

Form 4.02A

2009

Hfx. No. 315567

SUPREME COURT OF NOVA SCOTIA

BETWEEN:

Court Administration

~~ALBERT CARL SWEETLAND and THE ESTATE OF MARY AGNES ADDICOTT, MARY PATRICIA ADDICOTT-ANDREWS, AUDREY LEONE ADDICOTT-NGUYEN, RUTHANNE TOBIN, PAUL ALLEN ADDICOTT, JOHN WENDELL ADDICOTT, JILLIAN LEIGH ANDREWS, by her Litigation Guardian Mary Patricia Addicott-Andrews, JEFFREY PAUL ADDICOTT, JUSTINE LYNN ADDICOTT, SHENOA LEE MATHESON, CONNOR TOBIN, SHAWN ANDREW ADDICOTT, JORDYN AYRES, by her Litigation Guardian Mary Patricia Addicott-Andrews, and LYNDA TROTTIER, by her Litigation Guardian Mary Patricia Addicott-Andrews~~

Plaintiffs

- and -

**GLAXOSMITHKLINE INC., GLAXOSMITHKLINE PLC, GLAXOSMITHKLINE SERVICES UNLIMITED and SMITHKLINE BEECHAM CORPORATION**

Defendants

NOTICE OF ACTION Amended on this *27* day of *July*, 2010 pursuant to Civil Procedure Rule 83.04

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

- To: GLAXOSMITHKLINE INC.
- To: GLAXOSMITHKLINE PLC
- To: GLAXOSMITHKLINE SERVICES UNLIMITED
- To: SMITHKLINE BEECHAM CORPORATION

**Action has been started against you**  
The plaintiffs take action against you.

The plaintiffs started the action by filing this notice with the court on the date certified by the prothonotary. The plaintiffs claim the relief described in the attached statement of claim. The claim is based on the grounds stated in the statement of claim.

**Deadline for defending the action**

To defend the action, you or your counsel must file a notice of defence with the court no more than the following number of days after the day this notice of action is delivered to you:

- 15 days if delivery is made in Nova Scotia
- 30 days if delivery is made elsewhere in Canada
- 45 days if delivery is made anywhere else.

**Judgment against you if you do not defend**

The court may grant an order for the relief claimed without further notice, unless you file the notice of defence before the deadline.

**You may demand notice of steps in the action**

If you do not have a defence to the claim or you do not choose to defend it you may, if you wish to have further notice, file a demand for notice.

If you file a demand for notice, the plaintiffs must notify you before obtaining an order for the relief claimed and, unless the court orders otherwise, you will be entitled to notice of each other step in the action.

**Rule 57 - Action for Damages Under \$100,000**

Civil Procedure Rule 57 limits pretrial and trial procedures in a defended action so it will be more economical. The Rule applies if the plaintiffs state the action is within the Rule. Otherwise, the Rule does not apply, except as a possible basis for costs against the plaintiffs.

This action is *not within* Rule 57. [State “within” if the action is for an order for judgment under \$100,000, no other order (eg. injunction, declaration) is claimed, and the claim is based on debt, injury to property, injury to a person, supply of goods or services, breach of contract, breach of trust, or dismissal from employment.]

**Filing and delivering documents**

Any documents you file with the court must be filed at the office of the Prothonotary, 1815 Upper Water Street, Halifax, Nova Scotia (telephone # 424-4900).

When you file a document you must immediately deliver a copy of it to each other party entitled to notice, unless the document is part of an *ex parte* motion, the parties agree delivery is not required, or a judge orders it is not required.

**Contact information**

The plaintiffs designate the following address:

Raymond F. Wagner  
Wagners  
1869 Upper Water Street  
Halifax NS B3J 1S9

Documents delivered to this address are considered received by the plaintiffs on delivery.

Further contact information is available from the prothonotary.

**Proposed place of trial**

The plaintiffs propose that, if you defend this action, the trial will be held in Halifax, Nova Scotia.

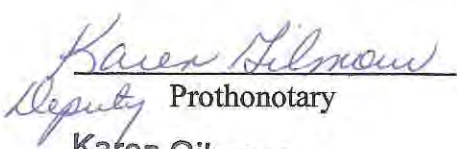
**Signature**

Signed *July 27*, 2010.

