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COURT OF QUEEN'S BENCH OF MANITOBA

B E T W E E N:

MARILYN WALLS and ETHEL NICK,	)	For the Plaintiffs:
	)	Wayne P. Forbes
Plaintiffs,	)	David A. Klein
	)	
- and -	)	For the Defendant:
	)	E. William Olson, Q.C.
BAYER INC.,	)	Peter J. Cavanagh
	)	Susan E. Paul
Defendant.	)	
	)	Judgment delivered:
	)	January 7, 2005

MacINNES, J.

[1] The plaintiffs have sued the defendant for damages alleging they have suffered injury as a result of their consumption of Baycol, a cholesterol-lowering prescription drug promoted and distributed by the defendant.

[2] The plaintiffs now move for certification of their action as a class proceeding under **The Class Proceedings Act**, C.C.S.M. c. C130 (the "**Act**").

[3] Health Canada approved Baycol for distribution and sale in Canada on February 18, 1998. Initial approval was for dosage levels of 0.2 and 0.3 milligrams. On December 22, 1999, Health Canada approved the distribution

and sale of Baycol at the increased dosage level of 0.4 milligrams, and on December 28, 2000, at the further increased dosage level of 0.8 milligrams.

[4] On July 16, 2001, the defendant sent a letter to health care professionals in Canada advising that between March 1998 and June 30, 2001, 31 cases of suspected rhabdomyolysis had been reported in Canada, including 8 cases resulting in renal failure and 1 death. On August 8, 2001, the defendant withdrew Baycol from the Canadian market. On August 10, 2001, Health Canada published a "warning" reporting that the withdrawal was because of reports of rhabdomyolysis associated with the drug. Health Canada went on to report that between March 1998 and August 8, 2001, 45 cases of rhabdomyolysis including 14 cases of acute renal failure and 1 death had been reported in Canada.

[5] Following the withdrawal of Baycol from the Canadian market, the Canadian Adverse Drug Reaction Monitoring Program of Health Canada released the Summary of Reported Adverse Drug Reactions pertaining to Baycol as at August 31, 2001. The Summary was a compilation of adverse drug reaction complaints reported to Health Canada pertaining to Baycol. The Summary stated that, as of that date, Health Canada had received 94 reports of Canadians who had reported suffering rhabdomyolysis, myalgia, myositis, muscle pain, renal failure, elevated CPK levels and other adverse reactions after taking Baycol.

[6] The plaintiffs, both retired persons resident in Manitoba, allege they were prescribed Baycol by their respective medical doctors. Each filled her

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prescription at a pharmacy of her choice, followed instructions for consumption and ingested Baycol. Each did so from the time Baycol was first prescribed for her until its recall and removal from the Canadian market.

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[7] The plaintiffs assert that each experienced and continues to suffer weakness, pain, muscle loss and damage to her muscle tissue, which have impaired and interfered with her enjoyment of life and regular daily activities.

[8] No statement of defence has yet been filed by the defendant. But based upon the evidence presented on the certification hearing, the defendant, while acknowledging the possible occurrence of rhabdomyolysis when Baycol was taken at its highest dosage, denies that it was negligent in any respect. The defendant asserts that Baycol was efficacious. It also asserts that the product monograph was accurate and was amended in a timely fashion when new information concerning the drug or its side effects was discovered. As well, it says that many of the conditions or symptoms complained of by or on behalf of patients were not the result of Baycol or if they were, they related to normal side effects of statin medications (of which Baycol was one) for which adequate warnings of those side effects had been given.

[9] One of the plaintiffs' counsel, Douglas Lennox, swore in an affidavit on June 25, 2003, that notwithstanding the absence of any formal notice of this action, 52 individuals from Manitoba and a total of 507 individuals from across Canada had already contacted his firm with respect to it.

[10] Prior to commencement of this action, class proceedings had already been commenced in respect of Baycol in British Columbia, Saskatchewan, Ontario, Quebec, and Newfoundland and Labrador. In British Columbia, the plaintiffs obtained a certification order. That order is under appeal, but the appeal has not been heard. In the meantime a settlement was negotiated with respect to those members of the class who contracted rhabdomyolysis (as defined in the settlement agreement) from the ingestion of Baycol. The settlement has been approved.

[11] In both the Ontario and Quebec proceedings, settlement agreements were reached settling the claims of those who contracted rhabdomyolysis (as defined in the settlement agreements). In Ontario, the settlement was approved. I am not aware of the present status of the Quebec proceeding. In neither Ontario nor Quebec has there been a certification motion as is now before me.

[12] I am not aware of the status of the Saskatchewan proceeding.

[13] In ***Wheadon v. Bayer Inc.*** (2004), 46 C.P.C. (5th) 155, a decision of the Newfoundland and Labrador Supreme Court, Trial Division, Barry J. heard a certification application and concluded that the plaintiffs had satisfied the certification criteria. His decision is under appeal. Counsel on the motion before me advised that the facts, evidence and issues in this case are virtually identical to the facts, evidence and issues in ***Wheadon, supra***.

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[14] Class proceedings are not new. They have, however, become more prevalent in Canada in recent years and as a result many provinces have enacted legislation to provide and establish a regime or rules of process for class proceedings. Manitoba did so by passing the **Act**, which received royal assent July 25, 2002 and was proclaimed in force January 1, 2003. The following are certain provisions of the **Act** relevant to the motion before me:

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PART 1

INTRODUCTORY PROVISIONS

Definitions
1 In this Act,

"**certification order**" means an order certifying a proceeding as a class proceeding;

"**class proceeding**" means a proceeding certified as a class proceeding under Part 2;

"**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;

. . .

PART 2

CERTIFICATION

Member of class may commence proceeding
2(1) One or more members of a class of persons may commence a proceeding in the court on behalf of the members of that class.

