a. the *Department of Health Act*,
 - b. the *Canada Health Act*; and
 - c. the *Food and Drugs Act*.
3. This action alleges negligent breaches of these and other obligations by the Minister of Health and the senior staff of Health Canada for the protection of the

public which obligations the Minister and his senior staff failed or neglected to exercise without reasonable excuse such that the injuries and damage at issue herein needlessly arose.

4. The negligence at issue includes the neglect or failure to exercise non-delegable obligations and duties for the protection of the public and the safety of individual Canadians.
5. The negligence of the Minister and of the senior staff of Health Canada in exercising these specific and direct non-delegable obligations and duties caused the injuries and damage at issue herein.
6. The *Charter* and other remedies sought against the Minister of Health make the Minister of Health a necessary and proper party to this action.
7. The Plaintiff admits the allegations in paragraphs 4, 9, 18 (in part), 78, 82 (in part), and 92 (in part), of the Defence of Her Majesty the Queen in Right of Canada ("HMQ").
8. The Plaintiff admits that portion of paragraph 18 of the Defence; "Since that time, all TMJ devices sold in Canada would be "devices" within the meaning of the Act." The Plaintiff states and the fact is these devices are now and have always been subject to the *Food and Drugs Act* ("the Act") and its Regulations.
9. At all material times, the devices at issue in this action were unsafe and known by Health Canada to be hazardous to the health of individual Canadians. The wrongs and negligence alleged against the Defendants cannot be excused or avoided by the subordinate regulations enforced from time to time.
10. The Plaintiff has no knowledge of the allegations in paragraph 25 and 45 of the

HMQ's Defence.

11. In 1973, the Act prohibited the sale of any device, which may cause injury to the health of the purchaser or user when used according to directions.
12. Section 19 of the *Food and Drugs Act*, R.S.C. 1985, Chapter F.27 reads:

“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.” (emphasis added).
13. When the *Food and Drugs Act* first came into force in 1954, the identical wording was then used in section 18.
14. This phrase has been in force without pause or suspension since 1954.
15. This phrase imposes a mandatory Statutory duty, and is not precatory.
16. Parliament gave the Minister no discretion to dispense with compliance or enforcement of this rule.
17. A principle purpose of the Act is to protect the health and safety of the public. The Minister of National Health and Welfare said the following when the Act was introduced in the House of Commons in 1953:

‘The purpose of the bill of course is to protect the Canadian people in matters of health, as well as against fraud in the manufacturing and sale of food and drugs... The bill is concerned with the prohibition of things that are injurious to the health and that are unfit for use, and with the prevention of deception in the manufacture and sale of goods consumed by the public.’

18. The Act gave enforcement powers to the Government of Canada under Part II of the Act. Parliament expected those powers to be exercised responsibly and not ignored.
19. The *Food and Drug Act* provided and provides Health Canada with the discretion to make regulations “for carrying the purposes and provisions of this Act into effect.” Once the discretionary policy decision was made to regulate, the crafting, promulgation, and enforcement of the individual Regulations were and are operational in nature and effect.
20. The Plaintiff states that under section 19 of the *Food and Drugs Act*, HMQ is responsible for enforcing the prohibition against devices that “may cause injury to the health of the purchaser or user thereof” being sold in Canada.
21. The Minister and Health Canada have a specific and direct non-delegable obligation and duty for the protection of health and safety of individual Canadians reasonably expected to purchase or use such devices.
22. The Plaintiff states and the fact is that at all material times, the Minister and Health Canada knew or ought to have known that the devices at issue in this action would cause injury to the health of the purchaser or user thereof.
23. With respect to paragraph 13 of the Defence, the identity of the manufacturer and the model of the device that was implanted in the Plaintiff, the date of the importation of the device into Canada, and the dates when it was regulated by Health Canada are information within the knowledge of the Defendant, which is responsible for regulating the importation of such a device.
24. With respect to paragraph 8 of the Defence, the Plaintiff states and the fact is that while there is a variation as to the severity and degree of injury depending

on individual recipient, the TMJ devices at issue in this action were all hazardous when used as expected or intended.