  
\_\_\_\_\_  
**RAYMOND F. WAGNER**  
Solicitor for Plaintiffs

**Prothonotary's certificate**

I certify that this notice of action, including the attached *amended July 27, 2010 14/SP* statement of claim, was filed with the court on *July 27th*, 2010.

*amended 14/SP*  
  
\_\_\_\_\_  
Deputy Prothonotary  
Karen Gilmour  
Deputy Prothonotary

**AMENDED STATEMENT OF CLAIM**

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

**I. OVERVIEW**

1. GlaxoSmithKline (“GSK”) resulted from a merger between GlaxoWellcome PLC and SmithKline Beecham PLC in January, 2001.
2. GSK is a pharmaceutical company that carries out research as its main focus. In addition it is involved in the developing, designing, manufacturing, distributing, and marketing of a number of pharmaceutical products.
3. GSK carried out research, developed, designed, tested, manufactured, distributed, and marketed the drug Avandia. Avandia is a prescription medication and is a member of a class of drugs known as thiazolidinediones, often referred to as “glitazones” or “TZDs”.
4. Avandia is a peroxisome proliferator-activated receptor- $\gamma$  (PPAR- $\gamma$ ), a drug that triggers a response by binding to specific cell receptors. It is widely used to lower blood sugar levels in patients with type 2 diabetes mellitus.
5. GSK has also marketed, promoted, sold and/or distributed the drugs Avandamet and Avandaryl. Avandamet combines Avandia and metformin in one single pill and is recommended and prescribed to treat type 2 diabetes mellitus. Avandaryl combines Avandia and glimepiride in one single pill and is also recommended and prescribed to treat type 2 diabetes mellitus.
6. During the Class Period, the Defendants researched, developed, designed, tested, manufactured, distributed, and marketed Avandia.
7. Living Class Members have all been prescribed Avandia. Deceased individuals through Class Members who are lawfully entitled claimants under the *Fatal Injuries Act*, R.S.N.S. 1989, c. 163 in this proceeding had been prescribed Avandia.

8. Living Class Members have been continuously harmed by their use of the medication Avandia as hereinafter described. Deceased individuals had been harmed by the use of Avandia that caused or materially contributed to their death.
9. In this action, the Plaintiffs seek, on their own behalf and on behalf of the Class:
  - (a) compensation for the personal injuries and other costs they have incurred as a result of having taken Avandia and/or;
  - (b) disgorgement of the benefits that accrued to the Defendants as a result of their wrongful acts; and
  - (c) damages in the form of total funds required to establish a medical monitoring process for the benefit of the Class Members.
10. The Plaintiffs seek to certify this action as a class proceeding and plead the *Class Proceedings Act*, S.N.S 2007, c. 28, as providing the basis for such certification. The Plaintiffs, as the Representative Plaintiffs, do not have any interest adverse to any of the members of the proposed Class. The Plaintiffs state that there is an identifiable class that would be fairly and adequately represented by the Plaintiffs; that the Plaintiffs' claims raise common issues which predominate over issues affecting only individual members; and that a class proceeding would be the preferable procedure for the resolution of such common issues.
11. The Plaintiffs propose to bring an opt-out common law class proceeding on behalf of themselves and a Class of other individuals resident in Canada, who were prescribed and ingested Avandia. The proposed Class, which will include Injury Class Members and Family Class Members, will be further defined in the Application for Certification.

## II. REPRESENTATIVE PLAINTIFFS AND CLASS

12. The Plaintiff, **Albert Carl Sweetland**, resides in Halifax, Nova Scotia.
13. The Plaintiff, **Mary Patricia Addicott-Andrews**, of Dartmouth, Province of Nova Scotia, is the daughter of the deceased, Mary Agnes Addicott.