Motion for certification by plaintiff
2(2) A person who commences a proceeding under subsection (1) must make a motion to the court for an order

(a) certifying the proceeding as a class proceeding; and

(b) appointing a representative plaintiff.

. . .

Certification of class proceeding
4 The court must certify a proceeding as a class proceeding on a motion under section 2 or 3 if

(a) the pleadings disclose a cause of action;

(b) there is an identifiable class of two or more persons;

(c) the claims of the class members raise a common issue, whether or not the common issue predominates over issues affecting only individual members;

(d) a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues; and

(e) there is a person who is prepared to act as the representative plaintiff who

(i) would fairly and adequately represent the interests of the class,

(ii) has produced a plan for the class proceeding that sets out a workable method of advancing the class proceeding on behalf of the class and of notifying class members of the class proceeding, and

(iii) does not have, on the common issues, an interest that conflicts with the interests of other class members.

. . .

Meaning of certification
5(2) An order certifying a proceeding as a class proceeding is not a determination of the merits.

. . .

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Certain matters not bar to certification
7 The court must not refuse to certify a proceeding as a class proceeding by reason only of one or more of the following:

(a) the relief claimed includes a claim for damages that would require individual assessment after determination of the common issues;

. . .

(d) the number of class members or the identity of each class member is not ascertained or may not be ascertainable;

[15] In addition to this legislation, a body of case law has built up particularly in recent years providing direction as to the purpose of class proceedings, and the procedure before and the role of the court in the certification process. The following are some passages and/or principles which I have drawn from certain of the cases and which I have found helpful in deciding this certification motion:

- ***Western Canadian Shopping Centres Inc. v. Dutton***, [2001] 2 S.C.R. 534, was a case which had originated in Alberta and which was brought under Rule 42 of the **Alberta Rules of Court**, Alta. Reg. 390/68, as no class proceeding legislation existed. The unanimous judgment of the Supreme Court of Canada was delivered by McLachlin C.J. After commenting upon various circumstances that might in today's world give rise to a class action, she wrote, at pp. 549-50:

> ... Conflicts like these pit a large group of complainants against the alleged wrongdoer. Sometimes, the complainants are identically situated *vis-à-vis* the defendants. In other cases, an important aspect of their claim is common to all complainants. The class action offers a means of efficiently resolving such disputes in a manner that is fair to all parties.
>
> Class actions offer three important advantages over a multiplicity of individual suits. First, by aggregating similar individual actions, class

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> actions serve judicial economy by avoiding unnecessary duplication in fact-finding and legal analysis. ...
>
> Second, by allowing fixed litigation costs to be divided over a large number of plaintiffs, class actions improve access to justice by making economical the prosecution of claims that would otherwise be too costly to prosecute individually. Without class actions, the doors of justice remain closed to some plaintiffs, however strong their legal claims. Sharing costs ensures that injuries are not left unremedied....
>
> Third, class actions serve efficiency and justice by ensuring that actual and potential wrongdoers do not ignore their obligations to the public. Without class actions, those who cause widespread but individually minimal harm might not take into account the full costs of their conduct, because for any one plaintiff the expense of bringing suit would far exceed the likely recovery. Cost-sharing decreases the expense of pursuing legal recourse and accordingly deters potential defendants who might otherwise assume that minor wrongs would not result in litigation....

And at pp. 554-56, she wrote:

> ... [F]our conditions emerge as necessary to a class action. First, the class must be capable of clear definition. Class definition is critical because it identifies the individuals entitled to notice, entitled to relief (if relief is awarded), and bound by the judgment. It is essential, therefore, that the class be defined clearly at the outset of the litigation. The definition should state objective criteria by which members of the class can be identified. While the criteria should bear a rational relationship to the common issues asserted by all class members, the criteria should not depend on the outcome of the litigation. It is not necessary that every class member be named or known. It is necessary, however, that any particular person's claim to membership in the class be determinable by stated, objective criteria....
>
> Second, there must be issues of fact or law common to all class members. ... The commonality question should be approached purposively. 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. It is not essential that the class members be identically situated *vis-à-vis* the opposing party. Nor is it necessary that common issues predominate over non-common issues or that the resolution of the common issues would be determinative of each class member's claim. However, the class members' claims must share a substantial common ingredient to justify a class action. Determining whether the common issues justify a

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> class action may require the court to examine the significance of the common issues in relation to individual issues. ...
>
> Third, with regard to the common issues, success for one class member must mean success for all. All members of the class must benefit from the successful prosecution of the action, although not necessarily to the same extent. A class action should not be allowed if class members have conflicting interests.
>
> Fourth, the class representative must adequately represent the class. ... [T]he court may look to the motivation of the representative, the competence of the representative's counsel, and the capacity of the representative to bear any costs that may be incurred by the representative in particular (as opposed to by counsel or by the class members generally). ... The court should be satisfied ... that the proposed representative will vigorously and capably prosecute the interests of the class....
>
> While the four factors outlined must be met for a class action to proceed, their satisfaction does not mean that the court must allow the action to proceed. Other factors may weigh against allowing the action to proceed in representative form. ... [T]he court has discretion to decide whether the class action should be permitted to proceed, notwithstanding that the essential conditions for the maintenance of a class action have been satisfied.

I pause here to note that s. 4 of the **Act** provides that the court must certify a class proceeding if the statutory criteria contained in the section are met. Three of those criteria were included and commented upon in the four conditions that McLachlin C.J. described as necessary to a class action. But the discretionary aspect of the court's decision continues under the **Act** in deciding whether the statutory criteria have been met, and particularly in respect of the criterion set forth in s. 4(d), that is, whether a class proceeding would be the preferable procedure.

Returning to ***Western Canadian, supra***, McLachlin C.J. wrote, at pp. 556 and 557:

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> ... The court should take into account the benefits the class action offers in the circumstances of the case as well as any unfairness that class proceedings may cause. In the end, the court must strike a balance between efficiency and fairness.
>
> . . . . .
>
> The need to strike a balance between efficiency and fairness also belies the suggestion that class actions should be approached restrictively.

