2009 Hfx. No. 315567

SUPREME COURT OF NOVA SCOTIA

B E T W E E N:

ALBERT CARL SWEETLAND and BARBARA FONTAINE

Plaintiffs

- and -

GLAXOSMITHKLINE INC. and GLAXOSMITHKLINE LLC

Defendants

Proceeding under the *Class Proceedings Act,* S.N.S 2007, c. 28

PLAINTIFFS' BRIEF RE:

MOTION FOR SETTLEMENT APPROVAL

HEARING DATE – JANUARY 29, 2019

Wagners
Suite PH301, Historic Properties
1869 Upper Water Street
Halifax, NS B3J 1S9
Solicitors for the Plaintiffs
Filed: December 14, 2018

PART I – OVERVIEW

1. The parties have reached a national Settlement Agreement[1] to resolve claims against the Defendants arising from the manufacture, marketing, distribution and sale of Avandia.

2. The Settlement Agreement provides for a minimum payment of $4,166,666 and a maximum payment of $6,750,000, depending upon the number of Settling Claimants approved for compensation under the proposed settlement.

3. Class Counsel believe the Settlement Agreement is in the best interests of Class Members. The Settlement Agreement provides compensation and certainty to Class Members. It avoids the delays and uncertainty of outcome associated with continuing litigation.

4. The proposed settlement is a product of compromise and it reflects the various risks of continuing litigation.

5. This case was certified as a class proceeding by Court order issued on December 7, 2016.[2] An appeal by the Defendants is currently in abeyance.[3] If litigation continues, there is a risk that certification may be defeated on one or more of the several grounds outlined by the Defendants in their Appeal Factum filed June 2, 2017, as more fully described below in Part IV(iii)(a).[4]

[1] Unless otherwise stated or required by context, the capitalized terms in this brief have the meanings given to them in the Settlement Agreement.
[2] Affidavit of Madeleine Carter affirmed December 14, 2018 and filed in support of the Plaintiffs' motion seeking approval of the Settlement Agreement ("Settlement Approval Affidavit"), para. 5.
[3] Settlement Approval Affidavit, para. 11.
[4] Settlement Approval Affidavit, para. 9, Exhibit "C".

6. If certification was upheld by the Court of Appeal, there is the risk the action may fail on its merits – at the common issues trial focusing on liability, or at the subsequent stage of assessing individual issues – on the basis of the various defences outlined by the Defendants in their Statement of Defence filed March 13, 2017, as more fully described below in Part IV(iii)(b).[5]

7. For the reasons expressed herein, it is respectfully submitted that the proposed settlement is within the range of reasonableness.

8. The settlement has been structured so that individuals who meet clearly defined eligibility criteria will be entitled to compensation. The settlement contemplates a fair and efficient resolution of these claims.

9. Accordingly, the Plaintiffs respectfully request an order: (i) approving the Settlement Agreement as being fair, reasonable and in the best interests of Class Members; (ii) approving the Settlement Approval Notice and Settlement Approval Notice Plan; and (iii) appointing RicePoint Administration Inc. as the Claims Administrator.

PART II - THE FACTS

i. Background

The Allegations & Regulatory Landscape

10. A proposed class action was commenced in this Honourable Court on August 18, 2009, on behalf of a primary class of individuals resident in Canada who were prescribed and

[5] Settlement Approval Affidavit, para. 8.

ingested Avandia, and a family class of their relatives entitled to make a claim under the *Fatal Injuries Act*, R.S.N.S. 1989, c. 163. The pleadings were then subject to three amendments: an Amended Statement of Claim was filed on July 27, 2010, a Fresh as Second Amended Statement of Claim was filed on June 5, 2015, and a Third Fresh as Amended Statement of Claim was filed on November 2, 2018. This final amendment was to reflect the substitution of Barbara Fontaine as the new representative plaintiff of the certified Family Class.[6]

11. For the purposes of the litigation, the term Avandia refers to three drugs: Avandia, Avandamet and Avandaryl. They all contain the ingredient rosiglitazone.[7]

12. The present action alleges that Avandia increases a user's risk of suffering adverse cardiovascular events, including congestive heart failure and ischemic heart attacks. As a result, the Plaintiffs allege, Avandia is defective or unfit for use, because it poses an unreasonable risk of harm. The Plaintiffs also allege that the Defendants failed to sufficiently warn Canadians about the risk of cardiovascular events caused by Avandia.[8]

13. The background against which this action occurs is an approximately eleven-year period during which research was undertaken into the association between Avandia and cardiovascular health. In response to the research, various regulatory actions were taken – and in some cases, subsequently retracted. During this period of time, the various statements and warnings by the Defendants relating to the association between Avandia and cardiovascular health were modified.

[6] Settlement Approval Affidavit, para. 3.
[7] Settlement Approval Affidavit, para. 4.
[8] Settlement Approval Affidavit, para. 4.

14. In April 2001, the Defendants undertook a six-year study titled Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycaemia in Diabetes (the "RECORD Study"). The RECORD Study compared the cardiovascular outcomes of Avandia with those of other commonly used diabetes medications, such as metformin and sulfonylurea.[9] Early results were reported to the United States Food and Drug Administration (the "FDA") in August 2006, indicating an increased risk of myocardial ischemic events in Avandia users.[10] Later interim results also indicated that Avandia users faced an increased likelihood of suffering heart failure.[11]

15. In 2007, in light of these interim results of the RECORD Study and other contemporaneous research into the connection between Avandia and cardiovascular health (as described in the Plaintiffs' certification record[12]), Health Canada required the Defendants to draw the attention of healthcare professionals to the apparent cardiovascular safety issues seemingly posed by Avandia, in the form of a public "Dear Healthcare Professional Letter". This warned of the "cardiac safety of Avandia", specifically myocardial infarction and cardiovascular death. Health Canada also placed restrictions on the prescription of Avandia, in that: (i) it was no longer approved as monotherapy or with sulfonylurea, except when metformin was not tolerated/contraindicated; (ii) it was contraindicated with all stages of heart failure; and (iii) it was not to be used with insulin or as triple therapy.[13]

[9] Affidavit of Lorraine Lipscombe, sworn January 15, 2015, para. 55 ("Lipscombe Affidavit"). The Lipscombe Affidavit was filed in support of the Plaintiffs' motion for certification.
[10] *Ibid*., para. 62.
[11] *Ibid*., paras. 89 and 90.
[12] Lipscombe Affidavit, paras. 55-68, 77-89 and Exhibits "F", "G", "I", "J", "K" and "L". See also Plaintiffs' Certification Brief for further explanation at paras. 12-25.
[13] Lipscombe Affidavit, paras. 73, 75 and 76; Affidavit of Michael Dull, sworn November 28, 2014, Exhibits "D", "G" and "H", filed in support of the Plaintiffs' motion for certification.

16. Additionally, on November 9, 2010, Health Canada implemented a "Patient Informed Consent Process" requiring patients to acknowledge in writing they had been informed of the heart-related risks of Avandia and were aware of other treatment options.[14] The product monograph for Avandia also came to include a black box warning that it causes fluid retention and congestive heart failure (although a warning regarding heart failure applicable to the whole class of thiazolidinediones ("TZDs") had been present since the first product monograph), and warning of an increased risk of cardiac ischemia.[15]

17. Avandia litigation in Canada was filed in the context of the then-current scientific literature and regulatory steps taken at the time highlighting the link between Avandia and cardiovascular risks. The present action was filed in August, 2009.

18. Subsequently, however, in 2013 a re-adjudication of the RECORD Study was undertaken through Duke University concluding, contrary to earlier interim findings, that it is not clear whether the risk of death, heart attack and stroke were truly different between rosiglitazone and metformin plus sulfonylurea.[16] Indeed with respect to stroke, the results of the re-adjudication of the RECORD Study suggested that in fact the incidence of stroke when taking Avandia may be lower than a comparator drug, as described further in paragraph 80, below.

19. In light of this development in the scientific literature that had previously supported the link between Avandia and cardiovascular risks, and largely on the basis of the re-

[14] Lipscombe Affidavit, para. 93 and Exhibit "N".
[15] Lipscombe Affidavit, paras. 71-72.
[16] Lipscombe Affidavit, para. 94; Affidavit of Rosalyn Theodore-McIntosh, sworn March 26, 2015, Exhibits "B", "C" and "D" ("Theodore-McIntosh Affidavit"). The Theodore-McIntosh Affidavit was filed by the Defendants in opposing the Plaintiffs' motion for certification.

adjudication of the RECORD Study, there was a reversal of the regulatory restrictions in the United States: in November 2013, the FDA concluded that Avandia did not appear to differ substantially from other anti-diabetic drugs in its risk of major cardiovascular events and death (other than the known and disclosed link between the whole class of TZD drugs and heart failure). There was removal of a black box warning for heart failure that the Defendants had, in May 2007, been required to add, and removal of a black box warning for heart attack that had been added in November 2007.[17]

20. The developments in the scientific research and regulatory action that had previously strengthened the Plaintiffs' action were repeatedly raised by the Defendants throughout this litigation, and were considered by Class Counsel in determining whether and how to resolve this action.

Procedural History of this Action

21. Legal proceedings, including proposed class actions, were filed in other jurisdictions across Canada. None has been certified other than the present action.

22. On December 7, 2016, this Honourable Court issued an order certifying the within action as a class proceeding (the "Certification Order"). The certified Classes are defined as:

    (a) All persons in Canada, including their estates, who were prescribed and ingested Avandia (the "Primary Class") and

[17] Theodore-McIntosh Affidavit, Exhibits "B", "C" and "D".

(b) The spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents and siblings of deceased members of the Primary Class (the "Family Class").

23. On December 22, 2016, the Defendants filed a Notice of Application for Leave to Appeal and Notice of Appeal (Interlocutory) with the Nova Scotia Court of Appeal seeking to reverse the Certification Order.[18]

24. On January 27, 2017, the Nova Scotia Court of Appeal issued an order, consented to by the Plaintiffs/Respondents, granting leave to appeal to the Defendants.[19]

25. On March 13, 2017 the Defendants filed their Statement of Defence with this Honourable Court.[20]

26. The hearing of the Defendants' appeal has been placed in abeyance until March 29, 2019 to allow the parties to engage in exploratory settlement discussions, such that if the proceeding has not been resolved by March 29, 2019, the parties are to seek the direction of the Nova Scotia Court of Appeal.[21] Notwithstanding that the appeal was ultimately placed in abeyance, the facta of the parties were filed with the Nova Scotia Court of Appeal. On June 2, 2017 the Defendants/Appellants filed their factum in support of their appeal.[22] On August 1, 2017 the Plaintiffs/Respondents filed their factum in response to the appeal.[23] Section 3.2 of the Settlement Agreement expressly reserves the Defendants' rights to

[18] Settlement Approval Affidavit, para. 6, Exhibit "A".
[19] Settlement Approval Affidavit, para. 7, Exhibit "B".
[20] Settlement Approval Affidavit, para. 8.
[21] Settlement Approval Affidavit, para. 11.
[22] Settlement Approval Affidavit, para. 9, Exhibit "C".
[23] Settlement Approval Affidavit, para. 10, Exhibit "D".

appeal the Certification Order if the Settlement Agreement is not approved or is otherwise terminated pursuant to its provisions.

