COURT FILE NO.: 05-CV-295910CP
DATE: 20071206

ONTARIO

SUPERIOR COURT OF JUSTICE

B E T W E E N:

FRANK PETER, MRS. BERNADETT PETER, MARK PETER, MS. BERNADETT PETER, BRIAN FREDERICK FOOTE, RHONDA LYNN LO MONACO, ANITA PRAIN and FRANCINE NOROUZI

Plaintiffs

- and -

MEDTRONIC, INC. and MEDTRONIC OF CANADA LTD.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

REASONS FOR DECISION

TABLE OF CONTENTS

COURT FILE NO.: 05-CV-295910CP
DATE: 20071206

ONTARIO

SUPERIOR COURT OF JUSTICE

B E T W E E N:	)	
	)	
FRANK PETER, MRS. BERNADETT PETER, MARK PETER, MS. BERNADETT PETER, BRIAN FREDERICK FOOTE, RHONDA LYNN LO MONACO, ANITA PRAIN and FRANCINE NOROUZI Plaintiffs	)	**Won J. Kim, Victoria Paris and Joel Rochon**, for the Plaintiffs
- and -	)	
MEDTRONIC, INC. and MEDTRONIC OF CANADA LTD. Defendants	)	**Patrick O'Kelly, Danielle Royal and Samaneh Hosseini**, for the Defendant
Proceeding under the *Class Proceedings Act, 1992*	)	**HEARD:** November 13 to 16, 2007

Hoy J.

REASONS FOR DECISION

INTRODUCTION AND CONCLUSION

[1] This action alleges that Medtronic, Inc. ("Medtronic U.S."), and its wholly owned subsidiary, Medtronic of Canada Ltd. ("Medtronic Canada", and collectively with Medtronic U.S. referred to in these reasons as "Medtronic"), breached their duty to warn of a defect in the batteries contained in, and were otherwise negligent in the design, testing, manufacture and distribution of, certain implantable cardioverter defibrillators ("ICDs") and cardiac resynchronization therapy defibrillators ("CRT-Ds") and conspired to conceal information relating to the potential battery shorting defect. The plaintiffs seek damages, or, in the alternative, an accounting and disgorgement of revenues, based on the doctrine of waiver of tort. In addition, derivative claims are advanced under family law legislation.

[2] The plaintiffs seek to have this action certified as a class proceeding pursuant to the *Class Proceedings Act, 1992*, S.O. 1992, c. 6 (the "CPA"). Medtronic opposes certification and moves to have portions of the plaintiffs' claim struck pursuant to Rules 21.01(b) and

25.11 of the *Rules of Civil Procedure*, R.R.O. 1990, Reg. 194. In the course of the certification hearing, the plaintiffs sought leave to amend their statement of claim to, among other things, plead breach of statute in support of their conspiracy claim.

[3] For the reasons that follow: the plaintiffs' claim in conspiracy shall be struck, with leave to amend to plead the overt acts taken by the conspirators; this action shall be certified as a class proceeding in respect of the classes and common issues identified in these reasons; and the plaintiffs shall proceed to amend their statement of claim to be in the form of the draft Second Fresh as Amended Statement of Claim provided to me during the hearing, together with the additional changes required or contemplated by these reasons.

BACKGROUND

[4] ICDs and CRT-Ds are medical devices implanted in the chests of patients with chronic heart disease.

[5] The heart, a muscular organ composed of four chambers, pumps blood throughout the body. The blood carries oxygen from the lungs to the entire body and wastes back to the lungs, liver and kidneys.

[6] The heart has an electrical system that keeps the heart beat regular and helps to keep the heart walls contracting in a coordinated and nearly simultaneous function. As a pump, the heart is most efficient when the heart rate is within the normal range. In some cases, the heart's electrical system functions abnormally, affecting the heart rate and pumping action.

[7] The medical condition when the heart beats (and pumps) too quickly is called tachyarrythmia. If the related impulses start in the lower chambers of the heart, called the ventricles, and the impulses are regular and fast, the condition is called Ventricular Tachycardia ("VT"). When the heart goes into VT, it does not pump blood efficiently and a patient may feel faint, dizzy and, in severe cases, may pass out. When a VT becomes unstable and irregular, it is called a Ventricular Fibrillation ("VF"). When the heart goes into VF, no blood is pumped to the body and a person with VF passes out within a few seconds. VF causes cardiac arrest.

[8] The medical condition when the heart beats (and pumps) too slowly is called bradycardia. A bradycardia patient may exhibit symptoms of fatigue, shortness of breath, dizziness, or, in more extreme cases, loss of consciousness because the heart is not pumping sufficient blood to the body. Cardiac arrest can result. Bradycardia patients whose hearts cannot sustain a minimum necessary heart beat of 30 beats per minute are regarded as "pacemaker dependent" because they need to have their hearts paced continually by a pacemaker or ICD.

[9] When a cardiac arrest occurs, the lack of blood flow to the brain and other body tissues can result in irreversible brain damage and other organ damage, leading to death. Restoration of a reliable heart rhythm must be accomplished almost immediately to be effective.

[10] ICDs monitor the heart for any abnormal rapid, slow or irregular rhythms. If the heart develops a life-threatening tachycardia, the ICD may immediately deliver an electrical shock,

or may attempt to terminate the rhythm by pacing the heart, and then to deliver an electrical shock to the heart if lower energy therapies fail. The ICD may also be programmed to operate as a pacemaker, so that electrical signals are sent to pace the heart when bradycardia is detected.

[11] A CRT-D can perform the same functions as an ICD. In addition, it can provide what is called cardiac resynchronization therapy or biventricular pacing. In some diseased hearts, some sections of the wall of the heart may be contracting while other or opposite sections are relaxing. This dyssychrony decreases the ability of the heart to pump blood. An ICD typically paces only one side of the heart; a CRT-D stimulates both the left and right ventricles to resynchronize their actions.

[12] According to Medtronic's expert, Dr. Simpson, the average age of patients being considered for an ICD is approximately 65.

[13] At issue in this action are four ICDs, the Marquis VR 7230, Marquis DR 7274, Maximo VR 7232 and Maximo DR 7278, and at least two CRD-Ts[*], the InSync Marquis 7277 and InSync III Marquis 7279, (collectively, the "Defibrillators") designed and manufactured by Medtronic U.S. and distributed in Canada by Medtronic Canada.

[14] The Defibrillators, like all ICDs and CRT-Ds, run on a battery that is sealed inside the device. The batteries have a limited life. Dr. Simpson advises patients who will be receiving an ICD to expect, as a "ball park" that the ICD will last four to seven years. The life of the battery depends on the particular kind of Defibrillator and the use to which it is put.

[15] In early 2003, during routine laboratory testing of machinery that was being qualified to add manufacturing capacity to its production line, Medtronic identified an issue involving potential premature battery depletion for the Chi 4420L battery (the "Battery") used in the Defibrillators. Medtronic's evidence is that, at that time, it had not received any reports from the field of early Battery depletion and had not received any explanted Defibrillators which exhibited the early Battery depletion seen in the laboratory testing. Medtronic says that, at that point, based on its standard post-marketing surveillance, the Defibrillators were performing within all performance parameters.

[16] ICDs and CRT-Ds are medical devices regulated by Health Canada. In the fall of 2003, Medtronic Canada applied for licence amendments from Health Canada to implement design changes to the Battery to address the premature depletion issue identified in its laboratory tests. The amendment application identified that internal shorts in the Battery had been observed under highly accelerated test conditions and that further testing was ongoing to determine the relevance of the test results to field performance.