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And at pp. 560-61, she wrote:

> The defendants' contention that there are multiple classes of plaintiffs is unconvincing. No doubt, differences exist. ... The fact remains, however, that the investors raise essentially the same claims requiring resolution of the same facts. While it may eventually emerge that different subgroups of investors have different rights against the defendants, this possibility does not necessarily defeat the investors' right to proceed as a class. If material differences emerge, the court can deal with them when the time comes.
>
> ... A class action should not be foreclosed on the ground that there is uncertainty as to the resolution of issues common to all class members. If it is determined that the investors must show individual reliance, the court may then consider whether the class action should continue.
>
> The same applies to the contention that different defences will be raised with respect to different class members. Simply asserting this possibility does not negate a class action. If and when different defences are asserted, the court may solve the problem or withdraw leave to proceed as a class.

- ***Hollick v. Toronto (City)***, [2001] 3 S.C.R. 158, was a class action brought under the **Class Proceedings Act, 1992**, S.O. 1992, c. 6 (the "**Ontario Act**"). The certification criteria are found in s. 5(1) of the **Ontario Act** and are very similar to those set forth in s. 4 of the **Act**. In ***Hollick, supra***, the Supreme Court of Canada dealt with the appellant's application for a

certification order. The court's judgment was delivered by McLachlin C.J. At p. 169, she wrote, "... the Act should be construed generously."

As well, she wrote, "The Act reflects an increasing recognition of the important advantages that the class action offers as a procedural tool."

She then reiterated some of her comments made in ***Western Canadian*** and went on to write, at p. 170:

> ... [I]t is essential therefore that courts not take an overly restrictive approach to the legislation, but rather interpret the Act in a way that gives full effect to the benefits foreseen by the drafters.
>
> It is particularly important to keep this principle in mind at the certification stage.

At pp. 170-71, she commented upon the nature of the certification stage:

> ... Thus the certification stage is decidedly not meant to be a test of the merits of the action.... Rather the certification stage focuses on the <u>form</u> of the action. The question at the certification stage is not whether the claim is likely to succeed, but whether the suit is appropriately prosecuted as a class action....
>
> [underlining in original text]

At pp. 171-73, McLachlin C.J. discussed whether the claims of the class members raise common issues:

> ... [A]n issue will be common "only where its resolution is necessary to the resolution of each class member's claim".... Further, an issue will not be "common" in the requisite sense unless the issue is a "substantial ... ingredient" of each of the class members' claims.
>
> ... [T]he issue is whether there is a rational connection between the class as defined and the asserted common issues....
>
> ... It falls to the putative representative to show that the class is defined sufficiently narrowly.

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> The requirement is not an onerous one. The representative need not show that everyone in the class shares the same interest in the resolution of the asserted common issue. There must be some showing, however, that the class is not unnecessarily broad — that is, that the class could not be defined more narrowly without arbitrarily excluding some people who share the same interest in the resolution of the common issue.
>
> [underlining in original text]

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She then addressed the question of evidence in support of a certification motion and the role of the court in respect of such evidence. At p. 174, she wrote:

> The question arises, then, to what extent the class representative should be allowed or required to introduce evidence in support of a certification motion.

She referred to the ***Report of the Attorney General's Advisory Committee on Class Action Reform*** (Toronto: The Committee, 1990) and expressed the view that it ...

> ... appropriately requires the class representative to come forward with sufficient evidence to support certification, and appropriately allows the opposing party an opportunity to respond with evidence of its own.

And at p. 175, she wrote:

> ... [T]he representative of the asserted class must show some basis in fact to support the certification order. ... [T]hat is not to say that there must be affidavits from members of the class or that there should be any assessment of the merits of the claims of other class members. However, ... the class representative will have to establish an evidentiary basis for certification.... In my view, the class representative must show some basis in fact for each of the certification requirements set out in s. 5 of the Act, other than the requirement that the pleadings disclose a cause of action.

McLachlin C.J. then discussed the preferability issue, that is, whether a class proceeding would be the preferable procedure for the fair and efficient resolution of common issues. In that regard she wrote, at p. 176:

> ... [T]he preferability inquiry should be conducted through the lens of the three principal advantages of class actions — judicial economy, access to justice, and behaviour modification....

And at pp. 177-79, she wrote:

> ... "[P]referable" was meant to be construed broadly. The term was meant to capture two ideas: first ... "whether or not the class proceeding [would be] a fair, efficient and manageable method of advancing the claim", and second, ... whether a class proceeding would be preferable "in the sense of preferable to other procedures such as joinder, test cases, consolidation and so on".... In my view, it would be impossible to determine whether the class action is preferable in the sense of being a "fair, efficient and manageable method of advancing the claim" without looking at the common issues in their context.
>
> The Act itself, of course, requires only that a class action be the preferable procedure for "the resolution of the <u>common issues</u>" ... and not that a class action be the preferable procedure for the resolution of the class members' claims. I would not place undue weight, however, on the fact that the Act uses the phrase "resolution of the common issues" rather than "resolution of class members' claims". As one commentator writes:
>
> > The [American] class action [rule] requires that the class action be the superior method to resolve the "controversy". The B.C. and Ontario Acts require that the class proceeding be the preferable procedure for the resolution of the "common issues" (as opposed to the entire controversy). [This] distinctio[n] can be seen as creating a lower threshold for certification in Ontario and B.C. than in the U.S. However, it is still important in B.C. and Ontario to assess the litigation as a whole, including the individual hearing stage, in order to determine whether the class action is the preferable means of resolving the common issues. In the abstract, common issues are always best resolved in a common proceeding. However, it is important to adopt a practical cost-benefit approach to this procedural issue, and to consider the impact of a class proceeding on class members, the defendants, and the court.