27. On October 23, 2018, this Court issued a Consent Order to amend the Second Amended Notice of Action and Statement of Claim, and an Amended Certification Order, both orders to reflect the substitution of a new representative plaintiff of the Family Class.[24]

Other Proposed Avandia Class Actions

28. Other legal proceedings relating to Avandia have been commenced across Canada. A list of 16 of these proceedings and their respective statuses as of July 9, 2018 is attached as Exhibit "F" to the Settlement Approval Affidavit. There is another list of these proceedings (without their respective statuses) attached as Exhibit "B" to the Settlement Agreement; it lists 18 proceedings, as it includes the proposed class action filed in Alberta by Docken & Company: *Ralito Bernales v. GlaxoSmithKline Consumer Healthcare Inc, et al*, Court File Nos. 1001-14991 and 1301-05007, and the action filed in Nova Scotia by Merchant Law Group, *Ronald Finck v. Glaxosmithkline Inc. et al*., Court File No. SH-300379.[25]

29. On April 30, 2012, August 1, 2014 and September 18, 2014, Siskinds LLP filed three individual actions relating to Avandia in Ontario. These actions allege negligence in design and warnings, which caused or materially contributed to each of the plaintiffs suffering cardiovascular harm. The background to the decision by Siskinds to file these individual actions is provided in paragraph 43, below.[26]

[24] Settlement Approval Affidavit, para. 12.
[25] Settlement Approval Affidavit, para. 14.
[26] Settlement Approval Affidavit, para. 15, Exhibits "G", "H", "I".

30. Kim Orr Barristers P.C. ("Kim Orr") is counsel in *Lloyd et al. v. GlaxoSmithKline Inc. et al* (Court File No. CV-11-434420-00CP), commenced in 2007 by the Merchant Law Group. In 2010, Kim Orr and Merchant Law Group agreed that Kim Orr would be the lead counsel and the two firms would work together.[27]

31. McPhadden Samac Tuovi ("MCST") is counsel for the plaintiffs in *Waheed v. GlaxoSmithKline Inc. et al*, Court File No. CV-09-385922CP, an overlapping Avandia proposed class action filed in Ontario in 2009.[28]

32. In November, 2010, carriage motions brought by Kim Orr and MCST were heard by Justice Strathy of the Ontario Superior Court of Justice. After the hearing but before the release of the Court's decision, the parties agreed to settle the carriage motion on the basis that Kim Orr would be appointed counsel for the plaintiffs in the *Lloyd* class action, and the *Waheed* action would be effectively stayed. The parties agreed that the MCST consortium would be permitted to participate in the class action but only at Kim Orr's discretion and that no steps could be taken without Kim Orr's approval. This agreement resulted in a consent carriage order dated November 19, 2010.[29]

33. In 2012, MCST brought a motion to transfer carriage to it, arguing that despite nearly three years passing, Kim Orr had still not brought a motion for certification. MCST said that it had prepared a certification record and asked that it be granted carriage of the proposed class action. Justice Belobaba of the Ontario Superior Court of Justice denied this request.[30]

[27] Settlement Approval Affidavit, para. 16, Exhibit "J".
[28] Settlement Approval Affidavit, para. 17.
[29] Settlement Approval Affidavit, para. 18.
[30] Settlement Approval Affidavit, para. 19.

34. The certification hearing in the *Lloyd* action began in December 2014. The certification motion was then adjourned to allow the plaintiffs to file better evidence. The motion has not resumed.[31]

35. Meanwhile the within action proceeded to certification, with the cooperation of Related Counsel Firms: McPhadden Samac Tuovi LLP, Consumer Law Group (formerly Orenstein & Associates), Ches Crosbie (formerly of Russell Accident Law) and Clint Docken. Consumer Law Group is counsel in the QC action of *Donna Woods v. GlaxoSmithKline Inc. et al*, Court File No. 500-06-000409-074. Consumer Law Group agreed to a temporary stay of the *Woods* action in February, 2017 in light of, and to support, the advancement of the within *Sweetland* action.[32] Ches Crosbie is counsel in the action *Clyde Wiseman v. GlaxoSmithKline Inc. et al*, Court File No. 2582 CP, filed in Newfoundland and Labrador. Clint Docken is counsel in the action *Ralito Bernales v. GlaxoSmithKline Consumer Healthcare Inc, et al*, Court File Nos. 1001-14991 and 1301-05007, filed in Alberta.

Settlement Discussions and Role of Siskinds

36. Siskinds began investigating Avandia-related claims in or around early 2007. While Siskinds did not commence a class proceeding, Siskinds took a number of steps to advance the Canadian Avandia litigation.[33]

[31] Settlement Approval Affidavit, para. 20.
[32] Settlement Approval Affidavit, para. 21.
[33] Settlement Approval Affidavit, para. 22.

37. In or around early 2010, after monitoring Avandia litigation and noting regulatory steps taken by Health Canada, Siskinds began to be retained by individuals with potentially strong claims.[34]

38. As no significant progress was being made at the time in the proposed Avandia class proceeding in Ontario, Siskinds began reviewing and preparing its individual Avandia cases for potential litigation.[35] Siskinds obtained and reviewed their clients' medical and pharmacy records (where available) and engaged in discussions with an expert in the field of cardiology to assist in evaluating these individual claims.[36]

39. On April 30, 2012, Siskinds filed the first of three individual actions, *Vinerskis v GlaxoSmithKline Inc*. (the "Vinerskis Action").[37] The parties to the Vinerskis Action engaged in protracted negotiations aimed at agreeing upon a Discovery Plan, including documentary production. As a result, the parties attended multiple Status Hearings and motions to extend the court-ordered timelines.[38]

40. In tandem with the pursuit of the Vinerskis Action, in June 2012 Siskinds commenced preliminary resolution discussions with Canadian and US defence counsel regarding Siskinds' individual claims.[39]

[34] Settlement Approval Affidavit, para. 23.
[35] Settlement Approval Affidavit, para. 24.
[36] Settlement Approval Affidavit, para. 25.
[37] Settlement Approval Affidavit, para. 26.
[38] Settlement Approval Affidavit, para. 27.
[39] Settlement Approval Affidavit, para. 28.

41. In or about November 2013, Siskinds provided US defence counsel with medical briefs for 150 of its individual cases for the purpose of engaging in settlement discussions. However these discussions failed to result in an agreement.[40]

42. After communications with US defence counsel failed to result in an agreement, Siskinds filed two additional individual actions in Ontario. *Fontaine v GlaxoSmithKline Inc*. was commenced by Statement of Claim dated August 1, 2014, and *Ravindrakumar v GlaxoSmithKline Inc*. was commenced by Statement of Claim dated September 18, 2014.[41]

43. Siskinds pursued individual litigation through these three "test cases", asserting different cardiovascular injuries, with knowledge that the filed class actions suspended applicable limitation periods, and that recommendations to clients relating to opting out of any certified class actions were never required as no opt out deadline ever arose.[42]

44. In or about November 2014, Siskinds approached Motley Rice LLC in an effort to re-engage in settlement discussions with US defence counsel.[43] Motley Rice LLC is a national plaintiffs' litigation firm in the US. Counsel from Motley Rice LLC sat on the Plaintiff Steering Committee for the Avandia Multi District Litigation ("MDL") before Judge Rufe in the Eastern District of Pennsylvania. Motley Rice settled a number of individual cases filed in the MDL, which included negotiating an Avandia Master Settlement Agreement.[44]

[40] Settlement Approval Affidavit, para. 29.
[41] Settlement Approval Affidavit, para. 30.
[42] Settlement Approval Affidavit, para. 31.
[43] Settlement Approval Affidavit, para. 32.
[44] Settlement Approval Affidavit, para. 33.

45. Siskinds engaged in discussions concerning resolution of the Siskinds' case inventory at various points in time, including with the Defendants' US settlement counsel, and at times through Motley Rice.[45]

46. In late 2015, Siskinds, working with Motley Rice LLC, re-engaged in negotiations with US defence counsel. The parties were able to reach an agreement in principle regarding which claims would be eligible for compensation.[46] However, no damages values were discussed.[47]

47. Around the same time, Siskinds and Canadian defence counsel reached an agreement for the Discovery Plan with respect to the three individual actions filed in Ontario by Siskinds.[48]

48. In February 2016, US defence counsel expressed interest to Siskinds in resolving all Canadian Avandia claims on a national basis.[49] Siskinds agreed to pause the individual actions in Ontario and to work collaboratively with Wagners to negotiate a Canada-wide settlement. By this time, the certification hearing with respect to the within action had been heard (September 15-18, 2015), and the Court had issued a January 15, 2016 decision inviting the Plaintiffs to submit further evidence on certain aspects of the certification test. On February 26, 2016, the Plaintiffs filed their supplemental evidence (and the Certification Order was later issued, on December 7, 2016).[50]

[45] Settlement Approval Affidavit, para. 34.
[46] These claims are part of the Pre-Approved Claimants, listed in the confidential schedule to the Settlement Agreement, who are deemed to be Approved Claimants under the Settlement Agreement.
[47] Settlement Approval Affidavit, para. 35.
[48] Settlement Approval Affidavit, para. 36.
[49] Settlement Approval Affidavit, para. 37.
[50] Settlement Approval Affidavit, para. 38.

49. On or about March 28, 2016, Siskinds and Wagners met with US and Canadian defence counsel in Philadelphia and began negotiating a national resolution to include the certified national class and the individual claims represented by Siskinds.[51]

50. This meeting did not result in a resolution, and there were no material resolution discussions subsequent to this, until after the within class action was certified.[52]

Negotiations and Settlement

51. Against the background of the action being certified and the Defendants filing an appeal, the parties entered into exploratory settlement discussions.[53]

52. Through a series of meetings and conference calls over the course of eleven months, the parties reached an agreement in principle to resolve these actions.[54]

53. The settlement was reached on the basis of a hybrid settlement structure, consisting of both a fixed payment (i.e. the Minimum Settlement Amount) and an additional, claims-made component (i.e. additional payment up to the Maximum Settlement Amount, based upon the number of Approved Claims). The Defendants' position was to restrict compensable conditions and minimize payments. Extensive negotiations occurred relating to structure, compensable conditions, eligibility criteria, and amount to be paid per claim. The nature of the compensable injury, causation, warnings and other matters were all debated at length.[55]

[51] Settlement Approval Affidavit, para. 39.
[52] Settlement Approval Affidavit, para. 40.
[53] Settlement Approval Affidavit, para. 41.
[54] Settlement Approval Affidavit, para. 41.
[55] Settlement Approval Affidavit, para. 41.

54. The final Settlement Agreement was executed on October 11, 2018. A copy of the Settlement Agreement is attached as Exhibit "E" to the Settlement Approval Affidavit.

ii. The Settlement Agreement

55. The Settlement Agreement resolves all outstanding Avandia litigation in Canada.

56. The settlement Class is defined as all persons in Canada, including their estates, who were prescribed and ingested Avandia ("Primary Class") and the spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents and siblings of deceased members of the Primary Class ("Family Class"), who do not Opt Out of the Nova Scotia Proceeding.