[17] Medtronic U.S. applied for comparable amendments in the U.S.

[18] Somewhere between February and April, 2004, Medtronic began to receive field reports from the Untied States of premature battery depletion. On or about September 2004, Medtronic Canada became aware of a field return from Canada that exhibited the internal

---

[*] A further two CRD-Ts - the InSync II Marquis 7289 and the InSync III Protect 7285 - may also be at issue. See paragraphs 71 and 74 below.

short. It notified Health Canada of this on October 14, 2004. By December, 2004, Medtronic had received nine field returns of devices with premature battery depletion.

[19] In February of 2005, some two years after the results of its laboratory testing, Medtronic Canada issued a press release and notice to physicians- referred to in these reasons as the "advisory"- advising that Defibrillators having batteries manufactured prior to December 2003 may experience rapid battery depletion due to a specific internal battery short mechanism. The notice provided that, "As part of ongoing returned product analysis, Medtronic has received nine (9) units... (approximately 1 in 10,000) that have exhibited this mechanism…While the current rate is 1 in 10,000 (.001%), bench testing data indicates that this rate may increase to between 0.2% and 1.5% over the second half of the device life."

[20] The notice further stated that devices with batteries manufactured after December 2003 were not affected because specific battery design changes were implemented in December 2003 that eliminated the possibility of this internal shorting mechanism. It explained that, "There is no provocative testing that predicts which of these devices will experience this issue. Once a short occurs, depletion can take place within a few hours to a few days, after which there is complete loss of device function."

[21] The notice suggested various patient management options, and indicated that Medtronic would provide a replacement device at no cost for patients who were pacemaker dependent or received frequent VT/VF therapy.

[22] On March 16, 2005, the United States Food and Drug Administration initiated a regulatory enforcement action against Medtronic U.S., ordering a total Class II recall of the 87,000 affected Defibrillators, and litigation has been commenced against Medtronic U.S. in the United States with respect to the Defibrillators. The applicable U.S. regulation defines a "recall" as, "a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure", and defines "Class II" as, "a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote".

[23] No regulatory action was taken in Canada.

[24] The total number of affected Defibrillators, worldwide, is approximately 87,000. In Canada, 2416 patients had implanted affected Defibrillators as at February 10, 2005. As at June 15, 2007, approximately 613 Defibrillators have been explanted and replaced in Canada.

[25] As at June 15, 2007, 89 of the 87,000 affected Defibrillators have been found by Medtronic, in the course of its returned product analysis, to have the battery shorting mechanism that prompted its field action in February of 2005. Of these 89, five were reported from patients in Canada. It is not known how many of the affected Defibrillators which patients have chosen not to have explanted, and which have therefore not been returned to Medtronic for analysis, have the battery shorting mechanism. To date, there have

been no reported deaths or serious injuries as a result of the battery shorting mechanism in Canada or elsewhere.

[26] In Canada, ICDs and CRT-Ds are purchased by hospitals. The evidence of Medtronic's expert, Dr. Simpson, is that his hospital receives funding in the amount of $32,000 per device from Ontario's Ministry of Health to cover the device, the lab, the nurses and all related health costs. Counsel for Medtronic orally advised that the cost to a hospital of a Defibrillator would be in the area of roughly $25,000.

THE TEST FOR CERTIFICATION

[27] Section 5(1) of the CPA sets out the test for certification:

> The court shall certify a class proceeding on a motion under section 2, 3 or 4 if,
>
> (a) the pleadings or the notice of application discloses a cause of action;
>
> (b) there is an identifiable class of two or more persons that would be represented by the representative plaintiff or defendant;
>
> (c) the claims or defences of the Class members raise common issues;
>
> (d) a class proceeding would be the preferable procedure for the resolution of the common issues; and
>
> (e) there is a representative plaintiff or defendant who,
>
> (i) would fairly and adequately represent the interests of the class;
>
> (ii) has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying Class members of the proceeding; and
>
> (iii) does not have, on the common issues for the class, an interest in conflict with the interests of other Class members.

[28] The plaintiffs must show some basis in fact for each of the certification requirements in section 5(1), other than the requirement in section 5(1)(a) that the pleading discloses a cause of action. See *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158 at para. 25.

THE 5(1)(a) REQUIREMENT: CAUSE OF ACTION, AND THE MOTIONS UNDER RULES 21.01 AND 25.11

[29] Rule 21.01(b) provides that a party may move to strike out a pleading on the ground that it discloses no reasonable cause of action. The test under Rule 21.01(b) is the same as the test under section 5(1) (a), and I therefore consider them together.

[30] In determining whether the pleading discloses a cause of action, no evidence is admissible. The pleading will be struck out only if it is plain, obvious and beyond a reasonable doubt that the plaintiff cannot succeed. See *Hollick* at para. 25 and *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 at para. 41 (C.A.). The material facts pleaded must be accepted as true, unless patently ridiculous or incapable of proof.

[31] Rule 25.11 provides that the court may strike out or expunge all or part of a pleading, with or without leave to amend, on the ground that the pleading may prejudice or delay the fair trial of the action; is scandalous, frivolous or vexatious; or is an abuse of the process of the court.

[32] As indicated above, the representative plaintiffs advance claims in negligence and conspiracy and, in the alternative, seek the remedy of disgorgement based on waiver of tort, and the family law representative plaintiffs make derivative claims for damages under the *Family Law Act*, R.S.O. 1990 c. F-3 ("FLA") and similar legislation of other provinces.

[33] I am satisfied, and Medtronic concedes, that the representative plaintiffs have pleaded the elements, and the material facts, necessary to make out a claim in negligence.

[34] Medtronic argues, however, that the plaintiffs' claim in conspiracy should be struck because the claim is duplicitous, and baldly pleaded. Medtronic concedes that I am bound by the Divisional Court's decision in *Serhan Estate v. Johnson & Johnson* (2004), 72 O.R. (3d) 296 (S.C.J.) aff'd (2006), 85 O.R. (3d) 665 (Div. Ct.), leave to appeal to C.A. ref'd without reasons, leave to appeal to S.C.C. ref'd, [2006] S.C.C.A. No. 494, that a claim based on waiver of tort giving rise to the remedy of disgorgement and an accounting is not certain to fail. However, it argues that in this case the plaintiffs have failed to plead material facts that would support a remedy based on waiver of tort, and that waiver of tort is not available where, as in this case, the Ontario Health Insurance Plan and other provincial health insurers have subrogated interests, and derivative claims are advanced under the FLA and similar provincial legislation.

The Conspiracy Claim

[35] I will first address the plaintiffs' claim in conspiracy.

[36] The following elements must be pleaded to make out a conspiracy under the second prong of the test for conspiracy in *Canada Cement Lafarge Ltd. v. British Columbia Lightweight Aggregate Ltd.*, [1983] 1 S.C.R. 452: the defendants acted in combination; their conduct was unlawful and directed towards the plaintiffs (alone or together with others); they should have known in the circumstances that injury to the plaintiffs was likely to occur; and the plaintiffs suffered actual damages.

[37] In the course of the hearing, the plaintiffs sought leave to amend their pleadings to, among other things, specify that the unlawful conduct relied on is alleged breaches of the *Food and Drugs Act,* R.S. 1985, c. F-27 ("FDA") and the *Medical Devices Regulations,* SOR/98-282 ("Regulations"), and applicable U.S. legislation and regulations, and not the alleged negligence of the defendants. While consenting to other amendments that the plaintiffs sought to make, Medtronic opposed this change. I am permitting the amendment. The plaintiffs had pointed to the alleged failure of Medtronic to make timely disclosure to the regulators in support of their negligence claim and Medtronic did not seek an adjournment of the certification motion if the amendment was permitted. I am satisfied there is no prejudice to Medtronic arising from the amendment that cannot be compensated for in the disposition of costs arising out of this motion. I proceed, therefore, on the basis that the alleged wrongful conduct is the breaches of the FDA and the Regulations.