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> ... I would endorse that approach.
>
> The question of preferability, then, must take into account the importance of the common issues in relation to the claims as a whole. ... [T]he Act contemplates that class actions will be allowable even where there are substantial individual issues: see s. 5. ... [T]he drafters rejected a requirement ... that the common issues "predominate" over the individual issues.... I cannot conclude, however, that the drafters intended the preferability analysis to take place in a vacuum. There must be a consideration of the common issues in context. ... [T]he preferability requirement asks that the class representative "demonstrate that, given all of the circumstances of the particular claim, [a class action] would be preferable to other methods of resolving these claims and, in particular, that it would be preferable to the use of individual proceedings"....
>
> ... In my view, the preferability analysis requires the court to look to all reasonably available means of resolving the class members' claims, and not just at the possibility of individual actions.
>
> [underlining in original text]

Lastly, McLachlin C.J., at pp. 182-83, wrote:

> ... The question of whether an action should be permitted to be prosecuted as a class action is necessarily one that turns on the facts of the case.

- ***Rumley v. British Columbia***, [2001] 3 S.C.R. 184, was a class proceeding commenced under the British Columbia legislation which is similar to the **Act**. The judgment of the court was again delivered by McLachlin C.J. At p. 200, she cautioned against over breadth of the putative class. She wrote:

> There is clearly something to the appellant's argument that a court should avoid framing commonality between class members in overly broad terms. ... [T]he guiding question should be the practical one of "whether allowing the suit to proceed as a representative one will avoid duplication of fact-finding or legal analysis". It would not serve the ends of either fairness or efficiency to certify an action on the basis of issues that are common only when stated in the most general terms. Inevitably such an action would ultimately break down into individual proceedings. That the suit had initially been certified as a class action could only make the proceeding less fair and less efficient.

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She also commented as to the flexibility provided to the court under the **Class Proceedings Act**, R.S.B.C. 1996, c. 50 (the "**British Columbia Act**"). At p. 202, she wrote:

> ... In my view the *Class Proceedings Act* provides the court with ample flexibility to deal with limited differentiation amongst the class members as and if such differentiation becomes evident.

I note that the **British Columbia Act** is very similar to the **Act**, and the certification criteria found in s. 4(1) are substantially identical to those set forth in s. 4 of the **Act**.

- In ***Wilson v. Servier Canada Inc.*** (2000), 50 O.R. (3d) 219, Cumming J. of the Superior Court of Justice of Ontario certified a class proceeding wherein the plaintiff was alleging defectiveness in and damages suffered as a result of ingestion of a prescription medication. This is the essence of the plaintiffs' claim in the present action. In his reasons he commented upon what he described as "[t]he crux of the defendants' response to the motion for certification" being the individuality of many of the issues. At p. 248, he wrote:

> Undoubtedly, a large number of individual issues will arise for each member of the class who claims that a disease has resulted from the consumption of the diet pills. Indeed, there will probably have to be individual discovery of these class members. The *CPA* contemplates a bifurcated process as necessary and appropriate to accomplish this.

And he continued, at p. 249:

> The *CPA* provides for a bifurcated procedure whereby common issues can be resolved on a class-wide basis and follow-up individual

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> issues dealt with on an individual basis. The *CPA* has several provisions to accommodate the necessary flexibility required....

Cumming J. was, of course, referring to the **Ontario Act**. The **Act**, however, is substantially similar in provision and, in my view, in intention.

As regards preferability, he wrote, at pp. 249-50, that that criterion required a two-fold analysis:

> ... First, is a class proceeding the preferable procedure because it constitutes a fair, efficient and manageable way of determining the common issues presented by the claims of the proposed class members?
>
> Second, will such determination of the common issues advance the proceeding in accordance with the policy objectives underlying the *CPA* — objectives such as access to justice, judicial economy and the modification of the behaviour of those who might otherwise be wrongdoers?
>
> A court must consider the following factors: whether the class is such that a class proceeding will be unmanageable or impractical; whether common issues of fact or law are significant as compared with questions affecting only individual members; whether many of the members of the class have a valid interest in individually controlling the prosecution of separate actions; whether the administration of the class proceeding will create significantly more difficulties than those likely to be experienced if a remedy were to be sought by other means;...
>
> ... Even though there may be common issues, the individual issues may overwhelm the common issues such that a class proceeding would not facilitate achievement of the underlying policy objectives of the *CPA*....
>
> That individual issues will remain after the common issues are tried is not an obstacle to certification.

[16] Let me turn then to consider this motion in light of the criteria set forth in s. 4 of the **Act**.

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[17] On the motion before me, the plaintiffs rely upon their amended statement of claim, the affidavit evidence of Marilyn Walls, Douglas Lennox and Dr. Keith Borden, and as well, the cross-examination of Marilyn Walls on her affidavit. The defendant filed affidavits of Dr. Lawrence A. Leiter, Douglas Grant, Manoj Saxena and Susan Paul. I received written briefs from the parties and heard oral submissions September 8, 9 and 10, 2004.

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[18] The defendant's position is that this action does not qualify for certification under the **Act** for a number of reasons:

(1) The proposed representative plaintiff does not, on the evidence, have a claim against the defendant that raises a genuine issue for trial. Accordingly, she cannot be a member of a class in an action against the defendant in respect of Baycol and she cannot fairly and adequately represent the interests of members of any properly defined class.

(2) Claims upon which common issues may arise must, for purposes of class certification, be limited to those that, on the evidence presented, raise a genuine issue for trial. The bald pleading that Baycol was defective or unfit is contradicted by unchallenged evidence and, accordingly, is not a colourable claim from which common issues may arise.