13. ~~The Plaintiff, **Audrey Leone Addicott-Nguyen**, of Jacksonville, State of Florida, United States of America, is the daughter of the deceased, Mary Agnes Addicott.~~
14. ~~The Plaintiff, **Ruthanne Tobin**, of Victoria, Province of British Columbia, is the daughter of the deceased, Mary Agnes Addicott.~~
15. ~~The Plaintiff, **Paul Allen Addicott**, of Timberlea, Province of Nova Scotia, is the son of the deceased, Mary Agnes Addicott.~~
16. ~~The Plaintiff, **John Wendell Addicott**, of Dartmouth, Province of Nova Scotia, is a son of the deceased, Mary Agnes Addicott.~~
17. ~~The Plaintiff, **Jillian Leigh Andrews**, by her litigation guardian Mary Patricia Addicott-Andrews, of Dartmouth, Province of Nova Scotia, is the granddaughter of the deceased, Mary Agnes Addicott.~~
18. ~~The Plaintiff, **Jeffrey Paul Addicott**, of Taiwan, is the grandson of the deceased, Mary Agnes Addicott.~~
19. ~~The Plaintiff, **Justine Lynn Addicott**, of Calgary, Province of Alberta, is the granddaughter of the deceased, Mary Agnes Addicott.~~
20. ~~The Plaintiff, **Shenoa Lee Matheson**, of Victoria, Province of British Columbia, is the granddaughter of the deceased, Mary Agnes Addicott.~~
21. ~~The Plaintiff, **Connor Tobin**, of Victoria, Province of British Columbia, is the grandson of the deceased, Mary Agnes Addicott.~~
22. ~~The Plaintiff, **Shawn Andrew Addicott**, of Kitchener, Province of Ontario, is the grandson of the deceased, Mary Agnes Addicott.~~

~~23. The Plaintiff, **Jordyn Ayres**, by her litigation guardian Mary Patricia Addicott-Andrews, of Kitchener, Province of Ontario, is the great-granddaughter of the deceased, Mary Agnes Addicott.~~

~~24. The Plaintiff, **Lynda Trottier**, by her litigation guardian Mary Patricia Addicott-Andrews, of Kitchener, Province of Ontario, is the great-granddaughter of the deceased, Mary Agnes Addicott~~

~~25. The Estate of Mary Agnes Addicott is also a Plaintiff in this action.~~

14. 26 The Plaintiffs, **Mary Patricia Addicott-Andrews**, brings this action as a daughters, sons, grandchildren and great-grandchildren of Mary Agnes Addicott, deceased, under provisions of the *Fatal Injuries Act*, R.S.N.S. 1989 c. 163, for the benefit of themselves herself as daughters, sons, grandchildren and great-grandchildren of Mary Agnes Addicott, deceased, and who, as a result of the death of Mary Agnes Addicott, deceased, lost guidance, support, care and companionship, and suffered pecuniary loss thereby suffering injury, loss and damage.

~~27. Particulars pursuant to section 5 of the *Fatal Injuries Act*, R. S. N. S. 1989, c. 163 as amended are as follows:—~~

~~(a) The names of the persons for and on behalf of whom the action is brought are:~~

~~(i) Mary Patricia Addicott-Andrews, born March 15, 1963, of Dartmouth, Nova Scotia, is the daughter of the deceased, Mary Agnes Addicott;~~

~~(ii) Audrey Leone Addicott-Nguyen, born July 17, 1962, of Jacksonville, Florida, is the daughter of the deceased, Mary Agnes Addicott;~~

~~(iii) Ruthanne Rutheanne Tobin, born October 16, 1958, of Victoria, British Columbia, is the daughter of the deceased, Mary Agnes Addicott;~~

~~(iv) Paul Allen Addicott, born April 30, 1954, of Timberlea, Nova Scotia, is the son of the deceased, Mary Agnes Addicott;~~