[38] Medtronic argues that while a claim in conspiracy, relying on negligence as the unlawful conduct, is clearly duplicitous of claims in negligence advanced against both alleged conspirators, a claim based on breach of the FDA and the Regulations also adds nothing, is duplicitous, and should be struck, because, as noted above, the plaintiffs will point to the alleged breaches of the FDA and the Regulations in advancing their claims in negligence. Medtronic argues that the plaintiffs are pleading conspiracy merely to broaden the ambit of discovery, and, based on *Elliott v. Canadian Broadcasting Corp.* (1993), 108 D.L.R. (4th) 385 (Gen. Div.), aff'd (1995), 125 D.L.R. (4th) 534 (Ont. C.A.), leave to appeal to S.C.C. ref'd, [1995] S.C.C.A. No. 393, the claim should be struck.

[39] In response, the plaintiffs refer me to *Dionisio v. Lucas*, [2006] O.J. No. 1212 (S.C.J.). In that case, the plaintiffs pleaded both the tort of deceit and conspiracy consisting of an agreement to commit the tort of deceit. Justice Ground, citing *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959, at paras. 53 and 54, held that the doctrine of merger did not require him to strike the conspiracy claim on that basis; the conspiracy claim would merge only if the plaintiffs succeeded at trial in establishing the tort of deceit. He struck the claim for conspiracy on another basis.

[40] In *Elliot v. Canadian Broadcasting Corporation,* both defamation and conspiracy, based on the defamation, were pleaded. Montgomery J. struck the claim in defamation. He held at page pages 398-399, "If the plaintiffs' claim for defamation cannot be sustained, neither can the conspiracy because there was no unlawful means." Accordingly, he struck the claim in conspiracy. While not the basis for his decision, he purported to distinguish *Hunt v. Carey Canada* on the basis that in that case the unlawful means differed from the tort, and stated that the doctrine of merger would also have resulted in the conspiracy claim failing: the defendants had planned to do something and they had done it, thereby allegedly committing the tort of defamation. The issue on appeal was whether the claim in defamation should have been struck. The merger argument was not addressed.

[41] It appears to me that *Hunt v. Carey Canada* is applicable, and that if the unlawful conduct in this case was the same as the alleged tort of negligence, the doctrine of merger would not result in the claim in conspiracy being struck at this juncture. In any event, in this case, the alleged breach of the FDA and the Regulations is only one thing that the plaintiffs rely on to found their claim in negligence. The scope of the alleged negligence and the alleged unlawful conduct founding the claim in conspiracy are not the same. Possibly, the

plaintiffs could proceed in conspiracy based on breach of the FDA and the Regulations alone. In the result, I do not strike the claim in conspiracy because it is duplicitous. In the circumstances, I am not satisfied that the conspiracy claim will delay the fair trial of the action, is scandalous, frivolous or vexatious or is an abuse of process of the court.

[42] Medtronic also argues that the conspiracy claim should be struck because the plaintiffs have failed to plead the tort of conspiracy with the degree of particularity required by *Westjet Airlines Ltd. v. Air Canada*, [2005] O.J. No. 2310 (S.C.J.), at paras. 28 and 29, and *Normart Management Limited v. West Hill Redevelopment Company Limited et al.* (1998), 37 O.R. (3d) 97 (C.A.).

[43] In *Normart*, at 104, the Court of Appeal held that when the tort of conspiracy is pleaded, the statement of claim should: describe who the parties are and their relationship to each other; allege the agreement between the defendants to conspire; state precisely what the purpose or what the objects of the alleged conspiracy were; set forth with clarity and precision the overt acts which are alleged to have been done by each of the alleged conspirators in pursuance and in furtherance of the conspiracy; and allege the injury caused to the plaintiffs.

[44] As to the parties to the conspiracy and their relationship with one another, the plaintiffs plead, at para. 64 of the draft Second Fresh as Amended Statement of Claim filed with me during the course of the hearing, Medtronic U.S. and Medtronic Canada, by their directors, officers, servants and agents, conspired and agreed together. At para. 25, the plaintiffs plead that Medtronic Canada is a division of Medtronic U.S. (In filing the Second Fresh as Amended Statement of Claim, this is to be revised to reflect a parent-subsidiary relationship.) The objects of the conspiracy are also pleaded at para. 64: to submit false, inaccurate, incomplete and misleading information to Health Canada and the FDA and to conceal the defects in the Defibrillators. The purposes of the conspiracy are set forth at para. 65. They include increasing or maintaining profits. The acts allegedly done in furtherance of the conspiracy are set forth in general terms in para. 66. For example, the plaintiffs plead that the defendants concealed adverse information regarding the testing and safety of the Defibrillators from the FDA. At paras. 67 to 69, the plaintiffs plead that the defendants breached the FDA and Regulations and other legislation in doing so. At para. 70, the plaintiffs plead that the conduct was directed toward the plaintiffs and the other Class members, that the defendants knew that Class members would be implanted with Defibrillators, and that the conspiracy would and did cause damages. Damages are pleaded at para. 72.

[45] The draft Second Fresh As Amended Statement of Claim does not set out with any degree of precision the overt acts undertaken by the alleged conspirators. From the evidence filed on this motion, it appears that the claim can be amended to do so. In the result, the claim in conspiracy is struck, with leave to amend to plead the overt acts taken by the conspirators with the requisite degree of particularity. In the balance of these reasons, I will proceed on the assumption that the claim in conspiracy will be amended to add the requisite particulars.

Waiver of Tort

[46] As Cullity J., the motions judge in *Heward v. Eli Lilly & Co*. (2006), 39 C.P.C. (6th) 153 (Ont. S.C.J.) at para. 24 (leave to appeal allowed by Lederman J. at [2007] O.J. No. 2709 (S.C.J.)), explains under the doctrine of waiver of tort, "in certain circumstances when tortious acts have been committed by a defendant, the person affected will be permitted to elect between the remedy of compensatory damages and an accounting for a disgorgement of profits. The tort is not waived in any meaningful sense as it provides the basis for whichever of the two remedies is chosen."

[47] The Divisional Court in *Serhan* concluded that the law is uncertain both as to whether waiver of tort is an independent cause of action or only a choice of remedy after an actionable wrong has been established, and as to when the remedy of an accounting and disgorgement of profits is available. It is possible that waiver of tort does not require proof of loss or damage. In light of this, the Divisional Court held that a claim for disgorgement of profits for wrongful conduct (in that case, the tort of conspiracy) was not certain to fail.

[48] Counsel for Medtronic pointed to para. 66 of the Divisional Court's decision in *Serhan* as support for its argument that waiver of tort is not available where the alleged wrongful conduct is negligence.

[49] Cullity J., the motions judge in *Serhan*, at para. 63 of (2004), 72 O.R. (3d) 296 (S.C.J.), found that, to the extent that proof of loss may not be required for the purpose of an accounting based on principles governing waiver of tort, the allegations of conspiracy by an unlawful act could provide a basis for such a claim. Allegations of negligence, and breach of duty to warn, were also advanced in *Serhan.* In that case, Cullity J. did not point to those allegations as a basis for a claim in waiver of tort.