57. Only Approved Claimants are eligible to receive compensation pursuant to the Settlement Agreement. Eligibility criteria are described below, in Part II(ii).

58. Class Members have a period of eight months after the Settlement Approval Notice is published during which to file their claims.[56]

59. To be an Approved Claimant, the Class Member must file a Claim Form with the Claims Administrator. Subject to approval of this Honourable Court, RicePoint Administration Inc. will be the Claims Administrator.

60. The Settlement Agreement provides for a Settlement Payment that is dependent upon the number of Settling Claimants (defined as Approved Claimants who return a signed release, in accordance with the Settlement Agreement). The Settlement Payment will not exceed

[56] Section 10, Settlement Agreement.

CAD$6,750,000. This is the Maximum Settlement Amount. The Minimum Settlement Amount is $4,166,666.67. These amounts are inclusive of compensation for Settling Claimants and the PHIs as well as interest, tax, costs, Class Counsel Legal Fees and Claims Administration Costs.[57]

61. Pursuant to section 5.1(a) of the Settlement Agreement, the Minimum Settlement Amount will be allocated as follows:

(a) $250,000 will contribute to disbursements and administration expenses;

(b) $3,666,666.67 will be paid for up to 200 Settling Claimants who satisfy criteria for a myocardial infarction ("MI"), coronary artery bypass grafting ("CABG") or percutaneous coronary intervention with stent placement ("Stenting") claim (that is, $18,333.33 per Settling Claimant, assuming there are 200 MI/CABG/Stenting Settling Claimants; there will be a *pro rata* increase if there are fewer than 200 MI/CABG/Stenting Settling Claimants);

(c) $200,000 will be paid for up to 60 Settling Claimants who satisfy criteria for a congestive heart failure ("CHF") claim (that is, $3,333.33 per CHF Settling Claimant, assuming there are 60 CHF Settling Claimants; there will be a *pro rata* increase if there are fewer than 60 CHF Settling Claimants).

62. Pursuant to section 5.1(b)(i) of the Settlement Agreement, the Defendants will pay an additional CAD$18,333.33 for each Settling Claimant who experienced an MI, CABG or Stenting above the 200 Settling Claimants contemplated in 5.1(a)(ii), up to an aggregate

[57] Section 5, Settlement Agreement.

total of 300 such Settling Claimants (i.e. up to an additional $1,833,333.33, reaching an aggregate total of $5,500,000 paid for such claims).

63. Pursuant to section 5.1(b)(ii) of the Settlement Agreement, the Defendants will pay an additional CAD$3,333.33 for each Settling Claimant with a CHF claim above the 60 Settling Claimants contemplated in 5.1(a)(iii), up to an aggregate total of 300 such Settling Claimants (i.e. up to an additional $800,000, reaching an aggregate total of $1,000,000 for such claims).

64. If there are more than 300 Settling Claimants with an MI, CABG or Stenting claim, any excessed unused portion of the aggregate capped total of $1,000,000 for CHF claims can be used for such MI, CABG or Stenting claimants, pursuant to section 5.1(c). However, any unused portion of the aggregate capped total of $5,500,000 for MI, CABG and Stenting claims may not be used for CHF claims in excess of the aggregate total of 300 provided for in section 5.1(b)(ii).

65. The amounts of $18,333.33 for MI, CABG and Stenting claims and $3,333.33 for CHF claims will be subject to *pro rata* reductions if the number of such Settling Claimants exceeds the cap on the Defendants' payment obligations.[58]

66. Pursuant to section 5.1(f), Class Members cannot receive compensation for both an MI/CABG/Stenting claim and a CHF claim,[59] and they will be awarded the higher

[58] Section 5.1(d), Settlement Agreement.
[59] Section 5.1(f), Settlement Agreement.

MI/CABG/Stenting amount if they satisfy the applicable criteria (see Compensation Protocol, section 2).

67. The eligibility criteria for MI, CABG, Stenting and CHF claims are set out in the Compensation Protocol. Only Approved Claimants who satisfy the eligibility criteria will receive compensation from the Settlement Payment. The Compensation Protocol is attached to the Settlement Agreement as Exhibit "A".

68. The Settlement aims to compensate, as quickly and efficiently as possible, the most meritorious claims advanced in this litigation. To this end, Approved Claimants will be compensated in accordance with the proposed Compensation Protocol and Claims Administration Protocol.

69. The proposed Claims Administration Protocol was designed to be a fair and efficient method of distributing compensation to Approved Claimants, through the allocation of settlement funds in proportion to the cumulative points awarded under the Compensation Protocol.

70. Class Members may appeal, in writing on the basis of the documentation provided to the Claims Administrator, the rejection and/or classification of their claim within a 30-day period after receiving notification from the Claims Administrator about whether their claim has been approved – and the points awarded – or rejected.

71. Family Class Members are not eligible to receive compensation under the Settlement Agreement. However, the estate of a deceased Primary Class Member is eligible to be compensated.

72. All claims must be proven by way of medical and/or other reliable documentary evidence, to show the use of the drug and a compensable injury. The evidentiary requirements are intended to be proportionate, reasonable, and fair, and ensure that only valid claims are compensated. Notably, there is no requirement for Class Members to establish causation on a balance of probabilities, linking the use of Avandia to the compensable injury, as they would have if the litigation were successful on the common issues and continued to an individual assessment stage.

73. The Compensation Protocol states that to be eligible to receive a settlement payment, a Class Member must provide medical records (physician and/or pharmacy records, and this may include a letter from a physician providing any necessary clarification of the contents of the record) demonstrating the occurrence of an MI, CABG, percutaneous coronary intervention with stent placement, or the initial onset or exacerbation of CHF. Medical or pharmacy records must establish that Avandia was taken for at least 30 days without interruption, and that the cardiac event occurred no more than one year after use stopped. The 30 days of Avandia use must have occurred or started prior to December 2010.[60]

(a) Eligible cardiovascular harm

74. There are four types of eligible cardiovascular harm under the Settlement Agreement: MI, CABG, Stenting and CHF.

75. Myocardial infarction (also known as heart attack) occurs when blood flow through a coronary artery abruptly ceases. The heart muscle supplied by the blocked artery is deprived of blood and oxygen, and it stops functioning. The longer it takes to re-establish

[60] Compensation Protocol, Exhibit "A" to the Settlement Agreement.

blood flow, the more heart muscle dies. That part of the heart muscle that has died does not regain function.[61]

76. A leading cause of myocardial infarction is coronary heart disease (also called coronary artery disease).[62] Plaque builds up inside the coronary arteries and can narrow or block the arteries, reducing blood flow and oxygen to the heart muscle, leading to myocardial infarction in severe cases. Coronary artery bypass grafting (CABG) is a type of surgery that improves blood flow to the heart. It is used for people who have severe coronary heart disease. During CABG, a healthy artery or vein from the body is connected, or grafted, to the blocked coronary artery. The grafted artery or vein bypasses the blocked portion of the coronary artery. This creates a new passage, and oxygen-rich blood is routed around the blockage to the heart muscle. CABG is invasive surgery.

77. Percutaneous coronary intervention with stent placement (formerly called angioplasty with stent placement) is a non-surgical procedure that results in the placement of a small stent structure in the blood vessels of the groin or arm through to the heart where the artery has narrowed due to plaque build up, in order to improve blood flow.

78. Both CABG and stent placement are medical interventions to address the problem of reduced blood flow and oxygen to the heart. They are designed to attempt to avoid the outcome of a myocardial infarction. Because a myocardial infarction is the most severe outcome, it is assigned the greatest allocation of base points in the Compensation Protocol, as described below. Of the two medical interventions, CABG and stent placement, CABG

[61] Affidavit of Dr. Robert Myers, sworn November 28, 2014, para. 27 ("Myers Affidavit"). Dr. Myers, staff cardiologist at Sunnybrook Health Sciences Centre in Toronto, provided his affidavit in support of the Plaintiffs' motion for certification.
[62] *Ibid*., para. 19.

is the more invasive and therefore warrants a higher allocation of base points than stent placement.

79. Congestive heart failure is one of the most common reasons for hospitalization in North Americans over age 65.[63] It is most often due to severe heart muscle weakness called dilated cardiomyopathy. Dilated cardiomyopathy is in turn most commonly due to heart damage caused by myocardial infarction or high blood pressure, though there are other causes such as alcoholism and viral infection, unrelated to cardiac disease. When the heart muscle is weak, it cannot pump blood forward effectively, and so blood backs up to the lungs and other parts of the body. Shortness of breath and leg swelling are common symptoms of congestive heart failure.[64]

80. While the question of general causation of another cardiovascular injury – stroke - was certified in the Certification Order, the parties agreed to exclude stroke from the eligible forms of cardiovascular harm under the Settlement Agreement. As already mentioned, the results of the RECORD Study were re-adjudicated in 2013. This is described in the certification record and briefs of the parties. In particular, there is a memorandum dated November 19, 2013 documenting the position of the Office of New Drugs, a branch of the United States Food and Drug Administration, with regard to the "continuing marketing of rosiglitazone-containing products (…) after careful consideration of the re-adjudication of the RECORD trial." This memorandum is attached as Exhibit "B" to the affidavit of Roslyn Theodore-McIntosh sworn March 26, 2015 and relied upon by the Defendants at certification. The memorandum states on page 1 of 28 that "In RECORD, the rate of

[63] Myers Affidavit, para. 37.
[64] *Ibid*., paras. 38-39.

myocardial infarction was not significantly increased relative to comparators (metformin and sulfonylureas). Although the point estimate for myocardial infarction in RECORD trends adversely (i.e., point estimate suggesting a ~14-17% increase relative to comparators), the magnitude of the risk increase is much smaller than reported in the meta-analyses and is not reconcilable with the point estimate of another cardiovascular outcome (i.e., stroke) which trends favorably (i.e., 20-30% decrease) [underline added]." In other words, the re-adjudication of RECORD indicated that "stroke estimates all favored rosiglitazone (not statistically significant)", rather than favoring a comparator, as summarized at page 11 of 28 of the memorandum. Stroke is excluded from eligibility for compensation under the Settlement Agreement.[65]

(b) Eligibility criterion: use no later than December 2010

81. The rationale for the criterion that Avandia use must have occurred prior to December 2010 in order to be eligible for compensation relates to the fact that on November 9, 2010 Health Canada imposed new restrictions on the use of Avandia (this was before the re-adjudication of RECORD, which led to the FDA's reversal of restrictions).[66]

82. As already discussed, on November 9, 2010, Health Canada required the Defendants to send to health care professionals notification that further to a Health Canada assessment of recent data suggesting an elevated risk of cardiovascular events in patients treated with Avandia, usage restrictions were placed on Avandia to only be used when other oral antidiabetic agents were ineffective at glycemic control or contraindicated. The restriction

[65] Settlement Approval Affidavit, para. 51.
[66] Settlement Approval Affidavit, paras. 52-53.

also required the patient's written, informed consent to take Avandia, after being counselled on the risks and benefits of Avandia, including the cardiovascular risks.[67]

83. At that time new boxed warnings were also added to the Canadian product monographs with information that rosiglitazone-containing products, like other TZDs, can cause congestive heart failure, that it is not recommended to patients with ischemic heart disease, and is subject to the noted restrictions on usage.[68]

84. This litigation alleges the inadequacy of warnings about cardiovascular risks. After December 2010, when this stringent informed consent process was implemented and heightened warnings were issued, the case for inadequate warning by the Defendants became comprised. Accordingly, the Compensation Protocol reflects the relative strength of claimants who ingested Avandia prior to December 2010.

