

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

KEVAN DRADY and KATHRYN ANNE TAYLOR

Plaintiffs

- 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*

REPLY

1. The Plaintiffs admit the allegations in paragraphs 5, 15 (in part), 16 (in part), 17, 19, 38, 41, 42, 58, 65, 92, 134, 144, 149, 150, 153, 158 (in part), 159, 191, 192, 193, and 214 of the Statement of Defence (“Defence”) of Her Majesty the Queen in Right of Canada (“HMQ”).
2. With respect to paragraphs 15 and 16 of the Defence, the Plaintiffs repeat and rely on their description of the temporomandibular joint as outlined at paragraphs 13 and 14 of the Fresh as Amended Statement of Claim, amended the 13th of February, 2003 (“Claim”).
3. The Plaintiffs admit that portion of paragraph 39 of the Defence; “TMJ devices are devices within the meaning of the Act and have therefore been subject to the Act.” The Plaintiffs state and the fact is these devices are now and have always been subject to the Act and Regulations at all material times.
4. The Plaintiffs admit that portion of paragraph 130 of the Defence that “TMJ

devices can and do result in giant cell reactions”.

5. The Plaintiffs admit that portion of paragraph 212 that reads “... the Attorney General admits that Health Canada has held itself out as having a responsive remedial system”, of HMQ’s Defence.
6. The Plaintiffs have no knowledge of the allegations in paragraphs 45, 46, 66, 76, 80, 81, 85, 204, 205, 210, and 213 of the HMQ’s Defence.
7. The Plaintiffs deny each and every other allegation contained in the HMQ’s Defence and put the Defendant to the strict proof thereof.
8. 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).
9. When the *Food and Drugs Act* first came into force in 1954, the identical wording was then used in section 18.
10. This phrase has been in force without pause or suspension since 1954.
11. This phrase imposes a mandatory Statutory duty, and is not precatory.
12. Parliament gave the Minister no discretion to dispense with compliance or enforcement of this rule.
13. 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.'

14. 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.
15. 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.
16. The Plaintiffs state 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.
17. With respect to paragraphs 10 and 28 of the Defence, the identity of the manufacturers of the devices that were implanted in the Plaintiffs, the dates of the importation of the devices into Canada, and the dates when they were regulated by Health Canada are information within the knowledge of the Defendant, which is responsible for regulating the importation of such devices.
18. With respect to paragraph 18 of the Defence, the term "alloplastic" is a term of art that refers to any synthetic implant material, not necessarily an inert plastic or

metal graft.

19. With respect to paragraph 26 of the Defence, while there is a variation as to the severity and degree depending on individual recipients, all TMJ implants cause damage when implanted in the human body. The Plaintiffs state and the fact is that the Defendant is severally directly liable for any and all damages caused by implantation of TMJ implants into the members of the proposed class as the Defendant knew these devices to be harmful but refused to take the operational steps it was obliged to take.
20. With respect to paragraph 27 of the Defence, the Plaintiffs state that if a regulation is in conflict with its enabling statute or any other statute enacted by Parliament, it is *ultra vires*.
21. The Plaintiffs state 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.
22. HMQ at all material times breached, and continues to breach, this duty.
23. The Plaintiffs state and the fact is that throughout the various “regulatory regimes” described in the Amended 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.
24. The Plaintiffs state and the fact is that this failure constitutes systemic negligence on the part of HMQ.
25. With respect to paragraph 33 of the Defence, the Ontario *Class Proceedings Act*

provides for certification of a national class action.

26. 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.
27. 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 Plaintiffs.
28. The Plaintiffs have expressly sought an Order that they 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 Plaintiffs state and the fact is that these health authorities and insurers have independent statutory rights and obligations and substantive rights in this action which the Plaintiffs cannot adequately represent.
29. With respect to paragraph 243 of the Defence, OHIP has never waived its right to subrogation in respect of TMJ devices.
30. With respect to paragraphs 35 and 36 of the Defence, the Plaintiffs state 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*.
31. As conceded by the Defendant in paragraph 39 of the Defence; "TMJ devices are devices within the meaning of the Act and have therefore been subject to the

Act.” The Plaintiffs state and the fact is these devices are now and have always been subject to the Act and Regulations at all material times.