[50] At para. 66 of the Divisional Court's reasons in *Serhan,* Epstein J. (as she then was) distinguished the recent decision of the British Columbia Supreme Court in *Reid v. Ford Motor Co.,* [2006] B.C.J. No. 993 (QL), 149 A.C.W.S. (3d) 804, dismissing a claim for waiver of tort. Justice Epstein wrote that several factors distinguished *Reid,* not the least of which was that the claim in *Reid* was framed in negligence, unlike in *Serhan,* where claims in fraud and conspiracy, in addition to negligence, were advanced.

[51] However, at para. 109 of *Serhan*, Epstein J. quotes John McCamus who, in relation to disgorgement relief, says, "the scope or ambit of the doctrine in terms of the list of torts for which disgorgement claims are possible remains a matter of some uncertainty." Justice Epstein then writes, "I agree". From this I take that, contrary to what seems to have been suggested by para. 66, *Serhan* holds that a claim based on waiver of tort, for disgorgement of profits, arising out of negligence, is not certain to fail. (I review this point because of my decision to strike the conspiracy claim in this action, with leave to amend. While confident that the amendment will be effected, there will be a lacuna while the amendment is underway.)

[52] Subsequently, Cullity J. came to the same conclusion in *Heward v. Eli Lilly.* In that case, decided after *Serhan,* the only tort relied upon by the plaintiffs was negligence. The plaintiffs alleged that the drug, Zyprexa, manufactured by the defendant gave rise to a

significantly increased risk of diabetes and similar complications. Cullity J. concluded that a deliberate breach of a duty of care was not a precondition to a disgorgement remedy and the plaintiffs' claim to the disgorgement remedy was not bound to fail. While leave to appeal this decision to Divisional Court was granted, leave was not granted on this issue.

[53] Counsel for Medtronic also argues that the plaintiffs have not adequately pleaded what wrongful conduct they rely on to found their claim for a remedy based on waiver of tort. Paragraph 75 of the draft Second Fresh As Amended Statement of Claim reads, "As a result of the conduct described herein, the Plaintiffs reserve to themselves the right to elect at the trial of the common issues to waive the torts of negligence and/or conspiracy and to have damages assessed in an amount equal to the gross revenue received by the Defendants, or alternatively, the net income received by the Defendants, or a percent of the sale of the Defibrillators." In the course of the hearing, counsel for the plaintiffs provided particulars as to the specific paragraphs of the pleading intended to be covered by that reference (namely paras. 6, 34, 58, 59, 63(d), 65, 71 and 74 of the draft Second Fresh As Amended Statement of Claim). When filed, the Second Fresh As Amended Statement of Claim shall be amended to reflect that the conduct at issue is the conduct described in those paragraphs. If inadequately pleaded now, I am satisfied that the wrongful conduct relied on will be adequately pleaded.

[54] Medtronic's final argument is that a waiver of tort claim cannot be maintained where there are subrogated interests or family law claims.

[55] I will deal first with the subrogated interests.

[56] Section 30(1) of the Ontario *Health Insurance Act*, R.S.O. 1990, c. H.6, provides that, where, as the result of the negligence or other wrongful act or omission of another, an insured person suffers personal injuries for which he or she receives insured services under the Act, the Plan ("OHIP") is subrogated to any right of the insured person to recover the cost incurred for past insured services and the cost that will probably be incurred for future insured services. Section 31(1) requires any person commencing an action to recover for loss or damages to include a claim on behalf of OHIP for the cost of the insured services. Section 33 provides that the trial judge shall, if possible, designate the portion of the injured person's damages that is in respect of insured costs, and section 34 provides that no release or settlement of a claim for damages for personal injuries where the injured person received insured services under the Act is binding on OHIP unless approved by OHIP's General Manager.

[57] The plaintiffs have asserted a claim on behalf of OHIP and other provincial plans.

[58] Medtronic argues that electing waiver of tort would be inconsistent with the statutory obligation of insured persons to pursue a claim for damages. It would, Medtronic argues, be tantamount to a waiver or release of the health insurers' subrogated claims, and, as indicated above, under the *Health Insurance Act*, OHIP's consent is required for a release.

[59] In my view, it is not plain and obvious that the plaintiffs' claim in waiver of tort cannot succeed because subrogated claims are advanced. Indeed, whether the consent of OHIP and other provincial insurers is a precondition to an election of waiver of tort, or whether the provincial insurers are simply entitled, on a proper interpretation of the *Health*

Insurance Act, to a portion of any disgorgement, appear to be common issues, may have been viewed as such in *Serhan* , and were viewed as such in *Heward v. Eli Lilly.*

[60] In *Serhan*, defective products used by diabetics to monitor their blood glucose levels were at issue. Cullity J. commented, at para. 16, that the devices were paid for by the Ontario Drug Benefit Program and, as noted by Epstein J. at para. 124 of the Divisional Court's reasons, included as a common issue, "for whose benefit is such an accounting to be made?" Epstein J. concluded," Questions of...to whom or what entities the assets in issue may be directed need to be developed on the basis of a full factual record."

[61] In *Heward v. Eli Lilly*, Cullity J., at para. 101, specifically expanded the common issue regarding the defendants' liability to account to include the provincial insurers who have subrogated claims. Leave was not given to appeal this aspect of the decision.

[62] In this case, the proposed common issue with respect to waiver of tort (set out below under my consideration of the common issue requirement) similarly asks whether, if the Class members can elect to have damages determined through an accounting and disgorgement of proceeds, for whose benefit is such accounting to be made. I take this to address the interests of the provincial health insurers. As suggested in *Heward v. Eli Lilly*, a more specific reference would be helpful.

[63] Family law claims, like the claims of the health insurers, are statute based.

[64] Section 61 of the Ontario *Family Law Act*, R.S.O. 1990, c. F.3 ("FLA") provides that if a person is injured or killed by the fault or neglect of another under circumstances *where the person is entitled to recover damages*, or would have been entitled if not killed, certain family members are entitled to recover their pecuniary loss resulting from the injury or death from the person from whom the person injured or killed is entitled to recover, or would have been entitled if not killed. The damages recoverable include an amount to compensate for the loss of guidance, care and companionship.

[65] Medtronic argues that if the plaintiffs elected to proceed by waiver of tort and obtain an accounting and disgorgement of revenues, they would not be "entitled to recover damages" within the meaning of the FLA, and FLA claimants would as a result be precluded from recovering damages. Therefore, Medtronic says, the claim in waiver of tort must be struck.

[66] In *Heward v. Eli Lilly*, FLA claims were advanced, and the claim in waiver of tort was not struck. Moreover, the FLA, unlike the *Health Insurance Act*, does not require a person claiming damages to advance a claim on behalf of family members, or restrict the ability of such persons to release or settle claims for damages without the consent of the family members. It is not plain and obvious to me that the waiver of tort claim cannot succeed because FLA claims are advanced. The argument that Medtronic advances can be determined at the common issues trial as part of proposed common issue (6), namely whether the Class can elect to have damages determined through an accounting and disgorgement of the proceeds of sale of the Defibrillators.

[67] For the above reasons, I conclude that the requirement in section 5(1)(a) is satisfied with respect to the causes of action in negligence and the claim for an accounting and disgorgement based on waiver of tort, and will be satisfied with respect to the cause of action of conspiracy, subject to the further amendments to the draft Second Fresh As Amended Statement of Claim contemplated above.

THE 5(1)(b) REQUIREMENT: AN IDENTIFIABLE CLASS

[68] Class definition is important because it identifies persons who are entitled to notice and relief, if awarded, and who will be bound by any judgment or settlement if they do not opt out.