(3) The only claims in respect of which there may be a genuine issue for trial relate to the quality and timeliness of warnings of risks of rhabdomyolysis associated with Baycol. In respect of such claims, numerous individual issues of fact in relation to both liability and damages are inextricably interwoven with any issues common to class members and, therefore, there are no issues that are a substantial ingredient of the claim of each class member, the resolution of which would materially advance the interests of each member of the putative class. Specifically, injury claims of persons with varying medical histories, who took different doses of Baycol at different times when the defendant had different knowledge about the medicine, in combination with gemfibrozil and in monotherapy, and under various product labels, cannot be adjudicated through a single proceeding.

(4) Class adjudication of the claims advanced in this action is not, on the facts of this case, the preferable procedure for the resolution of the claims of the putative class members. A class action would inevitably break down into a series of individual adjudications with the result that the policy objectives underlying the **Act** would not be achieved.

[19] The evidentiary threshold for meeting the statutory criteria is low. Or, as McLachlin C.J. wrote in ***Hollick***, "The requirement is not an onerous one."

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[20] Still, the law requires that the representative plaintiff must provide sufficient evidence to show some basis in fact for each of the certification criteria, other than that the pleadings disclose a cause of action. And the opposing party is entitled to provide evidence in response.

[21] But the case law and s. 5(2) of the **Act** make clear that the certification hearing is not a merits based hearing.

[22] In my view, the court must fill something of a gatekeeper function. It must consider the evidence adduced from both the party propounding certification and the party opposing, in light of the statutory criteria. But its consideration is from the perspective of form or procedure, not substance or merits. That is, does the evidence adduced on the certification hearing establish that a class proceeding is appropriate and preferable for the advancement of the intended action, consistent with the principal advantages of class actions, namely, judicial economy, access to justice, and behaviour modification. The question whether the evidence is sufficient to establish a genuine issue for trial is in my view, contrary to the submissions of the defendant, not a question for determination on the certification motion but one for later determination and one which requires a merits based assessment.

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Section 4(a) – Cause of Action

[23] Section 4(a) of the **Act** requires that the pleadings disclose a cause of action. No evidence need be provided. The defendant acknowledges that the plaintiffs' amended statement of claim discloses a cause of action.

Section 4(b) - Identifiable Class

[24] Section 4(b) of the **Act** requires that there is an identifiable class of two or more persons. The plaintiffs have proposed the following class for certification:

(a) all persons resident in Manitoba and elsewhere in Canada who were prescribed and ingested Baycol which was purchased in Canada and who claim personal injury as a result ("Injury Class");

(b) all persons who have a derivative claim on account of a family relationship with a person described in paragraph (a) ("Family Class"); and

(c) such other persons as the court recognizes or directs.

Excluded from the Injury Class are persons resident in Quebec, persons resident in a province other than Manitoba who are members of an already certified class action in that other province, and as well, persons who are entitled to participate in a settlement approved by the Ontario and British Columbia courts (and the Quebec courts as and when approval is given).

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[25] Here, the essential criteria for class membership are prescription and ingestion of Baycol purchased in Canada, and a claim for personal injury as a result.

[26] Prescription and ingestion of Baycol purchased in Canada are easily and objectively determinable.

[27] While it may be true that one's determination of personal injury may be subjective, the fact of a claim to personal injury is not. That is, it will be easy to determine objectively whether and which prospective plaintiff claims not only to have been prescribed and to have ingested Baycol purchased in Canada, but also to have suffered injury as a result.

[28] The proposed class definition is silent as to the merits of the claims, but as the criteria should not depend on the outcome of the litigation, it is not necessary that prospective class members be able to successfully establish that they have suffered injury. The criterion is simply that they claim to have suffered injury.

[29] As well, the criteria for class membership here bear a rational relationship to the proposed common issues and are not dependent on the outcome of the litigation. Moreover, the criteria are such as to ensure that the proposed class is not overly inclusive.

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[30] In this case, two persons are named as plaintiffs in the statement of claim. Each asserts as material facts that she was prescribed Baycol by her doctor, that her prescription was filled at the pharmacy of her choice, that she followed instructions for consumption and ingested Baycol, and that she continued so taking Baycol until its recall and removal from the Canadian market.

[31] Each plaintiff also alleges that she experienced and continues to suffer weakness, pain, muscle loss and damage to her muscle tissue, which have impaired and interfered with her enjoyment of life and regular daily activities.

[32] Neither claims to have suffered rhabdomyolysis.

[33] The plaintiff Marilyn Walls has sworn an affidavit confirming the allegations that she has made in the statement of claim. She briefly supplemented her affidavit evidence by answers given on her cross-examination on affidavit.

[34] The plaintiff Ethel Nick has not sworn an affidavit confirming her allegations nor has any such evidence been provided from any other source on this motion, specifically related to her.

[35] It would clearly have been preferable to have been provided with an affidavit from Ethel Nick. But, in the circumstances here, I conclude that her failure to do so is not fatal to establishment of this criterion.

[36] There is other evidence before me that is available for consideration.

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[37] Exhibit "D" to the affidavit of Douglas Lennox sworn June 25, 2003 is a Summary of Reported Adverse Drug Reactions to Baycol as at August 31, 2001 from the Canadian Adverse Drug Reaction Monitoring Program of Health Canada. It shows that as of that date, Health Canada had received 94 reports of Canadians who had reported suffering rhabdomyolysis, myalgia, myositis, muscle pain, renal failure, elevated CPK levels and other adverse reactions after taking Baycol.

[38] As well, Douglas Lennox swore that despite the absence of notice, 52 individuals from Manitoba and 507 individuals from across Canada had already contacted the plaintiffs' counsel's firm with respect to this action.

[39] Moreover, Douglas Grant, in his affidavit on behalf of the defendant sworn October 8, 2003, stated that in the case of Baycol as of September 15, 2003, the defendant's Drug Safety and Medical Information Department had received directly and through Health Canada 179 spontaneous reports which the defendant, after investigation, classified as "serious" cases. He also stated that a "serious" event is defined as ...

