CITATION: Houle, et al. v. St. Jude Medical Inc., et al. 2019 ONSC 2493
COURT FILE NO.: CV-17-00572508-00CP
DATE: 2019/04/23

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:	)	
	)	
SHIRLEY HOULE and ROLAND HOULE	)	*Margaret L. Waddell, John-Otto K. Phillips, Paul Miller,* and *Valerie Lord* for the Plaintiffs
Plaintiffs	)	
	)	
- and -	)	
	)	
ST. JUDE MEDICAL, INC. and ST. JUDE MEDICAL CANADA, INC.	)	*Caroline Zayid, Byron Shaw* and *Dorothy Charach* for the Defendants
	)	
Defendants	)	
	)	
Proceeding under the *Class Proceedings Act, 1992*	)	**HEARD**: April 23, 2019

PERELL, J.

REASONS FOR DECISION

A. Introduction

[1] This is a proposed class action under the *Class Proceedings Act, 1992*.[1] The Plaintiffs, Shirley Houle and Roland Houle, with the consent of the Defendants, St. Jude Medical Inc. and St. Jude Medical Canada, Inc. (collectively "St. Jude Medical") bring a motion for an Order: (a) certifying the action as a class action for settlement purposes; (b) approving the plan for disseminating the Notice of Certification and Notice of the Hearing for Settlement Approval; (c) approving the forms of the notices; and (d) granting a privacy and disclosure order to permit St. Jude Medical to produce the lists of the last known addresses of the Class Members to Class Counsel and the Claims Administrator.

[1] S.O. 1992, c. 6.

B. Facts

[2] The Houles brought their action on behalf of all persons resident in Canada as of the date of the certification order that have been implanted with the models of implantable cardioverter or cardiac resynchronization therapy defibrillators set out in the table below. These medical devices were manufactured by St. Jude Medical between January 2010 and May 23, 2015. The action was also brought on behalf of next-of-kin who may assert derivative claims.

Trade Name	Model	Trade Name	Model
Fortify Assura™ DR	CD2259-40Q	Quadra Assura MP™	CD3371-40C
Fortify Assura™ DR	CD2259-40	Quadra Assura MP™	CD3371-40QC
Fortify Assura™ DR	CD2359-40C	Quadra Assura™	CD3265-40Q
Fortify Assura™ DR	CD2359-40QC	Quadra Assura™	CD3367-40QC
Fortify Assura™ VR	CD1359-40QC	Quadra Assura™	CD3267-40
Fortify Assura™ VR	CD1259-40	Quadra Assura™	CD3267-40Q
Fortify Assura™ VR	CD1259-40Q	Quadra Assura™	CD3367-40C
Fortify Assura™ VR	CD1359-40C	Unify Assura™	CD3261-40Q
Fortify™ DR	CD2233-40Q	Unify Assura™	CD3361-40QC
Fortify™ DR	CD2233-40	Unify Assura™	CD3261-40
Fortify™ ST DR	CD2235-40	Unify Assura™	CD3361-40C
Fortify™ ST DR	CD2235-40Q	Unify Quadra™	CD3251-40
Fortify™ ST VR	CD1235-40	Unify Quadra™	CD3251-40Q
Fortify™ ST VR	CD1235-40Q	Unify™	CD3231-40
Fortify™ VR	CD1233-40	Unify™	CD3235-40
Fortify™ VR	CD1231-40	Unify™	CD3235-40Q
Fortify™ VR	CD1233-40Q		

[3] The Houles allege in the Amended Statement of Claim that St. Jude Medical was negligent in the manufacture or design of the Defibrillators and that it breached the duty to warn the Plaintiffs and the Class Members that the batteries in the defibrillators were prone to forming lithium clusters that could cause the batteries in the defibrillators to rapidly deplete prematurely.

[4] The Patient Class consists of all persons resident in Canada who were implanted with one of the Defibrillator models noted in the above table. The Derivative Class covers dependents of the Patient Class members under the *Family Law Act*[2] or similar provincial legislation.

[5] The Houles seek certification of the following common issues for settlement purposes only:

a. Were the Defendants negligent in failing to ensure that there were no defects in the Defibrillators?

b. Were the Defendants negligent in failing to warn the Class of a risk of

[2] R.S.O. 1990 c.F.3.

premature battery depletion with the Defibrillators in a timely fashion? and

c. If so, are the Defendants liable in damages to the Patient Class, the Family Class or the Provincial Health Insurers?

[6] On October 2, 2018, the Houles filed their factum for a contested certification motion. The certification motion did not proceed, and the parties undertook settlement negotiations.

[7] On April 18, 2019, after months of negotiations, the parties finalized a settlement of this proposed class action, subject to court approval.