[69] The class must be defined by reference to objective criteria, without reference to the merits of the action. There must be some rational relationship between the class and the common issues. The plaintiff has an obligation, although not an onerous one, to show that the class is not unnecessarily broad, in the sense that it could not be defined more narrowly without arbitrarily excluding some people who share the same interest in the resolution of the common issues. (*Hollick* at paras. 17, 20-21, and *Cloud* at para. 45.)

> 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.
>
> (*Hollick* at para. 21.)

[70] During the course of the hearing, the plaintiffs refined the definition of the primary class they seek to represent. As at the close of the hearing, they proposed the following two class definitions:

[71] "Class" or "Class Members" means all persons implanted in Canada with one of the Defibrillators listed below, containing a Chi 4420L battery manufactured prior to December 31, 2003:

Marquis VR 7230
Marquis DR 7274
Maximo VR 7232
Maximo DR 7278
InSync Marquis 7277
InSync II Marquis 7289
InSync III Marquis 7279
InSync III Protect 7285

[72] "Family Class" or "Family Law Claimants" means all family members who are entitled to assert a claim pursuant to the *Family Law Act* and related provincial and territorial legislation with respect to the following:

> (i) actual expenses reasonably incurred for the benefit of members of the Class;

(ii) traveling expenses incurred while visiting members of the Class during treatment or recover;

(iii) loss of income or the value of services provided for members of the Class where services, including nursing and housekeeping, have been provided; and

(iv) compensation for loss of support, guidance, care and companionship that they might reasonably be expected to receive from the members of the Class.

Medtronic does not challenge the definition of the Family Class, and I am satisfied that it meets the requirements of section 5(1)(b).

[73] Medtronic concedes that the plaintiffs have defined the Class by reference to objective criteria, but argues that the definition is overly broad, for four reasons. I deal with them in turn.

[74] First, the uncontroverted evidence of Medtronic is that the InSync II Marquis 7289 and InSync III Protect 7285 Defibrillators were never commercially sold or distributed in Canada. Therefore, it submits, they should be deleted from the Class definition. The plaintiffs argue, in response, that the Class definition is in respect of Defibrillators *implanted* in Canada, not Defibrillators commercially sold or distributed in Canada. The plaintiffs do not object to narrowing the definition to exclude these two devices, subject to the provision of evidence by Medtronic confirming that none of these devices were implanted in Canada. Determination of this issue is deferred, pending receipt of written submissions from the parties as to how a device not commercially sold or distributed in Canada could be implanted in Canada.

[75] Second, Medtronic says the Class should be defined by reference to batteries manufactured prior to December 2003, as opposed to prior to December 31, 2003. Given that the advisory sent out by Medtronic in February of 2005, on which doctors might have acted, is internally inconsistent, indicating both that only batteries manufactured prior to December 2003 potentially have the shorting problem, and that batteries manufactured after December 2003 were not affected, I have concluded that there is at this juncture some basis in fact for defining the Class by reference to the December 31 date. That being said, and as counsel for the plaintiffs acknowledge, it would be clearly distressing to patients who were not affected by the recall to be sent a certification notice. Accordingly, if Medtronic is able to provide evidence satisfactory to the plaintiffs that physicians were at the time made aware that only batteries manufactured prior to December 2003 potentially had the shorting problem, the Class definition will be further constrained.

[76] Third, Medtronic says that the Class definition is overly broad because it may include people who have not suffered damages. It urges me to qualify the definition of the Class by the requirement that persons must have suffered damages as a result of being implanted with such a Defibrillator. Medtronic submits that: patients whose Defibrillators were not explanted will only be able to argue that they suffered emotional distress; pursuant to *Vanek v. Great Atlantic & Pacific Co. of Canada* (1999), 48 O.R. (3d) 228 (C.A.), a plaintiff can only

recover for emotional distress that was both foreseeable and so serious that it resulted in a recognizable psychiatric illness; there is at this juncture no evidence that any of the Class members whose Defibrillators were not explanted suffers from a recognizable psychiatric illness as a result of worry about the Defibrillators; and the Class should accordingly be restricted to patients who have had their Defibrillators explanted.

[77] I am not satisfied that the Class definition is overly broad because it does not exclude patients who did not have their Defibrillators explanted and therefore includes patients who may not have suffered damages. As noted by Cullity J. in *Taylor v. Canada (Minister of Health)*, [2007] O.J. No. 3312 (S.C.J.), at para. 61, the possibility that some Class members will be unable to prove damages almost invariably exists. The statement of claim alleges that Class members have, among other things, incurred costs associated with monitoring the Defibrillators. Medtronic's February 2005 notice recommended quarterly follow-up procedures as a patient management option. The Canadian Heart Society's Medtronic Marquis Advisory dated February 21, 2005 also recommended, "more intensive follow-up with 3-month clinic visits" to reduce risk to patients. Medtronic's materials in support of the sealing order it sought in connection with this motion make clear that medical expertise in this area is concentrated in a few centres. It follows that at least some patients may have incurred or will incur additional travel expenses in connection with these more frequent visits. If Medtronic was found liable for negligent design, patients who did not have their Defibrillators explanted may be able to prove damages, even if they cannot prove that they suffered a foreseeable and recognizable psychiatric illness as a result of the battery problem.

[78] Fourth, Medtronic argues that there is not a rational relationship between the proposed Class definition and the proposed common issues in relation to the claims in conspiracy and waiver of tort, and that smaller subclasses should be created in relation to those claims, if they are permitted to proceed as a class proceeding.

[79] As discussed above, the alleged conspiracy, and the alleged wrongful conduct on which the claim in waiver of tort is founded, is that Medtronic suppressed the knowledge it acquired in early 2003 regarding potential premature battery depletion until February of 2005. Medtronic argues that Class members who had Defibrillators implanted prior to 2003 could not suffer damages as a result of the alleged conspiracy, or point to wrongful conduct as a basis for claim for waiver of tort. There is no evidence of anyone dying or suffering any physical illness as a result of the battery problem prior to the February 2005 announcement and, as the announcement had not been made, there could be no claims for emotional distress for worry or for expenses associated with additional monitoring.

[80] It is not clear to me that, if it was established that Medtronic's failure to publicly disclose the potential premature battery depletion amounted to wrongful conduct sufficient to found a claim in waiver of tort, patients, such as those who are pacemaker dependent or at risk for VT or VF, who were put at risk by that conduct, but did not suffer damages as a result of the conduct, would be foreclosed from pursuing a claim in waiver of tort. Accordingly, I am not convinced that a "waiver of tort" subclass needs to be created at this stage. It is of course open to the common issues judge to do so, if he or she thinks necessary.

[81] On the other hand, damages are an element of the tort of conspiracy and it would appear that Class members who had Defibrillators implanted prior to 2003 would not be able

to prove damages as a result of the conspiracy. If the plaintiffs are not successful on the common issues relating to negligence at the common issues trial, and it is necessary to create a conspiracy subclass at that time, the common issues judge can do so.

[82] In the result, I am satisfied that, subject to the possible elimination of the reference to the InSync II Marquis 7289 and the InSync III Protect 7285 following the receipt of supplemental written submissions from the parties, the Class definition is not overly broad and the requirement of section 5(1)(b) of the CPA has been met.

THE 5(1)(c) REQUIREMENT: COMMON ISSUES

[83] Section 1 of the CPA defines common issues:

> "common issues" means,
>
> (a) common but not necessarily identical issues of fact, or
>
> (b) common but not necessarily identical issues of law that arise from common but not necessarily *identical facts*[.]
>
> [emphasis added]

[84] *Hollick* at para. 18, explains the test to be applied:

> As I wrote in *Western Canadian Shopping Centres*, the underlying question is 'whether allowing the suit to proceed as a representative one will avoid duplication of fact finding or legal analysis'. Thus an issue will be common 'only where its resolution is necessary to the resolution of each Class member's claim' (para. 39). Further, an issue will not be 'common' in the requisite sense unless the issue is a 'substantial…ingredient' of each of the Class member's [*sic*] claims.