- ~~(v) John Wendell Addicott, born October 20, 1952, of Dartmouth, Nova Scotia, is the son of the deceased, Mary Agnes Addicott;~~
- ~~(vi) Jillian Leigh Andrews, by her litigation guardian Mary Patricia Addicott, born July 12, 1992, of Dartmouth, Province of Nova Scotia, is the granddaughter of the deceased, Mary Agnes Addicott;~~
- ~~(vii) Jeffrey Paul Andrews, born March 2, 1980, of Taiwan, is the grandson of the deceased, Mary Agnes Addicott;~~
- ~~(viii) Justine Lynn Andrews, born July 4, 1984, of Calgary, Province of Alberta, is the granddaughter of the deceased, Mary Agnes Addicott;~~
- ~~(ix) Shenoa Lee Matheson Matthews, born October 31, 1982, of Victoria, Province of British Columbia, is the granddaughter of the deceased, Mary Agnes Addicott;~~
- ~~(x) Connor Tobin, born February 19, 1985, of Victoria, Province of British Columbia, is the grandson of the deceased, Mary Agnes Addicott;~~
- ~~(xi) Shawn Andrew Addicott, born April 11, 1974, of Kitchener, Province of Ontario, is the grandson of the deceased, Mary Agnes Addicott;~~
- ~~(xii) Jordyn Ayres, by her litigation guardian Mary Patricia Addicott-Andrews, born December 28, 2000, of Kitchener, Province of Ontario, is the great granddaughter of the deceased, Mary Agnes Addicott; and~~
- ~~(xiii) Lynda Trottier, by her litigation guardian Mary Patricia Addicott-Andrews, born June 25, 1987-1997, of Kitchener, Province of Ontario, is the great granddaughter of the deceased, Mary Agnes Addicott.~~

~~29. 28. The Plaintiffs and Class Members have also suffered pain, loss of enjoyment of life, a probable shortening of life, loss of earnings and earning capacity, and therefore, claims both special damages and general damages as a result of ingesting Avandia.~~

15. Albert Carl Sweetland and Mary Patricia Addicott-Andrews claim on their own behalf and on behalf of all members of the Classes:

- (a) an order certifying this action as a class proceeding and appointing Albert Carl Sweetland as the representative plaintiff of a Injury Class, and Mary Patricia Addicott-Andrews as the representative plaintiff of a Family Class;

- (b) a declaration that the Defendants were negligent in the development, testing, design, manufacturing, licensing, distribution, marketing and sale of Avandia and are liable to the Classes for damages;

### III. DEFENDANTS

16. ~~29.~~ The Defendant, GlaxoSmithKline Inc., is a corporation incorporated pursuant to the laws of Canada, with head office situated in Mississauga, Ontario.
17. ~~30.~~ The Defendant, GlaxoSmithKline PLC, is a corporation incorporated pursuant to the laws of the United Kingdom, with offices situated in Brentford and Uxbridge, United Kingdom, and whose shares trade on the London and New York Stock Exchanges.
18. ~~31.~~ The Defendant, GlaxoSmithKline Services Unlimited, is a corporation incorporated pursuant to the laws of the United Kingdom, with offices situated in Brentford and Uxbridge, United Kingdom.
19. ~~32.~~ The Defendant, SmithKline Beecham Corporation, is a corporation incorporated pursuant to the laws of the United States, with offices situated in Philadelphia, Pennsylvania, United States of America.
20. ~~33.~~ The Defendants, GlaxoSmithKline Inc., GlaxoSmithKline PLC, GlaxoSmithKline Services Unlimited, and SmithKline Beecham Corporation, are hereinafter collectively referred to as "GSK"; and hereinafter references to GSK are intended to include the above mentioned corporations, their officers, employees, representatives, agents, and associates acting on behalf of GSK.
21. ~~34.~~ The main headquarters of GSK is in the United Kingdom. It also has operations based in the United States. GSK employs approximately 1,800 individuals in Canada and has 106,000 employees on a worldwide basis. GSK has an annual sale revenue of approximately \$45 billion CDN. GSK has operates worldwide. Its pharmaceutical products are sold in 40 countries.
22. ~~35.~~ The Defendants, at all material times are/were engaged in, involved in and/or responsible for the designing, testing, researching, formulation, development,

manufacturing, production, labelling, advertising, promoting, distribution and/or selling of Avandia in the US, Canada and elsewhere.

23. ~~36.~~ The business of each of the Defendants is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the designing, testing, researching, formulation, development, manufacturing, production, labeling, advertising, promoting, distribution and/or selling of Avandia in the US, Canada and elsewhere.

24. ~~37.~~ At all material times, the Defendants, all or any one of them, were carrying on business as, inter alia, the designers, testers, researchers, formulators, developers, manufacturers, producers, marketers, labelers, advertisers, promoters, distributors and/or sellers of Avandia in US, Canada and elsewhere.

#### **IV. AVANDIA**

25. ~~38.~~ Avandia (Rosiglitazone) is a brand-name anti-diabetic prescription drug used in the treatment of type II diabetes mellitus. The drug was approved by Health Canada on March 21, 2000 for the treatment of type II diabetes mellitus.