85. During negotiations with counsel for the Defendants, they argued that the cut-off date should be 2007, because Class Members (and prescribing physicians) ought to have been aware by this time of any purported risk.[69] This is based upon the publication in 2007 of a much-discussed meta-analysis by Dr. Steven Nissen and pharmacist Kathy Wolski (the "Nissen Study"),[70] comparing Avandia with placebo or comparator drugs, and finding a statistically significant increased risk of MI. The Defendants' argument is also supported by the fact that the subsequent regulatory steps taken in the US and in Canada, heightened the warnings with respect to the risk of cardiovascular events. The Nissen Study and the response of Health Canada are summarized by Dr. Lipscombe in her affidavit at paragraph

[67] Lipscombe Affidavit, para. 93 and Exhibit "N".
[68] Lipscombe Affidavit, para. 93 and Exhibit "N".
[69] Settlement Approval Affidavit, para. 53.
[70] Lipscombe Affidavit, Exhibit "F".

65-76. In May 2007, Health Canada responded to the Nissen Study by publishing a public communication, prepared by GSK, acknowledging the study and stating that its conclusions required confirmation. That same month, the FDA requiring a "black box" warning relating to heart failure in the Avandia label in the US. Later that year, in November of 2007, the FDA amended the label to include an increased risk of myocardial infarction. On June 1, 2007, Health Canada published GSK's public communication in a "Dear Healthcare Professional" letter. On November 6, 2007, Health Canada imposed new restrictions on the prescription of Avandia: it was no longer approved as monotherapy or with sulfonylurea, except when metformin is not tolerated/contraindicated; it was now contraindicated with all stages of heart failure (not just more severe stages); and it was now contraindicated for use with insulin or as triple therapy, as outlined by Dr. Lipscombe in her affidavit at paragraph 76.

86. Ultimately, after negotiating, Class Counsel's position was accepted, with the cut off date of December 2010 being accepted.[71]

(c) Eligibility criterion: no fewer than 30 days of continuous Avandia use

87. With respect to the eligibility criterion concerning the length of time that Avandia must have been ingested in order for a Class Member to qualify, this was a matter of negotiation between the parties.[72]

88. Counsel for the Defendants argued that the criterion should be 60 or more days of continuous use, as any causal link between Avandia and the qualifying cardiac event was

[71] Settlement Approval Affidavit, para. 53.
[72] Settlement Approval Affidavit, para. 54.

weak if Avandia had been taken for fewer than 60 days. However, ultimately the parties agreed on the eligibility criterion of a minimum of 30 days of use.[73]

(d) Allocation of Points

89. Approved Claimants are allocated points based on certain aspects of their claims: qualifying cardiac event, age, and presence or absence of certain pre-existing risk factors. The number of points allocated will correspond to the amount of compensation the Approved Claimant receives. This is intended to award the greatest compensation to the most meritorious claims, within a class-wide protocol that is efficient, streamlined and cost effective in order to maximize compensation received by Settling Claimants. It is also intended to treat similarly situated Approved Claimants as uniformly as possible.

90. The Compensation Protocol describes the points system, which involves an assignment of base points based on injury and age, and an optional adjustment of points based on the absence of risk factors.

91. Claimants with eligible MI claims receive 100 base points. Claimants with eligible CABG claims receive 75 base points. Claimants with eligible percutaneous coronary intervention with stent placement receive 50 base points. Drawing from separate compensation for CHF claims, there are 50 base points allocated to eligible CHF claims.

92. The different base point allocations for MI/CABG/Stenting claims is intended to be proportionate to the harm in question. As described above, a myocardial infarction is the most severe outcome of these three, therefore it merits the greatest compensation, while

[73] Settlement Approval Affidavit, para. 55.

CABG and stent placement are medical interventions to attempt to avoid the outcome of a myocardial infarction. CABG is more invasive than Stenting and therefore warrants a higher allocation of base points than Stenting claims.[74]

93. CHF claims are on average assessed at a lower quantum than MI/CABG/Stenting claims, with the Defendants paying an additional $3,333 per CHF claim (compared to $18,333 per MI/CABG/Stent claim) beyond the first 60 CHF claims contemplated by the Minimum Settlement Amount. The rationale is that the risks of CHF were known and warned of when Avandia was first approved, as stated by Dr. Lorraine Lipscombe in her affidavit sworn on January 15, 2015, at paragraph 43. The very first product monograph, in 2001 (Exhibit "D" to the Lipscombe Affidavit) references CHF, although, the Plaintiffs, argued, the references were "obliquely stated", relying upon the opinion of Dr. Lipscombe in her affidavit at paragraph 52. The warning of the potential association of Avandia with myocardial infarction came later than was warranted, as stated by Dr. Lipscombe in her affidavit at paragraph 46. The 2001 product monograph made no reference to the "possible signal of increased ischemic events". In April of 2006 the label included, for the first, time, in the "Warning" section a potential association of rosiglitazone with cardiac ischemia, as stated by Dr. Lipscombe at paragraph 61 of her affidavit. This warning was included as a result of the FDA conducting a review of a 52-week study performed by GSK in patients with pre-existing heart failure, as explained by Dr. Lipscombe at paragraph 60 of her affidavit. At paragraph 108 of her affidavit, Dr. Lipscombe provides her opinion that "GSK's awareness in 2005 of the risk of ischemia in high-risk patients such as those with coronary

[74] Settlement Approval Affidavit, para. 50.

artery disease should have prompted a warning to avoid Avandia in such patients until further scientific confirmation."

94. After a Class Member is assigned base points based on his or her compensable injury, there is an adjustment of points based on age, accounting for the fact that the baseline risk of cardiac events increases with age independent of prescription drug use.[75] Up to the age of 50, points are incrementally added to a claim. Over the age of 61, points are increasingly deducted from a claim.

95. Compensation is available to eligible Class Members without establishing causation. However, in an effort to provide the highest compensation to those with the strongest causation cases, without unduly complicating the claims process, Class Member can optionally provide a Risk Factor Declaration.

96. Class Members who swear an optional Risk Factor Declaration – a form declaring they experience none of the outlined risks – are awarded a 50% increase in their points.[76] The Risk Factor Declaration must be accompanied by a copy of the Class Member's general practitioner's medical records for the two years before the Class Member's cardiac event. The risks factors are:

[75] At paragraphs 18-20 of the Myers Affidavit, Dr. Myers explains the following: "Based on data from the Framingham Heart Study, the average annual rate of the first major cardiovascular event rises from seven per 1000 men ages 35-44, to 68 per 1000 men ages 85-94. CVD [cardiovascular disease] accounted for 38.5% of all deaths, or one out of every 2.6 deaths, in the United States in 2001. Almost 2600 Americans die of CVD every day, which translates into one death every 34 seconds. In 2001, approximately 32% of deaths from CVD occurred prematurely. An estimated 700,000 Americans per year have a new heart attack, and 500,000 per year will have a recurrent attack. A leading cause of heart attacks is atherosclerosis, or coronary heart disease (discussed further in the next section). Women tend to develop manifestations of coronary artery disease years later than men. The average age of a first heart attack is 65.8 for men and 70.4 for women. The lifetime risk of developing coronary heart disease after age 40 is 49% for men and 32% for women. CVD is the most common cause of death for those over age 65."

[76] At paragraph 33 of the Myers Affidavit, Dr. Myers states that cardiovascular risk factors include smoking, hypertension, diabetes, excessive alcohol use, and others.

(a) Pre-existing congestive heart failure

(b) Prior MI

(c) Pre-existing coronary artery disease

(d) Smoking within 1 year of cardiac event

(e) High cholesterol

(f) Hypertension

(g) Obesity (BMI of 30 or greater at or before their cardiac event)

(h) Alcoholism within 2 years of cardiac event

(i) Illegal drug use within 2 years of cardiac event

97. The allocation of compensation to the four eligible cardiovascular harms and the temporal requirement connecting the use of Avandia to the injury reflect the challenges Class Members would confront if they were to continue litigation.[77] There are considerable risks that would be associated with litigating claims relating to other types of cardiac injuries, and relating to other dates and durations of use which were excluded from the compensation awarded under the Settlement Agreement. The temporal restrictions and definitions of compensable injuries under the Settlement Agreement are rationally connected to the litigation risks.

iii. Estimated Number of Eligible Class Members Known to Class Counsel

98. At this stage, having reached a proposed settlement but prior to implementation, the precise numbers of Class Members and those eligible for compensation are unknown. Due to the opt-out nature of class actions, Class Members need not identify themselves prior to any

[77] Settlement Approval Affidavit, para. 48.

resolution in order to maintain a claim. Moreover, until a negotiated resolution and its terms of eligibility are negotiated, the qualifying criteria are unknown. Therefore there are inherent limitations on the information available to Class Counsel, and thus on the process of estimating the total number of eligible Class Members.

99. Class counsel are often contacted by individuals expressing interest in the action – at whatever early stage it may be at – who may ultimately not be a Class Member, as defined in a certification order, or may ultimately not be an eligible claimant under the negotiated terms of a settlement.

100. Due to the sequence of steps in a class action, medical records and other documents of individuals in firms' databases, which may be required to assess eligibility under a negotiated settlement, may not have been obtained prior to settlement steps being taken.

101. However, there is some information available to Class Counsel to enable a reasonably informed estimate of the number of eligible Class Members who may submit claims under the Settlement Agreement, if it is approved. The best available information is outlined below.

i. Class Counsel (Wagners, Siskinds LLP)

A. Wagners

102. To date there are 85 individuals who have contacted Wagners with respect to this litigation and have identified themselves as Class Members.[78]

[78] Settlement Approval Affidavit, para. 57.

103. Based upon a review of medical records in Wagners' possession, 16 contacts appear to have eligible MI claims, 1 contact appears to have an eligible CABG claim, and 5 contacts appear to have eligible CHF claims.[79]

104. Based upon a review of medical records in Wagners' possession, 37 contacts appear to be ineligible to receive compensation under the Settlement Agreement.[80]

105. With respect to the following contacts, some required documentation is currently unavailable, preventing a determination of whether they may be eligible or ineligible to receive compensation under the Settlement Agreement:

- 8 MI claims
- 1 stent claim
- 16 CHF claims[81]

106. One contact has provided no information (including about his injury) to assess eligibility.[82]

B. Siskinds LLP

107. There are the following number of Pre-Approved Claimants (listed in the confidential Schedule to the Settlement Agreement and who the parties agree are deemed to be Approved Claimants):

- 142 MI/CABG/Stent claims (one Pre-Approved Claimant overlaps with Wagners' database)

[79] Settlement Approval Affidavit, para. 58.
[80] Settlement Approval Affidavit, para. 59.
[81] Settlement Approval Affidavit, para. 60.
[82] Settlement Approval Affidavit, para. 61.