25. The Plaintiff states and the fact is that the Defendant is severally directly liable for any and all damage caused by implantation of the devices at issue in this action.
26. The damage suffered by the members of the class arose from the Defendant's negligence to prohibit, ban, recall, or warn about the hazards of the devices at issue herein.
27. The Plaintiff states and the fact is that the regulatory scheme as pleaded in the Defence cannot form any reasonable basis of Defence as it is the governing statute and not the subordinate regulation which prohibits the sale of the devices at issue and imposes the duties at issue on the Minister and Health Canada.
28. To the extent that the Defendants allege a regulation excuses the Defendants' neglect or failure to act at issue herein, such regulation is in conflict with its enabling statute and is therefore *ultra vires*.
29. The Plaintiff states and the fact is that throughout the various "regulatory regimes" described in the Defence, the duty of HMQ to reasonably protect the citizens of Canada from medical devices that cause harm pursuant to s. 19 of the *Food and Drugs Act* was, and continues to be, clear and immutable.
30. HMQ at all material times breached, and continues to breach, this duty.
31. The Plaintiff states and the fact is that throughout the various "regulatory regimes" described in the Defence, Health Canada failed to have in place management operations and procedures that would reasonably have prevented the issuance of Notices of Compliance for devices that cause harm.

32. The Plaintiff states and the fact is that this failure constitutes systemic negligence on the part of HMQ.
33. With respect to paragraph 14 of the Defence, the Ontario *Class Proceedings Act* provides for certification of a national class action.
34. The *Class Proceedings Act, 1992*, permits a representative plaintiff, prior to the certification motion, to plead causes of action which are not personal to the representative plaintiff, but are asserted in a representative capacity on behalf of members of the class who have those causes of action. The Ontario Health Insurance Plan ("OHIP"), as a subrogated representative plaintiff, can advance claims on behalf of extra-provincial health authorities.
35. On this basis, the extra-provincial health authorities, who are members of the subrogated class, who are not named as a Plaintiff, but whose claims are asserted in accordance with the *Class Proceedings Act, 1992*, are parties to this action by operation of law not by any voluntary act of the Plaintiff.
36. The Plaintiff has expressly sought an Order that she not be obliged to represent the interests of any subrogated Health insurer or government agency and has expressly requested an Order that these authorities and insurers be independently represented. The Plaintiff states and the fact is that these health authorities and insurers have independent statutory rights and obligations and substantive rights in this action which the Plaintiff cannot adequately represent.
37. With respect to paragraphs 15, 16, and 122 of the Defence, to the best of the Plaintiff's knowledge, information, and belief, OHIP and other extra-provincial health authorities have never waived their right to subrogation in respect of TMJ devices.

38. With respect to paragraphs 133 and 134 of the Defence, the Plaintiff states and the fact is that s.24 of the *Canadian Charter of Rights and Freedoms* supercedes s.22 of the *Crown Liability and Proceedings Act*.
39. As conceded by the Defendant in paragraph 18 of the Defence; "Since that time, all TMJ devices sold in Canada would be "devices" within the meaning of the Act." The Plaintiff states and the fact is these devices are now and have always been subject to the Act and Regulations at all material times.
40. The Plaintiff states that throughout the various regulatory schemes to the *Food and Drugs Act*, HMQ at all material times failed, and continues to fail, to enforce section 19 of the Act with respect to TMJ implants. The Plaintiff states and the fact is that this failure constitute systemic negligence on the part of the Defendant.
41. The Plaintiff states that throughout the various regulatory schemes to the *Food and Drugs Act*, HMQ at all material times has had actual knowledge of the sale in Canada of TMJ implant devices which 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.
42. The Plaintiff states and the fact is that HMQ at all material times has had actual knowledge that TMJ implant devices used according to directions or under such conditions as are customary or usual, did cause real and substantial injury to all recipients thereof and in some cases caused catastrophic injury or precipitated the recipient's death.
43. The Plaintiff states that the failure or refusal of the Minister of Health, specifically, and of HMQ, generally, to enforce section 19 of the Act with respect to TMJ

implants is unlawful and harmful to Canadians.