26. ~~39.~~ The sales for Avandia peaked in 2006 at approximately three billion dollars. At this time, Avandia sales were over over \$150 million in Canada. Approximately 7% of GSK's revenue was accrued from the sale of Avandia. Avandia was GSK's second best selling drug and the top-selling diabetes treatment.

27. ~~40.~~ Numerous meta-analysis studies have been conducted on the effect of Avandia on the risk of heart related health problems. These studies, including GSK's own study, has shown that there is a significant increase in the risk of heart attack in patients taking Avandia.

#### **V. NATURE OF THE ACTION**

28. ~~41.~~ The Plaintiffs and Class Members allege that the Defendants engaged in tortious conduct in the manufacturing, marketing, promotion, distributing and selling of Avandia in complete disregard for the health and safety of the Plaintiffs and Class Members.

29. ~~42.~~ The Plaintiffs and Class Members further allege that the Defendants were wholly and grossly negligent.
30. ~~43.~~ The Plaintiffs and Class Members further allege that the Defendants failed to warn the Plaintiffs and Class Members of the serious complications and problems that would ensue with the use of Avandia. These individuals were not given warning or, in the alternative, clear, complete and current warning of the health risks associated with the ingestion of Avandia.
31. ~~44.~~ The Plaintiffs and Class Members further allege that the Defendants expressly and impliedly breached warranties.
32. ~~45.~~ The Plaintiffs and Class Members further allege that they and thousands of other Canadians have sustained physical, mental, and economic harm through the use of Avandia as a result of the wholly and grossly negligent actions of the Defendants.
33. ~~46.~~ The Plaintiffs and Class Members further allege that the Defendants failed and/or chose not to adequately inform both users of Avandia and the doctors who prescribed the medication of the very serious risks associated with Avandia.
34. ~~47.~~ Avandia has caused damage to the physical and mental health of the Plaintiffs and Class Members.
35. ~~48.~~ The Plaintiffs allege on behalf of Class Members that the continued use of Avandia by Class Members creates ongoing risks to the health of the Class Members.
36. ~~49.~~ During the applicable times within the Class Period of May 1999 to the present when the Defendants were involved with the manufacture and distribution of Avandia they knew or ought to have known of the potential safety risks with the drug.
37. ~~50.~~ None of the Defendants took any steps to prevent harm to the Plaintiffs and the Class Members or to protect the health and safety of the Plaintiffs and Class Members.
38. ~~51.~~ Living Class Members have been prescribed and continue to be prescribed Avandia. Deceased individuals through Class Members who are lawfully entitled claimants

under the *Fatal Injuries Act*, R.S.N.S. 1989, c. 163 in this proceeding had been prescribed Avandia.

## VI. HARM TO THE PLAINTIFFS

39. ~~52.~~ Mary Agnes Addicott, deceased, was initially prescribed Avandia on April 23, 2004.

40. ~~53.~~ As a result of taking Avandia, Mary Agnes Addicott, deceased, suffered two heart attacks.

41. ~~54.~~ Further, as a result of taking Avandia, Mary Agnes Addicott, deceased, was also diagnosed with congestive heart failure on several occasions.

42. ~~55.~~ Further, as a result of taking Avandia, Mary Agnes Addicott, deceased, also developed other serious and adverse effects including fluid retention, swelling, shortness of breath, weakness, fatigue and weight gain.

43. ~~56.~~ Mary Agnes Addicott, deceased, discontinued the use of Avandia on November 6, 2004. She died on August 16, 2006.

44. ~~57.~~ Albert Carl Sweetland was initially prescribed Avandia on December 14, 2001.

45. ~~58.~~ As a result of taking Avandia, Albert Carl Sweetland suffered significant myocardial dysfunction and sustained congestive heart failure in January of 2007.

46. ~~59.~~ The Plaintiffs state that the personal injuries were caused by ~~or materially contributed to by Mary Agnes Addicott, deceased,~~ the use of Avandia.

47. ~~60.~~ The Plaintiffs and Class Members have suffered and continue to suffer from anxiety about their own and their family's health because of the effect that Avandia has had on their lives. The Plaintiffs state that all of the Defendants bear the responsibility to, *inter alia*, create a medical monitoring fund/mechanism as described below that would give Class Members access to experts who could address their health concerns.