- 34 CHF claims[83]

108. The eligibility criteria applied to the Pre-Approved Claimants were the same as those applicable under the Settlement Agreement.[84]

109. There are 917 contacts in Siskinds' database, including the above 176 Pre-Approved Claimants. This group includes anyone who had contacted Siskinds about Avandia litigation for any reason, with the result that some of these contacts may not be Class Members.[85]

110. Of these 917 contacts, there are 312 contacts who never responded to Siskinds' requests for information after initial contact was made. With respect to this group of 312 contacts, it is possible some of them may be eligible Class Members, and may submit a claim, but there has been no reply to Siskinds' attempts at contact.[86]

111. Of these 917 contacts, there are 202 contacts who have been determined to be ineligible, categorized as follows:

(a) Contacts deemed ineligible by GSK during the pre-approval process: 32. In the process of determining eligibility of Pre-Approved Claimants, Siskinds LLP sent medical records of 32 contacts to counsel for GSK. GSK determined these individuals to be ineligible under the agreed-upon eligibility criteria.

(b) Claims that were not submitted to GSK during the pre-approval process because Siskinds determined they did not satisfy eligibility requirements (e.g. no cardiac injury, did not take Avandia, or claims outside of timeline): 144

[83] Settlement Approval Affidavit, para. 62.
[84] Settlement Approval Affidavit, para. 63.
[85] Settlement Approval Affidavit, para. 64.
[86] Settlement Approval Affidavit, para. 65.

(c) Stroke cases: 26. Stroke is not compensated under the Settlement Agreement.[87]

112. Of these 917 contacts, there are 51 contacts for whom some required documentation is currently unavailable, preventing Siskinds from determining whether they may be eligible or ineligible to receive compensation under the Settlement Agreement.[88]

113. Of these 917 contacts, there are 128 contacts who, despite initially contacting Siskinds, later informed Siskinds they had retained another law firm or had no continuing interest in the Avandia litigation. It is presumed these 128 contacts are either counted among the Class Members contacts of other counsel, or are not Class Members.[89]

114. Further, of these 917 contacts, there are 48 contacts for whom the requisite medical records appear to be permanently unavailable. Siskinds has attempted to obtain the requisite records from hospitals, physicians, and pharmacies, as the case may be, but has been informed the records no longer exist.[90]

ii. Related Counsel Firms

A. Guardian Law (Calgary, AB)

115. There are 28 contacts in Guardian Law's database. This group includes anyone who had contacted Mr. Docken (at Guardian Law, or his predecessor law firms of Higgerty Law and Docken & Company) about Avandia litigation for any reason, with the result that some of these contacts may not be Class Members.[91]

[87] Settlement Approval Affidavit, para. 66.
[88] Settlement Approval Affidavit, para. 67.
[89] Settlement Approval Affidavit, para. 68.
[90] Settlement Approval Affidavit, para. 69.
[91] Settlement Approval Affidavit, para. 70.

116. Of these 28 contacts, there are 5 contacts who appear to have eligible MI claims based on medical records in possession of Guardian Law.[92]

117. Of these 28 contacts, 2 contacts may have eligible CHF claims, but that this cannot be verified one way or another until they have received further medical records.[93]

118. Of these 28 contacts, there are 21 contacts for whom the required documentation has not been received by Guardian Law to allow them to determine whether these contacts are Class Members, and further, whether they may be eligible under the Settlement Agreement.[94]

B. Patient Injury Law (Ches Crosbie) (St. John's, NL)

119. The *Wiseman* action in NL was not advanced after the action was filed, and that Mr. Crosbie has no information on potential Class Members in NL, other than the named proposed representative plaintiff in that action, Mr. Clyde Wiseman. Mr. Wiseman may have an eligible myocardial infarction claim, although this is presently unconfirmed.[95]

C. Consumer Law Group (Montreal, QC)

120. There are 514 contacts in Consumer Law Group's database. This includes anyone who had contacted Consumer Law Group about Avandia litigation for any reason, with the result that some of these contacts may not be Class Members.[96]

[92] Settlement Approval Affidavit, para. 71.
[93] Settlement Approval Affidavit, para. 72.
[94] Settlement Approval Affidavit, para. 73.
[95] Settlement Approval Affidavit, para. 74.
[96] Settlement Approval Affidavit, para. 75.

121. Of these 514 contacts, there are 6 contacts who appear to have eligible MI claims, 2 contacts who appear to have eligible CABG claims, 1 contact who appears to have an eligible stent claim, and 4 contacts who appear to have eligible CHF claims, based on medical records in possession of Consumer Law Group.[97]

122. Of these 514 contacts, there are an additional 21 contacts who may have eligible claims, based on partial medical records and information provided by these contacts – 18 claims in the MI/CABG/Stent categories, and 3 CHF claims - but that this cannot be verified one way or another until they have received further medical records.[98]

123. Apart from the 34 contacts described above, the required documentation for the remainder of the contacts has not been received by Consumer Law Group to allow them to determine whether these clients are Class Members, and further, whether they may be eligible under the Settlement Agreement.[99]

D. McPhadden Samac Tuovi LLP (Toronto, ON)

124. There are 10 contacts in the Avandia database of McPhadden Samac Tuovi LLP. This includes anyone who had contacted McPhadden Samac Tuovi LLP about Avandia litigation for any reason, with the result that some of these contacts may not be Class Members.[100]

125. Of these 10 contacts, 1 appears to have an eligible MI claim, and 1 appears to have an eligible stent claim. The remaining 8 contacts either appear to be ineligible based on

[97] Settlement Approval Affidavit, para. 76.
[98] Settlement Approval Affidavit, para. 77.
[99] Settlement Approval Affidavit, para. 78.
[100] Settlement Approval Affidavit, para. 79.

documentation in their possession, or they do not currently have enough information to make that determination.[101]

iii. Number of Contacts of Other Avandia Class Action Firms

126. Merchant Law Group filed proposed class actions in five jurisdictions: BC, AB, SK, MB and NL.[102] Other than the SK action, which was stayed on consent pending resolution of the *Lloyd* action in Ontario, no steps have been taken by Merchant Law Group in these actions subsequent to filing.[103]

127. There are approximately 1200 contacts in Merchant Law Group's database. Class Counsel are of the understanding that this group includes anyone who had contacted Merchant Law Group about Avandia litigation, with the result that this number may include people who are not Class Members, or who are ineligible for compensation under the Settlement Agreement.[104]

128. Based on the above available information, it is reasonable to anticipate that, if the Settlement Agreement is approved, the awards to Approved Claimants will not need to be subject to *pro rata* reductions: the Minimum Settlement Amount includes compensation for up to 200 Settling Claimants meeting the criteria for MI/CABG/Stenting claim, and compensation for up to 60 Settling Claimants meeting the criteria for a CHF claim, as outlined in s. 5.1(a) of the Settlement Agreement. There is further additional payment by the Defendants for up to 100 MI/CABG/Stenting claims (at $18,333.33 per claim), and up to 240 additional CHF claims (at $3,333.33 per claim), with any unused portion of the

[101] Settlement Approval Affidavit, para. 80.
[102] Settlement Approval Affidavit, para. 81.
[103] Settlement Approval Affidavit, para. 82.
[104] Settlement Approval Affidavit, para. 83.

aggregate capped total of $1,000,000 available for CHF claims to be used for MI/CABG/Stenting claims in excess of the aggregate capped total of $5,500,000 for such claims, as outlined in s. 5.1(b) and (c) of the Settlement Agreement. Therefore only if there are more than 300 CHF claims will CHF awards be subject to a *pro rata* reduction, and only if there are more than 300 MI/CABG/Stenting claims with no unused portion of the aggregate capped total of $1,000,000 available for CHF awards to be used for MI/CABG/Stenting claims in excess of 300, will MI/CABG/Stenting awards be subject to a *pro rata* reduction.[105]

129. Based on the currently available information outlined above, Class Counsel anticipates that the maximum number of claims contemplated by the Maximum Settlement Amount will not be reached (and thus no *pro rata* reductions required) as the total number of Settling Claimants is estimated to be at or below 300 for each category.[106]

iv. Estimated Net Recovery for Approved Claimants

130. Due to the unknown number of claims that will be submitted, RicePoint's cost proposal for claims administration costs consists of a fixed fee component of $55,000 and a per claim rate for each claim received by RicePoint.[107] The fixed fee includes case set up, escrow account activities, distribution of payments to Settling Claimants and PHIs, post-distribution activities (including attending to questions following distribution) and reporting to counsel for the parties after the Claim Deadline.[108]

[105] Settlement Approval Affidavit, para. 85.
[106] Settlement Approval Affidavit, para. 86.
[107] Settlement Approval Affidavit, para. 87.
[108] Settlement Approval Affidavit, para. 88.

131. The cost of processing individual claims is $75.00 per claim, and $35.00 per Risk Factor Adjustment review, if the optional Risk Factor Declaration is submitted by a claimant.[109]

132. Out of pocket costs (e.g. scanning, support centre emails and calls, bank fees) are extra, as are applicable taxes.[110]

133. Class Counsel estimates the maximum cost of claims administration as follows. Assuming the maximum contemplated number of MI/CABG/Stenting claims and CHF claims are submitted (i.e. 600 total), and assuming that each submitted claim includes an optional Risk Factor Declaration (to be reviewed for $35.00), the total *per claim* administration cost (excluding out of pocket costs and taxes) will be $66,000 ([$75 to process claim + $35 to review Risk Factor Adjustment] = $110 per claim x 600 [300 MI/CABG/Stenting claims + 300 CHF claims]. To this there must be added the fixed fee of $55,000, for a total estimated cost of claims administration of $139,150 (calculated as $55,000 + $66,000 = $121,000 plus 15% tax of $18,150). Again, out of pocket expenses will be additional.[111]

134. The estimated total cost of implementing the Hearing Notice Plan and the Settlement Approval Notice Plan is $41,245, inclusive of tax, representing equal costs of $20,622.50 for each stage.[112]

[109] Settlement Approval Affidavit, para. 89.
[110] Settlement Approval Affidavit, para. 89.
[111] Settlement Approval Affidavit, para. 90.
[112] Settlement Approval Affidavit, para. 91.