[85] As *Cloud* notes, at para. 52, this is a low bar. At para. 53, *Cloud* explains *Hollick*:

> In other words, an issue can constitute a substantial ingredient of the claims and satisfy s. 5(1)(c) even if it makes up a very limited aspect of the liability question and even though many individual issues remain to be decided after its resolution. In such a case the task posed by s. 5(1)(c) is to test whether there are aspects of the case that meet the commonality requirement rather than to elucidate the various individual issues which may remain after the common trial.

[86] As *Cloud* explains, at para. 65, the comparative extent of individual issues is a factor in assessing whether a class proceeding is the preferable procedure, not in considering whether the common issues requirement has been met.

[87] The plaintiffs propose the following nine common issues, which reflect various refinements made during the course of the hearing:

(1) Did the Defendants, or either of them, owe a duty of care to the Class in respect of the design, development, testing, manufacturing, licensing, assembling, distribution and sale of the Defibrillators?

(2) If so, did the Defendants, or either of them, breach such duty? If so, what was the nature of the breach?

(3) Did the Defendants, or either of them, owe a duty to the Class to warn of the potential battery shorting defect associated with the Defibrillators, and if so, when did such duty arise?

(4) If so, did the Defendants, or either of them, fail to warn the Class of the existence of the potential battery shoring defect associated with the Defibrillators?

(5) Did Metronic, Inc. and Medtronic Canada Inc. conspire one with the other to conceal information relating to the potential battery shorting defect associated with the Defibrillators in violation of the FDA and the Regulations? If so, what was the nature and purpose of the conspiracy?

(6) Can the Class elect to have damages determined through an accounting and disgorgement of the proceeds of the sale of the Defibrillators implanted in Class Members? If so, in what amount and for whose benefit is such accounting to be made?

(7) Should one or both of the Defendants pay punitive damages to the Class?

(8) Should one or both of the Defendants pay the costs of administering and distributing any recovery? If so, in what amount?

(9) Should one or both of the Defendants be ordered to pay prejudgment interest? If so, who should pay, and at what annual rate? Should the payment be simple or compound interest? How is the prejudgment interest to be calculated?

[88] Medtronic raises three objections with respect to the proposed common issues, two with respect to common issue (6), disgorgement, and one with respect to common issues (7), punitive damages.

[89] I am satisfied that the remaining proposed common issues are common issues, although, as discussed below, common issue (5) should be rephrased. These common issues will avoid duplication of fact finding and legal analysis and are necessary to the resolution of Class members' claims.

[90] Counsel for the plaintiffs clarified that the use of "conspire" in common issue (5) is intended to import all of the elements of the second prong of the test for conspiracy in *Canada Cement Lafarge*, except the requirement that the plaintiffs have suffered actual

damage. Actual damage is conceded by the plaintiffs to be an individual issue. Common issue (5) should be revised to reflect this.

[91] I will address Medtronic's three objections in turn.

[92] First, Medtronic argues that the first part of proposed common issue (6), electing disgorgement, is not a common issue because not every Class member will have the same interest in electing disgorgement. For example, a pacemaker dependent Class member, or a Class member who experiences frequent VT/VF episodes, who had her Defibrillator implanted after the issue of premature battery depletion was identified in early 2003, and before the public advisory in February 2005, and subsequently had her Defibrillator explanted, and experienced complications, resulting among other things in time off work, may have an interest in pursuing compensatory and punitive damages, rather than electing waiver of tort. On the other hand, a Class member who is neither pacemaker dependent nor at risk of VT/VF episodes, had her Defibrillator implanted before the premature battery depletion issue was identified, and has not had it explanted, may not have sustained damages and may therefore have an interest in electing disgorgement, if that remedy is indeed found to be available in response to the conduct at issue where no loss is sustained.

[93] Moreover, Medtronic argues, a Class member who can prove actual loss would be better served in not electing to pursue a claim in waiver of tort because doing so will result in delayed recovery. It points to the evidence that the average age of patients implanted with ICDs is 65. It submits that it may be simpler for an individual Class member to prove individual damages than to await the accounting. If the uncertainty surrounding the doctrine of waiver of tort has not been finally resolved by the courts, it is virtually certain that a decision by a common issues judge that the Class can elect, on waiver of tort principles, to have damages determined through an accounting and disgorgement of proceeds would be appealed, resulting in lengthy legal proceedings.

[94] The heart of Medtronic's objection is that there is a possible conflict between Class members on the issue of whether an election should be made, if an election can be made.

[95] As noted in *Western Canadian Shopping Centres v. Dutton* (2001), 201 D.L.R. (4th) 385, [2001] 2 S.C.R. 534 (S.C.C.) at paras. 39 and 40, for an issue to be "common", it is not essential that the Class members be identically situated vis-à-vis the opposing party or benefit from the successful prosecution of the action to the same extent. A class action should not, however, be allowed if Class members have conflicting interests.

[96] The plaintiffs contemplate that an election would be made by the representative plaintiffs with respect to all Class members, as opposed to elections on a member by member basis, and an aggregate award made in favour of Class members in an amount representing Medtronic's income from the sale of the Defibrillators. The plaintiffs do not provide details in their litigation plan as to how they propose such an aggregate award be allocated among the various Class members. Presumably, a process could be crafted, under the supervision of the Court, which would fairly take into account the individual circumstances of Class members. Individual claims might, for example, be required. Accordingly, I do not view the fact that different Class members would be entitled to different compensatory damages as fatal.

[97] That leaves the issue of whether it is in the best interests of a Class member who can prove actual damages to pursue a remedy based on waiver of tort, given the virtual certainty of appeals and delay, or whether Class members have conflicting interests.

[98] Whether or not a remedy based on waiver of tort is asserted, appeals and delay are likely if this matter proceeds to a common issues trial. If the remedy of disgorgement is available in the absence of proof of loss, it may be less costly for Class members who are in a position to prove actual loss to share in an aggregate award based on disgorgement, rather than proving loss on an individual basis. Moreover, if the common issues judge determines that all or a portion of the class is entitled to elect to have damages determined through an accounting and disgorgement of profits, a process could be established that would have regard to the possibly varying interests of Class members to determine whether or not the election should be made, and if so, with respect to which parts of the Class.

[99] Viewed differently, Medtronic's objection could be seen to be that the issue of law-entitlement to the remedy of disgorgement, as opposed to whether, if entitled, the election should be made- may not arise from common facts, because some of the Class members may not have suffered any loss, whereas others have. Whether or not there will be a conflict on the issue of entitlement will depend in part on what the law in relation to waiver of tort, and entitlement to the remedy of disgorgement, is found to be at the common issues trial, if the law is not clarified before that time. The factual differences pointed to by Medtronic may or may not prove to be material in relation to the entitlement to the remedy. If these factual differences prove material to the issue of entitlement, subclasses could be created by the common issues judge. Accordingly, common issue (6) should be rephrased so that, rather than reading, "Can the Class elect to ….", it reads, "Can all or part of the Class elect to….", and to add the related question, "If part, but not all, of the Class can so elect, which part or parts of the Class can so elect?"