> ... one that results in death or is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, results in a congenital abnormality or birth defect or which is an important medical event.

This definition is one that is standardized across regulatory bodies and pharmaceutical companies.

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[40] Dr. Keith Borden in his affidavit swore as to the practice and procedure for the reporting of adverse drug reactions. He provided his expert opinion as to whether the number of adverse drug reactions reported to monitoring agencies for a given drug and event can be equated to the actual number of people who suffered the adverse drug reaction in question. He swore, "The brief answer is no and this position is universally accepted among experts in the ADR [adverse drug reaction] monitoring community."

[41] He referred to an American text, ***Pharmacoepidemiology***, 3rd edition, 2000, in which the statement is made that such reports "generally represent only a small proportion of the events that have actually occurred."

[42] I am satisfied therefore, on the evidence before me, that the proposed class definition is objectively and clearly defined, that it is not overly inclusive, and that there is an identifiable class of two or more persons.

[43] I conclude that the criterion set forth in s. 4(b) of the **Act** has been met.

Section 4(c) - Common Issues

[44] Section 4(c) of the **Act** requires that the claims of the class members raise a common issue, whether or not the common issue predominates over issues affecting only individual members.

[45] Section 4(c) requires that the action raise common issues of fact or law. They need not be determinative of liability nor dominant issues in the litigation.

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But they must be issues common to all members of the class in the sense that their decision at a common issues trial will advance the litigation in some meaningful way. Are the common issues ones that will have to be decided in respect of the claim of every member of the class, and will their being decided in a representative action avoid duplication of fact-finding or legal analysis?

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[46] The plaintiffs here propose the following common issues:

(1) Does Baycol cause serious side effects and, if so, what are the nature and extent of those side effects?

(2) Was Baycol defective and/or unfit for its intended use?

(3) Was the defendant negligent and, if so, when and how?

(4) Did the defendant owe a duty of care to the class members?

(5) Did the defendant breach the standard of care expected of it and, if so, when and how?

(6) Should the defendant pay punitive damages, and, if so, to whom should they be paid, and in what amount?

Common Issue No. 1: Does Baycol cause serious side effects and, if so, what are the nature and extent of those side effects?

[47] The plaintiffs assert that common issue no. 1 is a common issue of fact. What problems did Baycol actually cause? How serious were its effects? They assert that these questions forming the proposed common issue are issues of

fact common to all class members and are contentious between them and the defendant. The defendant asserts that Baycol was simply a typical statin with the typical potential side effects associated with all statins in respect of which warnings were given and that there is no evidence before the court to suggest that Baycol was defective.

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[48] I disagree. One fact untypical of Baycol as compared with other statins is that its manufacturer withdrew Baycol from the market. Additionally, as I have already written, Douglas Grant swore:

> In the case of Baycol, as of September 15, 2003, Bayer Inc.'s Drug Safety and Medical Information Department has received directly and through Health Canada 179 spontaneous reports which Bayer Inc. has, after investigation, classified as "serious" cases.

[49] Furthermore, he swore that as of September 15, 2003, the defendant had received 393 spontaneous reports which are described as "non serious" cases, directly and through Health Canada.

[50] The certification stage is not a merits based determination. It may be that in due course, a determination will be made that none of the plaintiffs suffered any serious or provable effects from Baycol but there is evidence including that from the defendant of complaints which it has investigated and classified as serious cases.

[51] A factual inquiry as to the nature of the problems caused by an allegedly defective drug is an appropriate common issue. Cumming J. so found in ***Wilson, supra*** and in my view the same applies in this case. This issue is one

which can be determined at a common issues hearing and which will turn essentially on the evidence of expert witnesses. It will not require the evidence of plaintiffs who are members of the class. As well, a determination of this issue will advance the litigation.

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Common Issue No. 2: Was Baycol defective and/or unfit for its intended use?

[52] A number of cases have determined that a products liability case alleging defectiveness or unfitness for purpose is one ideally suited for class determination. In ***Harrington v. Dow Corning Corp.*** (2000), 82 B.C.L.R. (3d) 1, a decision of the British Columbia Court of Appeal, the court, at pp. 21-22, wrote:

> At the risk of oversimplifying a complex decision-path, I venture to suggest the first step in every products liability case alleging negligent design, manufacture, or marketing is the determination of whether the product is defective under ordinary use or, although non-defective, has a propensity to injure. Some American authorities refer to this step as "general causation", whether a product is capable of causing the harm alleged in its ordinary use.
>
> The second step is the assessment of the state of the manufacturer's knowledge of the dangerousness of its product to determine whether the manufacturer's duty was not to manufacture and distribute, or to distribute only with an appropriate warning. It may be prudent to refer to this as an assessment of the state of the art; it may be that a manufacturer did not but should have known of its product's propensity for harm.

[53] This common issue will raise a factual and legal inquiry into whether Baycol was defective and/or unfit for its intended purpose. It will entail a risk-based assessment of Baycol comparing it to other statins and, in particular, will

provide an opportunity for assessment of the state of the defendant's knowledge as to the dangerousness and/or unfitness of its product.

[54] This issue is one common to all proposed class members and its determination will advance the litigation.

[55] Again, this is not a merits based determination.

[56] But there is evidence before me to which I have already referred, specifically the Summary of Reported Adverse Drug Reactions from Health Canada and the affidavit of Douglas Grant, which is sufficient to meet the necessary evidentiary burden required on a certification motion.

Common Issue No. 3: Was the defendant negligent and, if so, when and how?

Common Issue No. 4: Did the defendant owe a duty of care to the class members?

Common Issue No. 5: Did the defendant breach the standard of care expected of it and, if so, when and how?