32. The Plaintiffs state 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 Plaintiffs state and the fact is that this failure constitute systemic negligence on the part of the Defendant.
33. The Plaintiffs state 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.
34. The Plaintiffs state 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.
35. The Plaintiffs state that HMQ’s failure or refusal to enforce section 19 of the Act with respect to TMJ implants is unlawful and harmful to Canadians.
36. 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.
37. 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)

38. 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.
39. 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 Plaintiffs state that the Defendant was grossly negligent in failing to develop appropriate tests to determine the safety and efficacy of TMJ implants.
40. The Plaintiffs state 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 Plaintiffs state and the fact is that this constitutes ongoing and systemic negligence. This is unlawful and *ultra vires* the Act.

41. 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.
42. 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.
43. 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*.
44. In the alternative, the use of a risk-benefit analysis for the approval of TMJ implants was at all material times grossly negligent.
45. The Plaintiffs state 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.
46. The Plaintiffs state 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 Plaintiffs state and the fact is that all material times, this risk-benefit analysis was *ultra vires* the *Food and Drugs Act*. The Plaintiffs state and the fact is this conduct on the part of the Defendant

constitutes systemic and ongoing negligence.

47. With respect to paragraph 41 of the Defence, Part II of the Act entitled “Administration and Enforcement”, including sections 21 to 31, is also significant.
48. With respect to paragraphs 51, 52, 53, 54, 55, 56, and 57 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 an breast 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.
49. With respect to paragraph 60 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)

50. The Plaintiffs state and the fact is that “grandfathering” was without foundation in law.
51. The Plaintiffs state 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.
52. 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.
53. With respect to paragraph 64 of the Defence, the Plaintiffs state that Notices of Compliance were issued where the employees of Health Canada were not satisfied that the pre-market review requirements had been met.
54. 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.
55. On January the 27th, 1994, on the coming into effect of Regulation SOR/94-135, the Defendant attempted to retroactively ratify this practice.
56. With respect to paragraph 69 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.

57. With respect to paragraph 70(g) of the Defence, the use of the phrase “submission of evidence of safety and effectiveness for all new devices and the issuance of a Notice of Compliance (or Supplementary Notice of Compliance) by Health Canada for the new devices, if the requirements of the Regulations are met” 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.
58. With respect to paragraph 76 of the Defence, to state that TMJ implants account to only a small fraction of devices and medical devices sold in Canada is irrelevant to the matters at issue in this action as 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.
59. With respect to paragraph 113 of the Defence, the Plaintiffs state and the fact is that this information package was not made known to any interested member of the public through any means of advertisement.
60. With respect to the defendant’s admission in paragraph 130 of the Defence that “TMJ devices can and do result in giant cell reactions”:
 - a. TMJ devices can and do result in giant cell reactions and osteoclast formation;
 - b. the implantation of TMJ devices result in giant cell reactions; and

- c. giant cell reactions and osteoclast formation are harmful and contrary to s. 19 of the Act.
61. The Plaintiffs state that paragraph 130 of the Defence is effectively an admission that TMJ implants cause harm.
62. This admission of giant cell reactions alone without any concomitant steps by the Defendant to prohibit the use of these devices is grossly negligent of their statutory duty.
63. With respect to paragraphs 138 to 140 and 172 of the Defence, the Plaintiffs' claim against HMQ is for the several liability of the Crown for the wrongs committed by its servants as alleged in the Claim.
64. With respect to paragraphs 154 to 169, 232, and 242 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.
65. Subparagraph 15.1(2)(b)(i) of the Medical Device Regulations (SOR/95-578) mandates specific requirements for informed consent for medical devices.
66. With respect to paragraph 173 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.
67. Reliance on manufacturer information alone for determination of the safety of

TMJ implants by HMQ was and is grossly negligent.

68. With respect to paragraph 182 of the Defence, 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.
69. 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.
70. 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.
71. The gross negligence and breaches of statutory duty are all breaches of the defendant's fiduciary duty to the Plaintiffs and the intended class.
72. These wrongs are a breach of s. 7 of the *Canadian Charter of Rights and Freedoms*.
73. Full particulars of the acts and omissions of the defendants and their servants are known to the defendants, and are unknowable to the Plaintiffs because of the spoliation pleaded in the Claim.
74. With respect to paragraphs 184 and 179 of the Defence, 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.

75. The Plaintiffs state 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 Plaintiffs state 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.
76. With respect to paragraph 252 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.
77. With respect to paragraph 254 of the Defence, section 45(1)(h) of the *Limitations Act* does not apply to Health Canada.
78. The Plaintiffs state 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.
79. The Plaintiffs repeat and rely upon the allegations set forth in their Claim.

14 October 2004

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Plaintiffs

Defendant

Court file no. 99 CV 181819 [TORONTO]

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Proceeding commenced at Toronto

REPLY

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