[100] Medtronic's second objection is to the inclusion of the determination of the amount of the disgorgement as part of common issue (6). It is on this issue that Lederman J. granted leave to the defendants to appeal Cullity J.'s decision in *Heward v. Eli Lilly* to Divisional Court. Lederman J. writes, at paras. 26 and 29:

> ¶26 While *Serhan* says entitlement to a remedy in waiver of tort may not require proof of loss, *Serhan* does not change the requirement that there be proof of a "wrongful gain" that will be subject to disgorgement or a constructive trust. Generally speaking, a gain is a "wrongful gain" only if it is attained through wrongful conduct; i.e. the wrongful conduct must cause the gain. Consequently, for the amount subject to disgorgement and constructive trust to be a common issue in the class action, the pleading and evidence must demonstrate a way to prove on a class-wide basis that the alleged wrongful conduct (*i.e.* "the failure to warn") caused the gain (*i.e.* "proceeds from Zyprexa sales").
>
> ¶29 To say with any confidence that Eli Lilly would not have derived proceeds from the sale of Zyprexa (the "gain") but for

> its failure to sufficiently warn of its side-effects (the "wrongful conduct"), the pleadings or evidence must, at the very least, support one of the following inferences: (1) the Class members would not have agreed to take Zyprexa if properly warned of the risks associated with the drug, or (2) Zyprexa would not have been approved for sale if Health Canada was properly warned of the risks associated with the drug. Absent these inferences, it seems the only way to determine the amount for which the defendants could be ordered to account in waiver of tort is to investigate whether each member of the class would not have taken Zyprexa if properly warned. This is the antithesis of a common issue.
> [emphasis original]

[101] In his reasons, Cullity J. found that the necessary causal link between the wrong and the amount claimed would be established if the plaintiffs could prove their claim that the defendants were negligent in placing Zyprexa on the market, or in continuing to market it after the date on which they first became aware of the alleged side effects. He concluded that if this was found, the defendants would not have derived any proceeds but for their breach of duty and, in this sense, the proceeds would have resulted from the wrong.

[102] The plaintiffs counter that the amount of the disgorgement was found to be a common issue in *Serhan*, and that, as Lederman J. carefully noted in granting leave to appeal in *Heward v. Eli Lilly*, while he had good reason to doubt the correctness of Cullity J.'s decision that the amount of disgorgement was a common issue, that does not mean that Cullity J.'s decision is wrong, or even probably wrong.

[103] Given the uncertainty that surrounds the issues of waiver of tort, and entitlement to disgorgement, and the approach adopted by the Divisional Court in *Serhan*, I believe that Cullity J.'s somewhat looser approach was probably the correct one at this stage, and that there is some basis in fact for concluding that the requisite causal link is similarly present in this case. In any event, in this case each of the plaintiffs has filed affidavit evidence to the effect that she or he would not have had a Defibrillator implanted if aware of the battery problem, and while there is no evidence that Health Canada has taken any action with respect to the Defibrillators, there is evidence of a recall by the regulators in the United States.

[104] As alluded to in my consideration of the identifiable class requirement, it is open to the common issues judge to create a "waiver of tort" subclass, or even subclasses, crafted with regard to his or her findings as to the boundaries of the doctrine of waiver of tort and remedy of disgorgement, including the requisite causal link.

[105] Medtronic's third, and final, objection is in relation to proposed common issue (7), punitive damages. It seeks to clarify that this issue speaks only to prima facie entitlement, and not to quantum. Medtronic directs me to *Boulanger v. Johnson & Johnson Corp.*, [2007] O.J. No. 179 (S.C.J.), at para.48 and Cullity J.'s decision in *Heward v. Eli Lilly*, at paras. 97 and 98, both of which contemplated that the punitive damages inquiry would be bifurcated between a preliminary consideration of the defendants' conduct and

entitlement, and a subsequent and final determination of liability for, and quantum of, punitive damages after an assessment of the compensatory damages. I accept Medtronic's submissions in this regard; in my view, as phrased, common issue (7) does no more than speak to entitlement. Common issue (7) would also include a determination, under the rubric of entitlement, of whether punitive damages can be awarded if the plaintiffs have elected disgorgement.

[106] As noted in my consideration of the section 5(1)(a) requirement, common issue (6) should be revised to more clearly address the interests of the provincial health insurers and to ask whether a Class member can elect to proceed by waiver of tort when family members advance FLA claims.

[107] In the result, subject to the various changes noted above, I accept all of the proposed common issues as common issues.

5(1)(d): PREFERABLE PROCEDURE

> [T]he preferability requirement has two concepts at its core. The first is whether or not the class action would be a fair, efficient and manageable method of advancing the claim. The second is whether the class action would be preferable to other reasonably available means of resolving the claims of Class members.
>
> (*Cloud* at para. 73)

[108] The question of preferability takes into account the importance of the common issues in relation to the claims as a whole. *Hollick* at para. 30.

[109] The analysis of the preferable procedure, "should be conducted through the demands of the three principal advantages of class actions - judicial economy, access to justice, and behavior modification…" *Hollick* at para. 27.

[110] It is conceded that in this case compensatory damages, and causation, in relation to compensatory damages, are individual issues.

[111] Medtronic argues that a class proceeding is not the preferable procedure because the individual issues that would need to be proved to establish causation and loss are so numerous and significant in relation to the common issues. It says that "mini-trials" would be needed to determine these issues. It argues that this case is not really a "mass tort"; only five Defibrillators implanted in Canada have been found by Medtronic to have the Battery defect at issue. I infer from this that Medtronic's position is that it would be preferable for the affected persons to proceed by way of individual action. Finally, it argues that if I am inclined to certify this action, I should do so with respect to the claims for negligence and punitive damages only. It submits that including the waiver of tort and conspiracy claims would result in complications and delays, and that given the age of the Class members, delay would not be consistent with the objective of access to justice and the inclusion of these claims would therefore result in the class proceeding not being the preferable procedure.

[112] I will deal first with the individual issues. Medtronic lists some 21 alleged individual issues in its factum which it says relate to causation and damages. They were summarized as follows in its oral submissions.

[113] Class members who had their Defibrillators explanted will have to establish that they did so because of the advisory. It does not appear to me that this would be difficult to do; presumably, physician's records, as well as the time at which the explant was done, could buttress evidence by a Class member as to why he or she had the procedure done.

[114] Those Class members will also have to establish when they would have otherwise had their Defibrillators explanted. If, for example, the Class member was in any event due to have an explant, damages for the explants procedure may not be appropriate or may be less than would otherwise be the case (assuming a breach of duty is established at the common issues trial.) Given Medtronic's own data as to average life span of the various devices, this should similarly not be difficult to do.

[115] Medtronic says that the nature of each Class member's heart disease will have to be considered to determine whether it was reasonable for the Class member to decide to have an explant as a result of the advisory. (If, given the Class member's particular heart condition, an explant was not necessary to avoid risk of cardiac arrest in the event of battery failure, Medtronic will argue that the patient should not be entitled to damages for undergoing the procedure.) Again, there are presumably medical records confirming each Class member's diagnosis and this should not be difficult to establish.

[116] Medtronic argues that there is some risk of failure with all medical devices, and that it will be necessary to determine each patient's understanding of the inherent risks associated with ICDs. Medtronic argues that if the Class member had accepted a certain level of inherent risk, then the Class member would not be affected by the breach of duty, assuming that the resultant risk was still within the overall risk parameters for the device. Medtronic says that it will be necessary to determine what each Class member's physician had advised the Class member as to inherent risk.

[117] The Class member's individual experience with the explant would also be relevant. For example, did the Class member suffer infection? Did he or she miss work as a result? Medical records will presumably be available to confirm any complications asserted, and for those Class members who are not retired, confirmation of missed employment should not be difficult.