44. From 1954 to the current date, the basic provisions of the *Food and Drugs Act* have remained unchanged. While the various Regulatory schemes evolved to provide a framework for increased specific requirements of proof of safety and efficacy, at all times TMJ implants were required to cause no harm under the Act.
45. Section 16 of the *Medical Devices Regulations*, RRC C. 871, 1977, further clarified the intent of Parliament by stating "no person **shall** import into Canada for sale a device the sale of which in Canada would constitute a violation of the Act **or** these Regulations." (emphasis added)
46. Volume 4, No. 1 of the Health Canada bulletin entitled "Medical Devices Surveillance", dated 1990 11 01, states "The sale of medical devices in Canada is subject to federal legislation. The Food and Drugs Act prohibits the sale of any medical device which is unsafe or falsely represented. To enforce the Act as it applies to medical devices, a set of specific definitions and requirements called the Medical Device Regulations was first promulgated in 1975." By enacting the Medical Device Regulations, the Defendant made a clear operational decision to continue to enforce the *Food and Drugs Act* with respect to medical devices such as TMJ implants.
47. At all material times, the Minister of Health had designated inspectors for the enforcement of the Act pursuant to his powers in Part II thereof and analysts for the purpose of the enforcement of this Act also as provided for in Part II thereof.
48. The inspectors and analysts so appointed conducted inspections, testing and analysis of the implants at issue herein and recommended a universal and general ban thereof at times and in a manner, full particulars of which are known to the Defendant but which have not been disclosed to the Plaintiff.

49. Contrary to the allegations contained in paragraphs 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, and 38, of the Defence, the Defendant's own inspectors and analysts were not primarily concerned about the non-compliant status of the Vitek TMJ implants sold in Canada but that all known alloplastic implants were known to be dangerous to the health and safety of recipients when implanted in any human temporomandibular joint.
50. The Defendant was warned by its own inspectors and analysts of real and present danger to implant recipients but ignored these warnings without reasonable or any justification or any excuse.
51. One of the analysts employed by the Defendant was Health Canada's senior scientist, Dr. Pierre Blais, who was employed by Health Canada between about 1972 and 1990.
52. Dr. Blais was discharged from his employment with Health Canada for refusing to destroy memoranda to the Minister warning of the dangers of alloplastic implants, full particulars of which are known to the Defendant and are unknown to the Plaintiff.
53. Since April 1, 1976, Health Canada was directly responsible for establishing the testing methods for TMJ implants. The original Regulations prohibited a manufacturer from selling a TMJ implant in Canada unless tests were made in accordance with an "acceptable method" which was defined as meaning a method approved in writing by the Director (s.13(1)). The tests had to indicate that the benefits claimed for the device were justified. Thus no importer could sell a device, e.g. TMJ implants made in the USA, unless the benefits claimed and the performance characteristics (defined as the properties and qualities associated with its capacity to carry out its patient related functions) were justified by tests in accordance with tests approved in advance by the Director or

by tests satisfactory to the Director (s. 13(2)). The Plaintiff states that the Defendant was grossly negligent in failing to develop appropriate tests to determine the safety and efficacy of TMJ implants.

54. The Plaintiff states and the fact is that at all material times, Health Canada conducted or purported to conduct risk-benefit analyses for the approval of the use and sale of TMJ implants in Canada. The Plaintiff states and the fact is that this constitutes ongoing and systemic negligence. This is unlawful and *ultra vires* the Act.
55. A risk-benefit analysis with respect to medical devices was first codified in the *Medical Devices Regulations* in 1998 (SOR/98-282), with no concomitant amendment to the Act. Regulations, as delegated legislation, cannot revoke a term of the Act.
56. Any attempt to avoid, ignore or revoke a requirement of the Act by use of the Regulations, without a corresponding amendment to the Act by Parliament, is unlawful.
57. A risk-benefit analysis for the approval of TMJ implants was at all material times unlawful and a violation of section 19 of the *Food and Drugs Act*.
58. In the alternative, the use of a risk-benefit analysis for the approval of TMJ implants was at all material times grossly negligent.
59. The Plaintiff states and the fact is that the ongoing and systemic decisions by Health Canada to violate section 19 of the Act were not and are not a *bona fide* exercise of discretion.
60. The Plaintiff states and the fact is that this represents a codification of the actual

practice that had been in effect since at least 1975 when the first *Medical Devices Regulations* were promulgated. At all material times, the Defendant actually practiced a risk benefit analysis in deciding which medical devices were to be issued Notices of Compliance. The Plaintiff states and the fact is that all material times, this risk-benefit analysis was *ultra vires* the *Food and Drugs Act*. The Plaintiff states and the fact is this conduct on the part of the Defendant constitutes systemic and ongoing negligence.