135. The total cost of notice and estimated cost of claims administration (assuming 600 total claims submitted, each with an optional Risk Factor Declaration, but excluding out of pocket expenses) is $180,395.[113]

136. From the Settlement Payment, $250,000 has been agreed to be paid as a contribution to the costs of administration and disbursements.[114]

137. Disbursements for which Counsel Counsel will seek Court approval will not exceed $400,000. The total of maximum disbursements and estimated total costs of notice and claims administration is: $400,000 (maximum disbursements) + $180,395 (estimated total costs of notice and claims administration, assuming 600 claims submitted each with a Risk Factor Declaration) = $580,395.[115]

138. After allocation of $250,000 from the Settlement Amount to pay a contribution to costs of administration and disbursements, a balance of $330,395 remains left to be paid from the Settlement Payment, in accordance with section 6.1 of the Settlement Agreement.[116]

139. If there are 300 approved MI/CABG/Stenting claims and 300 approved CHF claims, the Maximum Settlement Amount of $6,750,000 will be paid by the Defendants.[117]

140. Class Counsel has calculated the estimated average (i.e. without accounting for points adjustments) net amount to be received by Approved Claimants to be as follows,

[113] Settlement Approval Affidavit, para. 92.
[114] Settlement Approval Affidavit, para. 93.
[115] Settlement Approval Affidavit, para. 94.
[116] Settlement Approval Affidavit, para. 95.
[117] Settlement Approval Affidavit, para. 96.

recognizing that due to the unknown number of claims that are eligible and will be approved, some assumptions must be made:

> $6,750,000 [Maximum Settlement Amount]
>
> Minus legal fees of 25% plus tax = $1,940,625 [legal fees of $1,687,500 plus 15% tax, being $253,125)] [disbursements accounted for below]
>
> Minus $250,000 [Defendants' contribution to administration expenses/disbursements]
>
> Minus $330,395 [estimated remaining cost of administration expenses and disbursements, per above calculations]
>
> = $4,228,980 to be distributed to Approved Claimants, inclusive of a 10% allocation to PHIs for their subrogated claims.[118]

141. CHF claims are valued at approximately 18% of an MI claim ($3,333.33/$18,333,33 = 18.18%). Therefore, again assuming the Maximum Settlement Amount is paid (due to 300 Approved Claimants in each category), of that $4,228,980, $768,828 will be used to pay CHF claims, and $3,460,152 will be used to pay MI/CABG/Stent claims.[119] Assuming there are 300 of each such Approved Claimants, an Approved MI/CABG/Stent claimant will receive a net amount of $11,533.84 (of which 10% will be paid to the PHI) and an

[118] Settlement Approval Affidavit, para. 97.
[119] Settlement Approval Affidavit, para. 98.

Approved CHF claimant will receive a net amount of $2,562.76 (of which 10% will be paid to the PHI).[120]

v. Resolution of Provincial Health Insurer Claims

142. During the process of finalizing the terms of the proposed Settlement, Class Counsel (members of Siskinds LLP and/or Wagners) communicated by way of written letters and telephone calls with representatives of the Provincial Health Insurers ("PHIs") (all provincial and territorial Ministries of Health or equivalents, who fund medical services in Canada).[121]

143. After being informed of the particulars of the action, the identified litigation risks and rationale for recommending the Defendants' offer, and upon negotiation of the terms of settlement, the PHIs provided their instructions to Class Counsel that confirmed their approval of the Settlement Agreement and would accept 10% of the allocation made by the Claims Administrator for each Settling Claimant in satisfaction of all statutory authority for the recovery of costs of insured health or medical services they may have with respect to the Settling Claimant's use of Avandia, and would sign a release (Exhibit "F" to the Settlement Agreement) in return for such payment.[122]

144. To date, written confirmation of acceptance of the terms of the Settlement Agreement has been received by all jurisdictions.[123]

[120] Settlement Approval Affidavit, para. 99.
[121] Settlement Approval Affidavit, paras. 100-101.
[122] Settlement Approval Affidavit, para. 102.
[123] Settlement Approval Affidavit, para. 103.

vi. Notice to the Class

a) Hearing Notice

145. The Hearing Notice Plan approved by this Honourable Court by way of the Hearing Notice Approval Order issued on November 5, 2018 was implemented by RicePoint Administration Inc. with the cooperation of Class Counsel.[124]

b) Opt Outs

146. To date, Class Counsel have received one Opt Out Form from a Class Member intending to opt out of the action.[125]

c) Objections to Settlement Agreement

147. To date, Class Counsel have received no written objections to the Settlement Agreement.[126]

d) Settlement Approval Notice

148. If the proposed settlement is approved, the Settlement Approval Notice will be disseminated to the Class according to the methods described in the Settlement Approval Notice Plan (attached to the Settlement Approval Order).[127] The Settlement Approval Notice Plan essentially replicated the Hearing Notice Plan approved by this Court and provides for robust notice.

149. The Settlement Approval Notice will advise Class Members that the Court has approved the Settlement Agreement as being fair and reasonable and in the best interests of the Class.

[124] Settlement Approval Affidavit, para. 109.
[125] Settlement Approval Affidavit, para. 112.
[126] Settlement Approval Affidavit, para. 113.
[127] Settlement Approval Affidavit, para. 110.

It will also advise Class Members of the steps to be taken to participate in the settlement, and will help individuals determine whether they are eligible to claim compensation under the Settlement Agreement.

150. The Settlement Approval Notice highlights in plain language the primary aspects of the Settlement, provides information on important deadlines and contact information for inquiries, and directs Class Members to the dedicated settlement website to obtain details about the Compensation and Claims Administration Protocols and the claim form.

e) Claims Administrator

151. The Parties seek Court approval of the appointment of RicePoint Claims Administration Inc. ("RicePoint") as the Claims Administrator.[128]

152. In its role as Claims Administrator, RicePoint will be responsible for implementing certain aspects of the Settlement Approval Notice Plan and for overseeing the claims process under the Settlement Agreement.

153. RicePoint's vast experience in administering class action settlements is outlined in Exhibit "K" to the Settlement Approval Affidavit.[129]

PART III - THE ISSUES

154. The issues before this Honourable Court are:

(a) whether to approve the Settlement Agreement pursuant to section 38 of the *Act*;

[128] Settlement Approval Affidavit, para. 114.
[129] Settlement Approval Affidavit, para. 114, Exhibit "K".

(b) whether to approve the Settlement Approval Notice and Notice Plan; and

(c) whether to appoint RicePoint Administration Inc. as the Claims Administrator.

PART IV - LAW AND ANALYSIS

i. Legislative Requirement for Court Approval of Settlement

155. The requirement for court approval of a proposed class action settlement is set out in subsections 38(1) and (3) of the *Class Proceedings Act*[130] as follows:

> **38**(1) A class proceeding may be settled or discontinued only
>
> (a) with the approval of the court; and
>
> (b) on the terms or conditions the court considers appropriate.
>
> …..
>
> (3) A settlement under this Section is not binding unless approved by the court.

ii. General Principles for Approval

156. The legal test for approval of a class action settlement is whether it is fair and reasonable and in the best interests of the class as a whole. A court, without making findings of fact on the merits of the litigation, must examine the proposed settlement with the interests of class members in mind, while having regard to the claims and defences in the litigation and any objections raised to the settlement.[131] The benefits to the class must be weighed against the risks, delays and expense of continuing litigation.[132]

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[130] S.N.S. 2007, c. 28 (Plaintiffs' Authorities, Tab 16).
[131] *Lozanski v. Home Depot, Inc.,* 2016 ONSC 5447 at para. 72 [*Home Depot*] (Plaintiffs' Authorities, Tab 4).
[132] *Stewart v. General Motors of Canada Ltd*., [2008] O.J. No. 4426 (Ont. S.C.J.) at para. 23 (Plaintiffs' Authorities, Tab 8).

157. Settlements are a product of compromise. The standard is one of reasonableness, not perfection.[133]

158. In *Nunes v. Air Transat A.T. Inc.*,[134] Justice Cullity of the Ontario Superior Court of Justice summarized the following principles to be applied on a motion for settlement approval:

> (a) to approve a settlement, the court must find that it is fair, reasonable, and in the best interests of the class;
>
> (b) the resolution of complex litigation through the compromise of claims is encouraged by the courts and favoured by public policy;
>
> (c) there is a strong initial presumption of fairness when a proposed class settlement, which was negotiated at arm's-length by counsel for the class, is presented for court approval;
>
> (d) to reject the terms of the settlement and require the litigation to continue, a court must conclude that the settlement does not fall within a zone of reasonableness;
>
> (e) it is not the court's function to substitute its judgment for that of the parties or to attempt to renegotiate a proposed settlement. Nor is it the court's function to litigate the merits of the action or, on the other hand, to simply rubber-stamp a proposal; and
>
> (f) the burden of satisfying the court that a settlement should be approved is on the party seeking approval.

159. In determining whether to approve a settlement, a court takes into account factors such as the following:

> (a) likelihood of recovery or likelihood of success;
>
> (b) amount and nature of discovery evidence;
>
> (c) proposed settlement terms and conditions;

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[133] See e.g. *Ford v. F. Hoffmann-La Roche Ltd.* (2005), 74 O.R. (3d) 758 (Ont. S.C.J.) at paras. 113 – 118 [*Ford*] (Plaintiffs' Authorities, Tab 3); *Martin v. Roman Catholic Diocese of Antigonish*, 2009 NSSC 331 at para. 58 [*Martin*] (Plaintiffs' Authorities, Tab 5).

[134] *Nunes v. Air Transat A.T. Inc.*, [2005] O.J. No. 2527 at para. 7 (Plaintiffs' Authorities, Tab 6).

(d) recommendation and experience of counsel;

(e) future expense and likely duration of litigation;

(f) recommendation of neutral parties, if any;

(g) number of objectors and nature of objections;

(h) the presence of arms-length bargaining and the absence of collusion;

(i) degree and nature of communication by counsel and the plaintiffs with class members during the litigation;

(j) information conveying to the court the dynamics of, and the positions taken by the parties during, the negotiation; and

(k) the risk of not unconditionally approving the settlement.[135]

160. These factors are to guide the process, and invariably some factors will hold greater significance than others, depending on the case at hand. Weight should be attributed accordingly.[136]

161. Plaintiffs have an obligation to provide sufficient information to permit a court to exercise its function of independent approval. However, while a court requires sufficient information to exercise an objective, impartial and independent assessment of the fairness of the settlement in the circumstances, a court considering a settlement "need not possess evidence to decide the merits of the issue, because the compromise is proposed in order to avoid further litigation. At minimum, a court must possess sufficient information to raise its decision above mere conjecture."[137]

[135] *Ibid*., paras. 6-7; *Martin*, *supra* at para. 57 (Plaintiffs' Authorities, Tab 5).
[136] *Parsons v. The Canadian Red Cross Society*, [1999] O.J. No. 3572 (Ont. S.C.J.) at para. 73 [*Parsons*] (Plaintiffs' Authorities, Tab 7).
[137] *Ford*, *supra* at para. 123 (Plaintiffs' Authorities, Tab 3).

162. Moreover, in situations where the litigation may continue if the settlement is not approved, a court must be mindful that there are constraints on the extent to which parties may fully disclose the strengths and weaknesses of their case.[138]

163. In this case, there is an extensive certification record to assist the Court's assessment of the overall fairness of the settlement.

iii. Analysis

164. In negotiating the Settlement Agreement, Class Counsel was attuned to certain litigation risks. The litigation risks described herein relate also to other relevant factors in assessing the settlement, such as likelihood of success, the risk of the settlement not being approved, and the likely duration of litigation were it to continue.