[118] I have concluded that, taking into account the importance of the common issues in relation to the claim as a whole, a class proceeding is the preferable procedure. The resolution of the common issues will significantly advance the claim. A class proceeding will, I believe, be manageable.

[119] I note that I would have come to the same conclusion had waiver of tort not been advanced, and the ability of the class to elect to have damages determined through an accounting and disgorgement of proceeds was not a common issue. This case is different than *Serhan*, where the only evidence of damage or injurious effects to Class members was the pain involved in obtaining additional blood samples, and as a result of which Cullity J.

would not have certified the action but for the waiver of tort claim, which arguably does not require proof of damages. Here, there is evidence of damage: pain and suffering in connection with explants, in some cases hospital costs and in some cases loss of income.

[120] Determination of the identified common issues in a class proceeding will clearly serve the objective of judicial economy. Since the advisory, 613 Defibrillators have been explanted and replaced in Canada. If certified, expert evidence regarding the various types of heart disease, the level of risk to different patients of Battery failure, the level of inherent risk associated with all medical devices, the level of risk associated with the explant procedure, and evidence regarding what Medtronic knew when and regulatory compliance, need only be adduced once. Whether Medtronic's response was, as it asserts, proactive, conservative and timely, or in breach of a duty owed to Class members, and the scope of the doctrine of waiver of tort and the availability of the remedy of disgorgement will only have to be determined once.

[121] Medtronic is a global leader in the design and manufacture of medical devices. It has very considerable resources at its disposition. It is clear that expert evidence will be required and that complex legal issues will have to be determined; having regard to the likely range of damages, it would be prohibitive for Class members to pursue these claims individually. Access to justice also favours certification.

[122] As noted above, Medtronic's position is that it acted properly in making the advisory when it did and that premature disclosure of issues identified in a laboratory setting, which may not arise in a clinical setting, can lead to panic and overreaction. Medtronic's evidence is that, even in this case, many explants, each with attendant procedural risks, which in its view were unnecessary, were effected as a result of its advisory. A balance must be struck, Medtronic submits, between the legitimate objective of transparency of information and the reality that completely raw and unfiltered information delivered in great quantity would likely undermine the objective of effective communication from manufacturers to patients. Medtronic argues that this balance is best resolved through the regulatory body and through collaborative guidelines developed in the medical community.

[123] As Medtronic recognizes, the objective of behavior modification looks more broadly at similar defendants who are potential wrongdoers, and not just at the particular defendants: *Pearson v. Inco Ltd.* (2006), 78 O.R. (3d) 641 at paras. 87 and 88 (C.A.). Certification in this case might be seen as promoting greater transparency of communication by manufacturers of medical devices. On the other hand, it would be unfortunate if the threat of class actions resulted in manufacturers of medical devices flooding the public with notice of any design change, without exercise of considered judgment of risk. On balance, given the U.S. recall notice, behavior modification might be seen as a positive factor in this instance. The outcome of this motion is not, however, affected by this factor.

[124] While I fully appreciate that at present waiver of tort is a jurisprudential morass, I do not accept Medtronic's argument that if I certify this action, I should only do so with respect to the claim in negligence and for punitive damages. In *Heward v. Eli Lilly*, breach of duty and prima facie entitlement to punitive damages, as well as liability to account by waiver of tort, were certified. Whether or not the Class can elect to have damages determined through an accounting and disgorgement can, in the first instance, be determined

at the same time as the common issues relating to breach of duty, conspiracy and prima facie entitlement to punitive damages. As indicated above, while I have no doubt that a decision regarding liability for disgorgement by waiver of tort will be appealed, it is reasonable to assume that other findings at the common issues trial would also be appealed.

5(1)(e): THE REPRESENTATIVE PLAINTIFF, A WORKABLE PLAN

[125] The proposed representative plaintiffs for the Class are: Frank Peter and Rhonda Lo Monaco, who had Defibrillators implanted before the issue of premature battery depletion was identified and had them explanted after the announcement; Brian Frederick Foote, who was implanted after the issue was identified, and before the advisory, and who has not had his Defibrillator explanted; and Francine Norouzi who similarly was implanted between the time the issue was identified and the advisory, but who had her Defibrillator explanted. All are resident in Ontario.

[126] The proposed FLA Class representative plaintiffs are Frank Peter's wife and adult children, Mrs. Bernadett Peter, Mark Peter and Ms. Bernadett Peter, and Ms. Lo Monaco's mother, Anita Prain.

[127] This action has been vigorously and capably prosecuted. Class counsel have agreed to act on a contingency basis. An application has been made to the Class Proceedings Fund for financial support in respect of disbursements. Counsel have undertaken to fund disbursements, if or to the extent they are not funded by the Fund.

[128] I have addressed Medtronic's argument that not every member will have the same interest in electing disgorgement in my consideration of common issue (6). On the revised wording of common issue (6), the representative plaintiffs do not have, on that issue, an interest in conflict with the interests of other Class members. As discussed under my consideration of the identifiable class requirement and common issue (6), depending on what the law in relation to entitlement to the remedy of disgorgement is found to be at the common issues trial, the common issues judge may issue directives as to how the election is to be made, if appropriate create subclasses, or even determine that common issue (6) is not a common issue.

[129] In this case, the identity of the Class members (including, for this purpose, provincial insurers) can be determined. Notification of Class members will be straight forward and effective.

[130] The plaintiffs' litigation plan provides that, assuming the common issues are resolved in favour of the plaintiffs, the plaintiffs will ask the Court to make individual assessments of compensatory damages or, at the election of the plaintiffs, award an aggregate amount representing Medtronic's income from the sale of the Defibrillators, and to make an aggregate award of punitive damages. It contemplates that the individual issues can be determined by streamlined individual assessments or mini-hearings.

[131] Medtronic correctly points out that the plaintiffs' litigation plan does not set out how, if it is determined that all or some of the Class members are entitled to elect a disgorgement remedy based on waiver of tort principles, the decision whether or not to elect

will be made, and how it proposes that the Class members would share in any aggregate, disgorgement-based award.

[132] Given the uncertainty surrounding the doctrine of waiver of tort, and when the remedy of an accounting and disgorgement of profits is available, this lack of precision is understandable, and probably, at this stage, unavoidable. If, once the applicable law is determined, a workable plan is not put forward, common issue (6) could, as indicated above, be de-certified.

[133] I am satisfied that the requirements of section 5(1)(e) are met. In doing so, I am not at this juncture approving the plaintiffs' proposal in its litigation plan that punitive damages be determined on an aggregate basis. I address punitive damages under my consideration of the common issues.

COSTS

[134] If the parties are unable to agree on costs, then the plaintiffs shall provide brief written submissions, not exceeding 10 pages, within 14 days of the release of these reasons, and Medtronic shall provide responding submissions within 10 days thereafter. No reply submissions shall be provided without leave. If a party is of the view that the above timetable is unreasonable, having regard to the approaching holiday season or for any other reason, I may be spoken to.

_____

Hoy J.

Released: December 6, 2007

COURT FILE NO.: 05-CV-295910CP
DATE: 2007126

ONTARIO

SUPERIOR COURT OF JUSTICE

B E T W E E N:

**FRANK PETER, MRS. BERNADETT PETER,
MARK PETER, MS. BERNADETT PETER,
BRIAN FREDERICK FOOTE,
RHONDA LYNN LO MONACO,
ANITA PRAIN and FRANCINE NOROUZI**

- and -

**MEDTRONIC, INC. and
MEDTRONIC OF CANADA LTD.**

REASONS FOR DECISION

Hoy J.

Released: December 6, 2007