[57] In ***Bouchanskaia v. Bayer Inc.***, [2003] B.C.J. No. 1969, Gray J. of the British Columbia Supreme Court, in the certification application of the Baycol class proceeding commenced in British Columbia, did not certify the issue whether the defendant owed a duty to the class members but rather combined that issue with the issue of whether a duty of care was breached. In ***Wheadon***, Barry J. exercised his discretion to combine common issues nos. 3, 4 and 5 into one common issue, namely, "Did the Defendant breach a duty of care owed to

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class members and if so, when and how?" In ***Wheadon***, the plaintiffs advised that they were amenable to this approach and they have similarly advised me of that position here. Moreover, counsel advised that the case before me was identical in all material respects to ***Wheadon***. In the circumstances, I choose to exercise my discretion, as did Barry J. in ***Wheadon***, to combine common issues nos. 3, 4 and 5 into one common issue as he did, namely, "Did the Defendant breach a duty of care owed to class members and if so, when and how?"

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[58] The defendant admits that it owed a duty of care to patients prescribed Baycol but seems to assert that that duty was to provide adequate warnings concerning its potential side effects. It asserts that this proposed common issue is one which cannot be determined on a basis that is common to all class members and that its resolution would not materially advance the interests of each and every member of the putative class. It says instead that this is an issue that will be dependent upon the individual circumstances of each claimant tied to the state of the defendant's knowledge from time to time, as well as the state of knowledge of the individual class members and/or their advisers at the time the medication was ingested.

[59] In addition, the defendant asserts that it would still be necessary to determine whether the failure to meet the duty of care was the proximate cause of the harm suffered by any claimant which issue of legal causation will depend

on numerous individual factors, including the role of the prescribing physician, and can only be resolved on an individual basis.

[60] Even assuming proof of a breach of the duty of care as a common issue, there is no doubt that each class member will have to prove causation and damages and that this will require individualized hearings. But it is clear that the need for individualized hearings does not preclude a class proceeding.

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[61] The issue of breach of duty of care is one that has been frequently certified in products liability class actions and, from the perspective of a common issue, focuses upon the defendant's knowledge and conduct from time to time. It is an issue which will advance the litigation. If this common issue were determined in favour of the defendant, the litigation would end. If it is not, the issue would have been proved once and for all and would assist in moving the litigation forward to individualized hearings with respect to causation and presumably other individualized issues as well. Again, this common issue can be resolved without participation of class members.

Common Issue No. 6: Should the defendant pay punitive damages, and, if so, to whom should they be paid, and in what amount?

[62] The defendant asserted before me, as it did before Barry J. in ***Wheadon***, that before a court should certify as a common issue whether punitive damages would be awarded, there must first be a finding that there is at least one common issue relating to claims for compensatory damages that would

materially advance the interests of all class members. It asserted as well that there are no colourable claims for compensatory damages that give rise to common issues in this case which would advance the interests of all class members and accordingly, a claim for punitive damages should not be certified as a common issue.

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[63] Barry J., at p. 194 of ***Wheadon***, wrote:

> As I have decided above that there are colourable claims for compensatory damages that give rise to certifiable common issues, these objections of Bayer no longer apply. ... Whether the plaintiffs are entitled to punitive damages and the quantum thereof is entirely dependant on the conduct of the defendant. It is a common issue which can be decided without the involvement of class members.

[64] I agree with his comments and inasmuch as I, too, have decided that there are colourable claims for compensatory damages that give rise to certifiable common issues, the defendant's objections no longer apply in the case before me. I am prepared to certify this as a common issue.

Section 4(d) – Preferable Procedure for Fairness and Efficiency

[65] In ***Hollick***, McLachlin C.J. wrote, at p. 176:

> ... [T]he preferability inquiry should be conducted through the lens of the three principal advantages of class actions — judicial economy, access to justice, and behaviour modification....

And, at pp. 177-78, she wrote:

> ... "[P]referable" was meant to be construed broadly. The term was meant to capture two ideas: first the question of "whether or not the class proceeding [would be] a fair, efficient and manageable method of advancing the claim", and second, the question of whether a class proceeding would be preferable "in the sense of preferable to other procedures such as joinder, test cases, consolidation and so on".... In my

> view, it would be impossible to determine whether the class action is preferable in the sense of being a "fair, efficient and manageable method of advancing the claim" without looking at the common issues in their context.
>
> The Act itself, of course, requires only that a class action be the preferable procedure for "the resolution of the common issues" (emphasis added) ....
>
> The question of preferability, then, must take into account the importance of the common issues in relation to the claims as a whole.

[66] She went on to write that the **Ontario Act** contemplates that class actions would be allowable even where there are substantial individual issues, that it was not necessary that the common issues "predominate" over the individual issues, and that in the preferability analysis the court should look to all reasonably available means of resolving the class members' claims and not simply the possibility of individual actions.

[67] In this case, the defendant has argued that there exists a very large number of individual issues which would have to be determined in order to finally dispose of the litigation. Indeed, in its brief, it listed them, as seen by the defendant. The list is long and the issues are significant.

[68] The defendant argues that any common issue, or the common issues as a whole, would be overwhelmed by the individual issues that would need to be decided to resolve the litigation. It argues as well that given the substantial number and importance of the individual issues, judicial economy would not be enhanced nor would duplication of fact-finding or legal analysis be avoided by the certification of the proceeding.

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[69] I do not agree. While it is undoubtedly true that there will be many, and many important, individual issues which may have to be decided before this case is finally resolved, there clearly are common issues of importance which can be decided once only, thus avoiding possible inconsistency in fact-finding and enhancing judicial economy and the advancement of the litigation.

[70] As well, certification of the proceeding will clearly promote access to justice. This case, as with so many products liability cases, is one where the cost of litigating a claim on an individual basis will, if it does not exceed the amount of the likely recovery, be wholly disproportionate to it. In the result a requirement for individual claims as distinct from class proceedings would substantially inhibit, if not wholly prohibit, the ability of individuals to advance what they consider to be a justifiable claim.