165. The litigation risks are present first at the certification stage (as the Defendants have appealed certification) and, if certification is upheld, at trial. Risks would remain present through the individual assessment stage that would follow the common issues trial to assess specific causation and damages.

a) Risks at Certification Appeal

166. The Defendants vigorously opposed certification.

167. This case was certified as a class proceeding, but an appeal by the Defendants is currently in abeyance. With this appeal comes the risk that certification may be defeated on one or

[138] *Dabbs v. Sun Life Assurance Co. of Canada* (1998), 40 O.R. (3d) 429 at para. 16 (Gen. Div.), aff'd (1998), 41 O.R. (3d) 97 (C.A.), leave to appeal to S.C.C. refused, [1998] S.C.C.A. No. 372 (Plaintiffs' Authorities, Tab 2).

more of the several grounds outlined by the Defendants in their Factum filed June 2, 2017,[139] including:

(a) The certified primary class of "all users" is impermissibly and unnecessarily broad and lacks a "rational relationship" between the cause of action, class definition and common issues. The class would be almost entirely persons "who have suffered no harm and for whom there can be no cause of action";

(b) There lacks a "credible or plausible" methodology for proving the common issues of general causation on a class-wide basis, and moreover the general causation inquiry will not obviate the need for an individual inquiry into specific causation, therefore there is no meaningful advancement of the case by answering the general causation issue;

(c) The underlying disease – diabetes – treated by Avandia itself causes heart failure, heart attack and stroke, and there is no evidence of a methodology to determine whether Avandia or diabetes caused the cardiovascular event;

(d) Individual causation will be unique to a specific patient and will always require individual inquiry, therefore a class proceeding is not the preferable procedure; and

(e) The Chambers Judge erred in certifying enterprise liability as a common issue.

168. The Defendants heavily relied, at certification, on the re-adjudication of the Record Study to say that "the US Regulator found that there was no increased risk of heart attack or other major adverse cardiovascular events for patients treated with Avandia when compared to standard-of-care drugs and required that reference to increased risk of heart attack be removed from the boxed warning."[140]

[139] Settlement Approval Affidavit, Exhibit "C".
[140] Defendants' certification brief, filed August 7, 2015, para. 23.

169. The Defendants also argued at certification that those with type II diabetes "are at a very high risk for heart disease with eighty percent of them having a cardiovascular complication".[141]

170. The Defendants identified several other "risk factors that contribute to a patient suffering a cardiovascular event such as a heart attack or congestive heart failure."[142]

171. The Defendants attempted to illustrate the challenges posed by establishing specific causation in their analysis of the claims of the representative plaintiffs, at paragraphs 28 to 35 of their certification brief.

172. With respect to the adequacy of the warnings about cardiovascular risks, the Defendants argued that Avandia underwent an approval process overseen by Health Canada, and that it "remains an approved drug in Canada and continues to be available for prescription by duly qualified physicians to patients who, in their clinical judgment, would benefit from the drug."[143] The Defendants argued that the product monograph obtained specific approval of Health Canada.[144]

b) Risks at Liability Common Issues Trial

173. The certified common issues are as follows:

> 1. (a) Can AVANDIA cause or contribute to heart failure? If so, what is the magnitude of this increased risk?

[141] *Ibid*., para. 11.
[142] *Ibid*., para. 13.
[143] *Ibid*., para. 19.
[144] *Ibid*., para. 20.

(b) Can AVANDIA cause or contribute to heart attacks? If so, what is the magnitude of this increased risk?

(c) Can AVANDIA cause or contribute to strokes? If so, what is the magnitude of this increased risk?

2. (a) If the answer to (1)(a) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of heart failure? If so, when?

(b) If the answer to (1)(b) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of heart attack? If so, when?

(c) If the answer to (1)(c) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of stroke? If so, when?

3. (a) If the answer to (1)(a) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of heart failure?

(b) If the answer to (1)(b) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of heart attack?

(c) If the answer to (1)(c) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of stroke?

4. Is each of the Defendants responsible in law for the acts or omissions of either one or both of the other Defendants in respect of the design, development, fabrication, manufacture, sale, import, distribution, and/or marketing of AVANDIA in Canada?

5. By virtue of unjust enrichment and/or waiver of tort, are the Defendants liable on a restitutionary basis:

(a) to account to any of the Classes, including provincial insurers which have subrogated claims, for any part of the proceeds of the sale of AVANDIA? Or, in the alternative,

(b) such that a constructive trust is to be imposed on any part of the gross revenue from the sale of AVANDIA for the benefit of the Classes, including the provincial insurers which have subrogated claims?

174. The Settlement reflects the risk that if certification was upheld by the Court of Appeal, the action may nevertheless fail on its merits at the common issues trial focusing on liability, due to the various defences outlined by the Defendants in their Statement of Defence filed March 13, 2017, including:

(a) The Defendants complied with its regulatory obligations, and was approved by Health Canada;

(b) The Defendants properly disclosed information to Health Canada as it became available to the Defendants;

(c) Contrary to the allegations of inadequate warning, the product monographs included warnings about heart failure and referred to ischemic heart disease from the time Avandia was approved, in 2000, and the warnings were amended and strengthened in subsequent years as scientific literature became available;

(d) Additionally, the product label was amended in the United States in 2007 to include a boxed warning about a trial reporting a potential association between Avandia and myocardial ischemic events although available data was inconclusive, and in the United States in 2011 to add that Avandia might be associated with an increased risk of myocardial infarction;

(e) After the U.S. Food and Drug Administration required, in 2013, re-examination of data on the cardiovascular safety of Avandia (the RECORD trial), the FDA concluded that Avandia did not appear to differ substantially from other anti-diabetic drugs in its risk of

major cardiovascular events and death (other than the known and disclosed TZD class effect of heart failure). The boxed warning about myocardial infarction was directed by the FDA to be removed;

(f) The Risk Evaluation and Mitigation Strategy for Avandia was eliminated in 2015 because the FDA concluded that the REMS was no longer necessary to ensure the benefits of Avandia outweigh the risks;

(g) Avandia was prescribed and dispensed by "learned intermediaries" (physicians and pharmacists, respectively) who have a duty to pass on adequate warnings of a product's risks, and the Defendants informed the learned intermediaries of all relevant information, including adequate clear warnings as known to the Defendants at relevant times;

(h) The learned intermediaries, not the Defendants, were equipped to and responsible for providing patient-specific relevant information to the Class Members, and therefore if Class Members suffered harm, which the Defendants deny, the learned intermediaries had access to appropriate information when they decided to prescribe it, and the Class Members freely assumed the risk of any harm they allege to have suffered;

(i) Avandia is fit for its intended uses under the guidance and decision-making of a learned intermediary;

(j) Any injuries alleged to be caused or contributed to by Avandia are the result of individual Class Member characteristics, including the underlying condition of diabetes, for which Avandia was prescribed, pre-existing medical histories and co-morbidities, or are the result of the negligence of others over which the Defendants are in no way liable.

175. With respect to the defence outlined in (j) above, the fact that diabetes is itself a risk factor for cardiovascular diseases, including injuries compensable under the Settlement Agreement, is undisputed. One of the Plaintiffs' experts, Dr. Robert Myers, a staff cardiologist at Sunnybrook Health Sciences Centre in Toronto, provided an affidavit in

support of the Plaintiffs' motion for certification. At paragraph 50 of Dr. Myers' affidavit he states:

> Diabetes significantly increases the risk of developing atherosclerotic cardiovascular disease, including heart attacks and strokes up to five-fold. In fact, diabetes is the most common cause of heart attack in young patients.

176. Dr. Myers continues in paragraphs 51 and 52 of his affidavit to explain how elevated blood glucose levels in individuals with diabetes can lead to obstructed arteries, in turn resulting in myocardial infarction and heart failure.

177. With respect to causation, the Defendants argued at certification that there was no "signature harm" that could be caused by Avandia. This argument, excerpted from the Defendants' certification brief, could pervade the common issues trial:

> [T]here is no "Avandia heart attack" as distinct from a "diabetic heart attack". Diabetics are at marked risk for heart attack as a result of their underlying disease. There is no known methodology for identifying the causal role, if any, that Avandia may have played in a patient's heart attack without close review of each individual case focused on specific causation.[145]

178. If the Plaintiffs were successful at the common issues trial, it would not be determinative of Class Members' claims: individual assessments of specific causation and harm, and individual quantification of damages, would still need to occur. If litigation were to continue, each Class Member would also have to establish that his or her injury occurred before he or she ought to have been aware of the likelihood of risk. Therefore even

[145] Defendants' certification brief, filed August 7, 2015, p. 3.

resolution of the common issues in favour of the Class may result in minimal or no recovery for some Class Members.

179. Regardless of the outcome of the common issues trial, the potential for an appeal would exist. With an appeal comes delay, expenses, and further uncertainty.

c) Risks at Individual Issues Stage

180. If the Plaintiffs were successful at the common issues trial and proceeded to the individual issues stage to resolve any remaining individual issues – establish proof of damages and specific causation – Class Members would continue to face the risk that their individual claims would fail. The Defendants could continue to dispute liability on a case-by-case basis, arguing that any injuries alleged to be caused or contributed to by Avandia are the result of individual Class Member characteristics, including the underlying condition of diabetes, for which Avandia was prescribed, pre-existing medical histories and co-morbidities, or are the result of the negligence of others over which the Defendants are not liable.

181. With respect to the evaluation of the risks facing the subrogated claims of the PHIs, there is, in addition to the litigation risks applicable to the overall claims of Class Members (which have a direct bearing on the value of the subrogated claims of PHIs), the evidentiary challenge of establishing specific causation as to which of the incurred cardiovascular health expenses were caused by the Defendants' negligence in failing to provide adequate warnings, compared to those expenses incurred simply due to treatment of the underlying diabetes disease process or due to Avandia being prescribed regardless of the strength of the warnings.

d) Delay

182. In Class Counsel's view, any additional value to an award of damages that may result from a trial on the merits would be speculative and uncertain in light of the litigation risks identified by the Defendants and discussed in these submissions. In addition, it would come with delay and further costs.

183. Continued litigation would bring the likelihood of delays caused by the Defendants' pending appeal of certification or, subsequently, of an appeal of the outcome of the common issues trial if certification was upheld.

184. The reasonableness of the settlement is also confirmed in light of the inherent uncertainty associated with litigation, as discussed earlier in these submissions.

iv. Recommendation and Experience of Counsel

185. The Settlement Agreement was negotiated in good faith by experienced counsel with expertise in class action litigation.[146]

186. As Justice Strathy stated in *Ainslie v. Afexa Life Sciences Inc.*:[147]

> It is not the court's responsibility to determine whether a better settlement might have been reached. Nor is it the responsibility of the court to send the parties back to the bargaining table to negotiate a settlement that is more favourable to the class. Where the parties are represented - as they clearly are in this case - by highly reputable counsel with expertise in class action securities litigation, the court is entitled to assume, in the absence of evidence to the contrary, that it is being presented with the best reasonably achievable settlement and that class counsel is staking his or her reputation and experience on the recommendation.