61. Apart from Sections 3, 18, 19, and 20, of the Act, which address advertising, sales, practices, labeling, and standards for devices, Part II of the Act entitled "Administration and Enforcement", including sections 21 to 31, is also significant.
62. With respect to paragraphs 22 and 23 of the Defence, between 1975 to 1982, the Regulations did not impose an obligation on the manufacturers and importers to provide to Health Canada prior to selling TMJ implant, with information concerning the tests performed on the devices, or information in respect of the safety and effectiveness of the devices. Health Canada failed or refused to conduct any prudent or reasonable safety and effectiveness screening for devices before and during this time.
63. With respect to paragraph 43 of the Defence, the term "grandfathering" was applied by Health Canada to the Canadian regulatory system. The Regulatory Analysis Statement of the *Medical Devices Regulations, amendment, SOR/94-135*, states:

The requirement pertaining to implantable devices in Part V came into effect in October, 1982. **Implantable devices that were sold or advertised in Canada prior to that date are not subject to the requirements of Part V and are commonly referred to as "grandfathered" devices.** A "grandfathered" device becomes a "new device", subject to the full requirements of Part V, when a manufacturer changes some characteristic of the "grandfathered" device (i.e. its design,

material of construction, or recommended use).

Since October 1988, the Department has administratively permitted the continued sale of "new devices" and "grandfathered" devices in the situation where the ownership of a firm changes, provided that the new owner confirms that the characteristics of the device will remain unchanged. . .

The Department believes that stopping the sale of a "new device" or a "grandfathered" device is reasonable when a characteristic of the device is altered or when the Department has reason to question the safety or effectiveness of the device. However, it considers such a stoppage unreasonable when due solely to a change in the name of the manufacturer. The amendment will permit the continued sale of these devices by the new manufacturer provided that the new manufacturer submits certain information to the Department. (emphasis added)

64. The Plaintiff states and the fact is that "grandfathering" was without foundation in law.
65. The Plaintiff states and the fact is that if "grandfathering" was lawful, then its implementation by Health Canada in the circumstances of this case with respect to TMJ devices was grossly negligent.
66. The Defendant's current attempt to deny its practice of "grandfathering" is egregious and warrants special remedies for the benefit of the Plaintiff class so as to protect them from continuing gross negligence by Health Canada.
67. With respect to paragraph 24 of the Defence, the Plaintiff states that Notices of Compliance were issued where the employees of Health Canada were not satisfied that the pre-market review requirements had been met.
68. From 1988 until 1994, Health Canada allowed certain manufacturers to escape the requirements of Part V of the 1977 Revised and Consolidated Regulations (RRC C. 871). This practice was without legal authority.

69. On January the 27th, 1994, on the coming into effect of Regulation SOR/94-135, the Defendant attempted to retroactively ratify this practice.
70. With respect to paragraph 26 of the Defence, the use of the word and/or phrase “analysis”, “in certain circumstances”, and “issue” is an attempt by the Defendant to recast its relationship with and duties owed to the class in such a way that its relationship and duties are vague rather than explicit.
71. The use of the phrase “A Notice of Compliance was issued when the information submitted by the manufacturer met the safety and effectiveness requirements set out in the regulations.” is an attempt by the Defendant remove its obligation on the part of Health Canada to conduct a pre-market review of the safety and effectiveness of all new devices and to place that non-delegable duty on the manufacturers, importers, and distributors.
72. The Plaintiff states and the fact is, the Defendant had actual knowledge of harm which it refused to act upon or neglected to act upon in circumstances which amount to gross negligence and a direct breach of Health Canada's responsibility to regulate such devices.
73. With respect to paragraphs 32 to 38 and 61 to 71 of the Defence, the Plaintiff repeats and relies upon the facts set forth in paragraphs 33 to 57 of the Claim. Health Canada was aware that Vitek Inc. had made a submission for TMJ implants prior to the Plaintiff's surgery on April the 22nd, 1998, and that TMJ Implants from Vitek Inc. were being sold in Canada.
74. Further to paragraph 47 of the Claim, the Health Canada inspector was told by a representative of Instrumentarium that the TMJ implants made by Vitek Inc. that were in Instrumentarium's possession had Notices of Compliance. The Health Canada inspector and other staff relied on this information from the

Instrumentarium representative rather than follow up on the Health Canada inspector's findings from the visit to Instrumentarium.