[71] As regards behaviour modification, the defendant asserts that Baycol was withdrawn voluntarily, that it was not required to do so by Health Canada, and that the drug has not been sold in Canada since August 8, 2001. While the plaintiffs dispute this to some degree, there is certainly evidence that the defendant did act voluntarily and responsibly at the time of the withdrawal of Baycol and in the steps it instituted thereafter with respect to refunding patients for their purchase of the drug.

[72] As well, it has embarked upon a program of attempting to resolve claims for anyone who has experienced serious side effects and in particular

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rhabdomyolysis as a result of taking Baycol, notwithstanding that it does not admit liability and has defended claims advanced.

[73] But that is only one aspect of the issue of behaviour modification. Another was succinctly stated by McLachlin C.J. in ***Western Canadian*** where she wrote, at p. 550:

> ... [C]lass actions serve efficiency and justice by ensuring that actual and potential wrongdoers do not ignore their obligations to the public. Without class actions, those who cause widespread but individually minimal harm might not take into account the full costs of their conduct, because for any one plaintiff the expense of bringing suit would far exceed the likely recovery.

[74] And in ***Wilson***, Cumming J. wrote, at p. 250:

> Finally, the policy objective of behaviour modification is fostered through a class proceeding. If a drug is defective and liability attaches to a manufacturer or seller, a significant incidental result is that the pharmaceutical industry is more likely to take greater care in the development and testing of new products to ensure their safety before marketing them. ... The *CPA*'s goal has been described as inhibiting "misconduct by those who might ignore their obligations to the public".... The *CPA* serves to assist in regulating the pharmaceutical industry for an important public policy objective through class proceedings commenced in the private sector.

[75] Consistent with the foregoing comments, I conclude that requiring the proposed class members to proceed on an individual claim basis would not be the appropriate procedure here. Nor in my view would joinder of individual claims or a test case for purposes of resolving the common issues. As well, a class proceeding under the **Act** permits both the resolution on a one-time basis of the common issues and the determination of individual issues.

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[76] I conclude that a class proceeding would be the preferable procedure for this case.

Section 4(e) – Representative Plaintiff

[77] Section 4(e) of the **Act** states there must be a person who is prepared to act as the representative plaintiff who would fairly and adequately represent the interests of the class, who has produced a workable litigation plan for the class proceeding, and who is not in a conflict of interest on the common issues with the interests of other class members.

[78] In this case, Marilyn Walls is proposed as the representative plaintiff. The defendant argues that she does not qualify as a representative plaintiff, as on the evidence she does not have a colourable claim. I have already decided otherwise. I am satisfied on the evidence that she is one who would fairly and adequately represent the interests of the class. She does not have a conflict of interest on the common issues with the interests of the other class members.

[79] As well, I am satisfied that the litigation plan put forward by the plaintiffs' counsel on her behalf is a workable and suitable litigation plan for advancement of this action as a class proceeding on behalf of all class members. The litigation plan can of course be amended as the action progresses.

[80] In the circumstances, I have no hesitation in deciding that the criterion set forth in s. 4(e) has been satisfied.

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[81] In conclusion, I am satisfied that all of the statutory criteria set forth in s. 4 of the **Act** have been satisfied by the plaintiffs.

[82] I, therefore, allow the plaintiffs' motion for certification of the proceeding as proposed and in respect of the common issues as proposed.

[83] Counsel should proceed immediately to settle the terms of the certification order.

[84] Both judicial authority and s. 5(2) of the **Act** make clear that a certification hearing is not a merits based hearing. I have stated that on several occasions in the course of these reasons. I did so because almost invariably, in my view, the arguments advanced by the defendant were arguments that invited a merits determination based upon evidence submitted by the defendant. As is clear, the **Act** contemplates and provides for a bifurcated process. In due course, the defendant will have the opportunity to proceed in a fashion that will necessitate a merits based determination.

[85] The defendant's motion brief was filed December 16, 2003. In its brief, it argued that the action should be stayed and/or the motion adjourned pending the hearing of a certification motion in the proceeding commenced in Ontario. In early January 2004, I allowed the defendant's application for adjournment. Thereafter, as referred to in these reasons, a settlement agreement was negotiated in respect of the Ontario proceeding (as has also occurred in British Columbia and in Quebec). When the plaintiffs' certification motion was argued

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before me on September 8, 9 and 10, 2004, the application for stay of this action was not renewed.

[86] Notwithstanding that, I would be prepared to entertain such a motion at this time should either party wish to apply. There is clearly a tension between the interests of the plaintiffs and of the defendant. But the jurisprudence tells us that two of the advantages of a class action proceeding are judicial economy and the avoidance of unnecessary duplication of fact-finding or legal analysis. In my view, this applies to a possible multiplicity of proceedings not simply within a province, but throughout the country.

[87] In this case, as I have already written, the plaintiffs' counsel acknowledged that the Newfoundland and Labrador proceeding (***Wheadon***) was virtually identical in terms of facts, evidence and issues to this action. What is the judicial economy of having proceedings go forward in two provinces and with the accompanying risk of inconsistent findings?

[88] On the other hand, I understand that the plaintiffs who are residents of Manitoba have an entitlement to their day in court with reasonable dispatch. Again, however, the jurisprudence tells us that the court should attempt to strike a balance between efficiency and fairness. While recognizing the interests of the plaintiffs, is it fair that the defendant should have to defend essentially the same action in more than one province?

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[89] Regrettably, there is no legislation that would take control of a class proceeding for all of Canada. I am told by counsel that there is often informal accommodation achieved between counsel for the various parties. In my view, that is something that ought certainly to be done here. A stay of this action for a period of time to permit such attempts to be concluded is something that may be considered by the parties or may be sought by the defendant.

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______________________________J.