[146] Settlement Approval Affidavit, paras. 105-109.
[147] 2010 ONSC 4294 at para. 31 (Plaintiffs' Authorities, Tab 1).

187. Class Counsel recommended acceptance of the final settlement as being fair and reasonable and in the best interests of the Class. This was accepted by the Representative Plaintiffs and the PHIs.[148]

188. When assessing the reasonableness of the Settlement Agreement and of the estimated net recovery per Class Member, it must be considered that there is an absence of on-point, relevant case law awarding damages in pharmaceutical actions against manufacturers for an alleged failure to warn about cardiovascular harm allegedly caused by the pharmaceutical in question. Indeed, there are no such reported decisions in individual actions or class actions. In any event, in a class action involving various considerations of individual Class Members' specific circumstances, which have bearing on the strength of their individual claims for liability (e.g. causation) and damages, any comparison with reported decisions is of limited utility. Indeed, courts have cautioned against determining the reasonableness or adequacy of a proposed class action settlement by a comparison to what could be obtained by an individual claimant under the tort model:[149]

> **82** An award of damages in personal injury tort litigation is idiosyncratic and dependent on the individual plaintiff before the court. Here, although the settlement is structured to account for Class Members with differing medical Conditions by establishing benefits on an ascending classification scheme, no allowances are made for the spectrum of damages which individual class members within each level of the structure may suffer. The settlement provides for compensation on a "one-size fits all" basis to all Class Members who are grouped at each level. However, it is apparent from the evidence before the court on this motion that the damages suffered as a result of HCV infection are not uniform, regardless of the degree of progression.
>
> …
>
> **84** It is apparent, in light of Dr. Anderson's evidence, that in the absence of evidence of the individual damages sustained by class members, past precedents of damage awards

[148] Affidavit of Albert Carl Sweetland, sworn December 6, 2018; Affidavit of Barbara Fontaine, sworn December 5, 2018. With respect to the PHIs, see paragraphs 142-144 above.
[149] *Parsons, supra*.

> in personal injury actions cannot be applied to this case to assess the reasonableness of the settlement for the class.

189. Therefore the process of valuing the within Class Member claims involves drawing on the experience of Class Counsel in evaluating the case law that is available, and recognizing the material distinctions between that case law and the circumstances at hand.

190. At Schedule "C" to this brief is a summary of decisions in individual personal injury cases demonstrating the wide range of damages awarded to individual claimants for cardiovascular harm. These decisions arise in a variety of factual scenarios, involving multiple injuries, and after the action has been fully litigated. This case law is of limited utility in evaluating the reasonableness of the present proposed settlement.

191. While we are aware of no Canadian decision awarding damages after a trial of a class proceeding against a pharmaceutical manufacturer for failure to warn about risks, the settlement approval decision in *Voutour v. Pfizer Canada Inc*.[150] details some relevant considerations. The claim was pleaded in the amount of $1.5 billion, but the $12 million settlement was approved.[151] This decision reflects the "genuine risks of proving liability, including the difficulties of proving a breach of a duty of care and of proving causation of harm" that inhere to the subject matter of such claims.[152] Pharmaceutical product liability cases are recognized as highly complex with significant risks and drawn-out litigation.[153]

[150] 2011 ONSC 7118 (Plaintiffs' Authorities, Tab 9).
[151] *Ibid*., para. 65.
[152] *Ibid*.
[153] *Ibid*., para. 73.

v. Approval of the Settlement Approval Notice and Notice Plan

192. If the proposed settlement is approved, the Settlement Approval Notice will be disseminated to the Class according to the methods described in the Settlement Approval Notice Plan (attached to the Settlement Approval Order).

193. Class Counsel will cooperate with RicePoint Administration Inc., if approved as Claims Administrator, to implement the Settlement Approval Notice Plan.[154]

194. The Settlement Approval Notice highlights in plain language the primary aspects of the Settlement, provides information on important deadlines and contact information for inquiries, and directs Class Members to the dedicated settlement website to obtain details about the Compensation and Claims Administration Protocols and the claim form.

vi. Appointment of Claims Administrator

195. The Parties seek Court approval of the appointment of RicePoint Claims Administration Inc. as the Claims Administrator.

196. In its role as Claims Administrator, RicePoint will be responsible for implementing the Settlement Approval Notice Plan and overseeing the claims process under the Settlement Agreement.

197. As demonstrated in Exhibit "K" to the Settlement Approval Affidavit, RicePoint has extensive experience administering class action settlements, including, in particular, pharmaceutical class actions.

[154] Settlement Approval Affidavit, paras. 110-111.

PART V - RELIEF SOUGHT

198. Class Counsel is confident that resolving this matter pursuant to the terms of the Settlement Agreement is in the best interests of the Class.

199. Class Counsel respectfully requests an order: (i) approving the Settlement Agreement as being fair, reasonable and in the best interests of Class Members; (ii) approving the Settlement Approval Notice and Settlement Approval Notice Plan; and (iii) appointing RicePoint Administration Inc. as Claims Administrator.

ALL OF WHICH IS RESPECTFULLY SUBMITTED, this 14th day of December, 2018.

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SCHEDULE "A"

AUTHORITIES

Authorities Referred to in Brief:

1. *Ainslie v. Afexa Life Sciences Inc.*, 2010 ONSC 4294
2. *Dabbs v. Sun Life Assurance Co. of Canada* (1998), 40 O.R. (3d) 429 at (Gen. Div.), aff'd (1998), 41 O.R. (3d) 97 (C.A.), leave to appeal to S.C.C. refused, [1998] S.C.C.A. No. 372
3. *Ford v. F. Hoffmann-La Roche Ltd.* (2005), 74 O.R. (3d) 758 (Ont. S.C.J.)
4. *Lozanski v. Home Depot, Inc.*, 2016 ONSC 5447
5. *Martin v. Roman Catholic Diocese of Antigonish*, 2009 NSSC 331
6. *Nunes v. Air Transat A.T. Inc.*, [2005] O.J. No. 2527
7. *Parsons v. The Canadian Red Cross Society*, [1999] O.J. No. 3572
8. *Stewart v. General Motors of Canada Ltd*., [2008] O.J. No. 4426 (Ont. S.C.J.)
9. *Voutour v. Pfizer Canada Inc*., 2011 ONSC 7118

Authorities Referred to in Schedule "C":

10. *Briffet v. Gander & District Hospital Board*, [1996] N.J. No. 34
11. *Dillon v. LeRoux*, [1994] B.C.J. No. 795
12. *Gros v. Victoria General Hospital*, 2000 MBQB 172
13. *Hewlett v. Henderson*, 2006 BCSC 300
14. *Marchand v. Jackiewicz*, 2010 ONSC 1796
15. *Potrie v. Langdown*, [1996] B.C.J. No. 318

SCHEDULE "B"

LEGISLATION

16. *Class Proceedings Act*, S.N.S. 2007, c. 28

SCHEDULE "C"

Individual Personal Injury Awards For Cardiovascular Harm

1. *Briffet v. Gander & District Hospital Board*:[155] The Newfoundland Court of Appeal upheld a damage award of $40,000 ($60,067 today) for negligent medical care resulting in a debilitating heart attack.[156] The injuries in this case were pervasive; lasting damage was done to the plaintiff's heart, and he could no longer exert himself physically.[157] This caused a "significant curtailment of his daily activities and … substantial adjustments to his normal enjoyment of life."[158]

2. *Dillon v. LeRoux*:[159] The British Columbia Court of Appeal upheld a general damages award of $100,000 ($156,476 today) to compensate for a heart attack requiring an angioplasty, which ultimately caused permanent damage to the plaintiff's heart.[160] A family doctor, working on-call in an emergency room, failed to call an internist in response to the plaintiff's complaints; the resultant delay in diagnosis caused the heart attack and related injuries.[161] While the award was considered "generous," it was affirmed on the basis of the "very substantial physical disability" suffered by the Plaintiff.[162]

3. *Gros v. Victoria General Hospital*:[163] When the plaintiff suffered a heart attack minutes after discharge from the hospital, he sued the hospital for the resultant brain damage,

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[155] [1996] N.J. No. 34 (Plaintiffs' Authorities, Tab 10).
[156] *Ibid*., para. 264.
[157] *Ibid*., para. 249.
[158] *Ibid.*
[159] [1994] B.C.J. No. 795 (Plaintiffs' Authorities, Tab 11).
[160] *Ibid*., para. 15, citing [1992] B.C.J. No. 1971.
[161] *Ibid.*
[162] *Ibid*., paras. 94-95.
[163] 2000 MBQB 172 (Plaintiffs' Authorities, Tab 12).

memory loss, depression, and cognitive difficulties he experienced.[164] Non-pecuniary damages were calculated, though not awarded, in the amount of $85,000 ($118,364 today).

4. *Hewlett v. Henderson*:[165] The plaintiff suffered a heart attack as the result of a negligent diagnostic delay. As a result, he reported cognitive difficulties, fatigue, and ongoing headaches.[166] While the Court accepted the evidence from the plaintiff's family doctor that his cardiac function was relatively normal in the aftermath of the heart attack,[167] the Court quantified general damages at $100,000 ($123,028 today).[168] This amount reflected the multiple invasive surgeries that were necessitated by the negligence, as well as "significant pain and suffering [and] the knowledge of significantly reduced life expectancy as a result of the heart attack."[169] Given the fact that appropriate intervention would have only saved a portion of the damage, the plaintiff was ultimately awarded $30,000 ($36,908 today).

5. *Marchand v. Jackiewicz*:[170] When a heart attack was caused by operating on a patient with strep throat, which was left undiagnosed despite complaints to a family doctor, the Plaintiff sued for several resultant injuries. Liability was not established, but general damages were calculated at $150,000 ($171,337 today). This considerable award was justified on the basis that "[s]he experienced multiple organ failure … and nearly died. She went into septic shock. She required a second emergency surgery."[171] The heart attack and related

[164] *Ibid*., para. 9.
[165] 2006 BCSC 300 (Plaintiffs' Authorities, Tab 13).
[166] *Ibid*., para. 79.
[167] *Ibid*., para. 96.
[168] *Ibid*., para. 86.
[169] *Ibid.*
[170] 2010 ONSC 1796 (Plaintiffs' Authorities, Tab 14).
[171] *Ibid*., para. 61.

emergency procedure also caused an incision "from her pubis to sternum [that] has resulted in dramatic scarring" and necessitated homecare for an extended period of time.[172]

6. *Potrie v. Langdown*:[173] A motor vehicle accident caused a neck injury and dissection of the left anterior artery, which resulted in a heart attack three years later. The plaintiff further suffered bilateral thoracic outlet syndrome, a cervical injury that required surgical fusion, and fibromyalgia in the aftermath of the crash.[174] She was awarded general damages in the amount of $140,000 ($210,235 today).

[172] *Ibid.*
[173] [1996] B.C.J. No. 318 (Plaintiffs' Authorities, Tab 15).
[174] *Ibid.*, paras. 26-27, 43.