75. With respect to paragraph 53 of the Defence, the Plaintiff states and the fact is that this information package was not made known to any interested member of the public through any means of advertisement.
76. TMJ devices can and do result in giant cell reactions and osteoclast formation.
77. The implantation of TMJ devices result in giant cell reactions.
78. Giant cell reactions and osteoclast formation are harmful and contrary to s. 19 of the Act.
79. TMJ devices can and do result in giant cell reactions, which are a response to the introduction of a foreign substance into the human body.
80. The Defendant had knowledge of giant cell reactions and took no concomitant steps to prohibit the use of these devices, which is grossly negligent of their statutory duty.
81. The Plaintiff reiterates that her claim is against HMQ is for the several liability of the Crown for the wrongs committed by its servants as alleged in the Claim.
82. With respect to paragraphs 37, 38, 70, 71, 84 to 93, 114 and 121 of the Defence, all TMJ implants were required by the Act and the Regulations at all material times to pass a threshold of safety and effectiveness, which could not be waived by a patient, hospital, surgeon, or provincial health authority.
83. Subparagraph 15.1(2)(b)(i) of the Medical Device Regulations (SOR/95-578)

mandates specific requirements for informed consent for medical devices.

84. With respect to paragraph 99 of the Defence, Health Canada information letter IL No. 721 states "The Health Protection Branch has a mandate to ensure that the requirements of the *Food and Drugs Act* applicable to medical devices are met." This IL also states that the Health Protection Branch relies on information obtained through surveillance activities, research, inspections, sample testing, problem report investigations and the hospital visit program.
85. Reliance on manufacturer information alone for determination of the safety of TMJ implants by HMQ was and is grossly negligent.
86. In 1994, the Post-Market Surveillance Section of the Research and Surveillance Division of the Medical Devices Bureau made a proposal for an information package that was to be sent directly to patients with TMJ implants, but to the detriment of all recipients of devices, was not.
87. The preparation of this information and warning package is an admission that the Defendant had a duty to inform patients directly of the risks associated with medical devices, and had the authority and mandate to do so.
88. Recalls of medical devices are within the mandate of HMQ as provided by the Act and the Regulations. For HMQ to allow a device to be recalled from the distributor and/or manufacturer while failing to inform the patient of the risks associated with the device would and did constitute gross negligence.
89. The gross negligence and breaches of statutory duty are all breaches of the defendant's fiduciary duty to the Plaintiff and the intended class.
90. These wrongs are a breach of s. 7 of the *Canadian Charter of Rights and*

Freedoms.

91. Full particulars of the acts and omissions of the defendants and their servants are known to the defendants, and are unknowable to the Plaintiff.
92. The use of the term “implantees” rather than “recipients” of TMJ implants is an attempt by the Defendant to artificially recharacterize its relationship with and duties owed to the members of the class.
93. The Plaintiff states and the fact is, the term “recipient” is a term used as recently as March 2004 on page 5 of the *Report of the Auditor General to the House of Commons, Chapter 2 - Regulation of Medical Devices*, to identify the Public, which is classified in a separate group distinct from health care professionals and health care facilities. The Plaintiff states that the Defendant owes residents of Canada a direct duty of care in the circumstances pleaded in this action, and is severally liable to them for the damage at issue.
94. With respect to paragraph 129 of the Defence, section 7 of the *Public Authorities Protection Act* was repealed in 2002 and does not apply to Health Canada in any event.
95. With respect to paragraph 130 of the Defence, section 45(1)(h) of the *Limitations Act* does not apply to Health Canada.
96. The Plaintiff states that the Defence sets forth no reasonable Defence at law, and pray leave to move to strike the Defence notwithstanding having taken the fresh step of having delivered this Reply.
97. The Plaintiff repeats and relies upon the allegations set forth in her Claim.

1 August 2006

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Defendant

Court file no. 99 CV 181819 [TORONTO]

Ontario

SUPERIOR COURT OF JUSTICE

Proceeding commenced at Toronto

FRESH AS AMENDED REPLY

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