[8] The main terms of the Settlement Agreement are as follows.

a. St. Jude Medical agrees to pay settlement proceeds totalling $5 million in the aggregate.

b. The $5 million will be held in an interest-bearing trust account for the benefit of Class Members, pending settlement approval.

c. The settlement funds are to be allocated on the following basis:

i. $4.0 million to compensate the Class Members and Provincial Health Insurers, to be distributed in accordance with the Referee Guidelines and Distribution Protocol after deduction of approved Class Counsel fees and any Administration Expenses exceeding $250,000;

ii. $250,000 towards Administration Expenses relating to the Settlement; and;

iii. $750,000 for costs of the action, to be applied towards the total legal fees payable to Class Counsel as determined by the Court. Approval of Class Counsel's fees will therefore be sought calculated on the basis of a recovery for the Class of $4,250,000.

d. Class members whose Defibrillators were replaced as a result of premature battery failure, or electively replaced on doctors' orders in response to the Health Canada advisory published on October 10, 2016, will receive $10,000 more or less.

e. Explanted Class Members who suffered complications will receive additional compensation.

f. All other Class Members will receive a payment of up to either $100 or $500 depending on whether they were implanted before or after the date by which St. Jude Medical arguably, ought to have issued a warning about the potential of the batteries in the Defibrillators to short from the formation of lithium clusters.

g. Under the Settlement Agreement there are three classes of claimants; namely:

i. Eligible Explant Claimants means Patient Class Members who either (i) had a Defibrillator replaced due to premature battery depletion where the battery depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters, or (ii) had a Defibrillator replaced

between October 10, 2016 and August 8, 2017 on an elective basis in response to the St. Jude advisory issued in Canada on October 10, 2016 provided that the electively replaced Defibrillator had been implanted for less than five years at the time of the replacement.

ii. Eligible Non-Explant Claimants are Patient Class Members who are not Eligible Explant Claimants.

iii. Derivative Class or Derivative Class Members means all dependants of Patient Class Members asserting the right to sue the Releasees independently or derivatively by reason of their familial relationship to a Patient Class Member, including pursuant to the *Family Law Act*, R.S.O. 1990 c. F.3 or similar legislation in any other Province or Territory in Canada.

h. The Settlement Agreement provides an "extraordinary" injury fund for those Class Members who experienced complications with their Defibrillators, died, or who otherwise incurred out-of-pocket expenses. Guidelines are provided for the Referee in the Settlement Agreement outlining the criteria for compensation for extraordinary injuries.

i. The Settlement Agreement includes a term that permits St. Jude to terminate the agreement if an opt-out threshold is exceeded.

j. The Provincial Health Insurers or all Canadian provinces and territories have agreed to the Settlement Agreement. They will receive $417,250 from the settlement, to be distributed *pro rata* according to the number of confirmed Class Members resident in each province or territory.

k. The Settlement Agreement requires the Claims Administrator to pay the net Settlement Funds in accordance with the Distribution Protocol in the following order:

i. payment of the Administration Expenses;

ii. payments to the Provincial Health Insurers;

iii. payments to the Eligible Non-Explant Claimants;

iv. payment of compensation to the Eligible Extraordinary Injury Fund Claimants (*i.e.* those with complications following explant surgery);

v. payment of compensation to any Derivative Class Members who are the next-of-kin of persons who would have been Eligible Explant Claimants but who died, and the death was caused or contributed to by the battery in the Defibrillator shorting due to lithium cluster formation;

vi. payment of compensation to the Eligible Explant Claimants; and

vii. payment cy-près of any amount remaining at the end of the administration period to the Heart and Stroke Foundation of Canada.

l. The Settlement Agreement provides that the Claims Administrator will be responsible for the dissemination of the various notices, other than a press

release and web postings to be completed by Class Counsel and a web posting by St. Houle Medical.

[9] Epiq Class Action Services has agreed to act as Claims Administrator, subject to court approval.

[10] The parties have agreed on the form and content of the Notices of Certification and Notice of Hearing for Settlement Approval and the plan for their distribution. The Notice Protocol contemplates that within fifteen days from the date of certification, St. Jude Medical will provide to the Claims Administrator and to Class Counsel lists of Patient Class Members, including their names, last known addresses, the type of Defibrillator implanted and the serial numbers of the implanted Defibrillators, to the extent such information is available. The Claims Administrator will then deliver the Certification Notice by direct mail to the Patient Class Members at the last known address.

[11] Class Counsel will also publish a national press release in English and in French, and mail or email any Class Member who had previously provided their contact information to Class Counsel. Class Counsel will further publish updates on their firm websites.

C. Discussion

[12] The court is required to certify the action as a class proceeding where the following five-part test in s. 5 of the *Class Proceedings Act, 1992* is met: (a) the pleadings disclose a cause of action; (b) there is an identifiable class of two or more persons that would be represented by the representative plaintiff; (c) the claims 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 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.

[13] The fact that an action is certified on consent for settlement purposes does not dispense with the need to meet the certification criteria but they may be less rigorously applied in a settlement context.[3]

[14] In the present case, I am satisfied that all of the criteria for certification have been satisfied and that the incidental relief should be granted.

[15] Order accordingly.

Perell, J.

Released: April 23, 2019

[3] *Osmun v. Cadbury Adams Canada Inc.*, [2009] O.J. No. 5566 at para. 21 (S.C.J.).

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