## VII. CAUSES OF ACTION

### (a) Conspiracy

- ~~48.~~ ~~59.~~ During the class period the Defendants, by their directors, officers, servants and agents, wrongfully, unlawfully, maliciously and lacking bona fides, conspired and agreed together, the one with the other and with persons unknown, as hereinafter set out.
- ~~49.~~ ~~60.~~ The Plaintiffs pleads that the Defendants' conspiracy involved both lawful and unlawful means with the predominant purpose of causing the Plaintiffs and the other Injury Class Members to acquire and ingest Avandia when they knew or should have known that such use would cause harm to the Injury Class Members and the Family Class Members.
- ~~50.~~ ~~61.~~ The Defendants conspired with each other and others to unlawfully market, distribute, advertise and sell Avandia, intending that their conduct be directed towards the Injury Class Members, when they knew or should have known that in the circumstances, injury and damage to the Injury Class Members and the Family Class Members was likely to result. They derived substantial compensation and revenues from the conspiracy.
- ~~51.~~ ~~62.~~ As a result of the conspiracy, the Plaintiffs and the other Injury Class Members have suffered damage and loss, including other side effects as a result of the use of Avandia.
- ~~52.~~ ~~63.~~ As a further result of the conspiracy, Family Class Members have suffered damages and loss, and continue to suffer damages and loss, including actual expenses reasonably incurred for the benefit of the Injury Class Member, a reasonable allowance for loss of income or the value of services provided to the Injury Class Member and an amount to compensate for the loss of guidance, care and companionship they might reasonably have expected to receive from the Injury Class Member.
- ~~53.~~ ~~64.~~ Some, but not all, of the Defendants' concerns, motivations and intentions in engaging in the conspiracy were to:

- (a) increase the sales of Avandia and their profits;
- (b) increase or hold their market share;
- (c) avoid adverse publicity;
- (d) place their profits above the safety of Injury Class Members and others;
- (e) maintain brand trust and corporate image;
- (f) avoid alerting the Injury Class Members, Health Canada, the FDA, health practitioners, the public and their competitors to the dangerous properties and effects of Avandia; and
- (g) cause the Injury Class Members to ingest and continue to ingest Avandia and thereby suffer harm.

54. 65. In furtherance of the conspiracy, the following are some, but not all, of the acts carried out by the Defendants or one or some of them:

- (a) they submitted false, inaccurate and misleading information to Health Canada for the purpose of obtaining approval to market Avandia in Canada;
- (b) they concealed and disguised information about the dangerous properties and effect of Avandia from Health Canada, from health practitioners and from Injury Class Members;
- (c) they misled Injury Class Members, health practitioners and others about the efficacy, safety and effect of Avandia;
- (d) they refused to issue correcting information or to stop selling Avandia even after its harmful effects and addictive properties became manifest;
- (e) they decided not to warn Class Members and others in Canada of the dangers of taking Avandia; and

- (f) they developed and used marketing and promotional strategies that covered up the truth about Avandia's dangerous properties and effect.

**(b) Negligence**

55. ~~66.~~ Each of the Defendants owed a duty of care to the Plaintiffs and Class Members and breached the requisite standard of conduct expected of them in the circumstances.

56. ~~67.~~ The Defendants negligently breached their duty of care in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that they, directly and indirectly, advertised, marketed and promoted Avandia for the treatment of diabetes, even though Avandia, in fact, was not safe or effective for any purpose because it caused serious cardio-vascular events. Furthermore, GSK failed to adequately warn of the increased risk of serious cardio-vascular events which GSK knew or should have known about.

57. ~~68.~~ The Plaintiffs and Class Members state that their damages were caused by the negligence of the Defendants. Such negligence includes but is not limited to the following, that the Defendants jointly and severally:

- (a) chose not to ensure that Avandia was not dangerous to recipients during the course of its use and that the drug was fit for its intended or reasonably foreseeable use;
- (b) chose to inadequately test Avandia in a manner that concealed the magnitude of the risks associated with its use, including but not limited to the risk of serious heart problems;
- (c) misinformed Health Canada by providing it with incomplete and inaccurate information;
- (d) conducted inadequate or no follow-up studies on the efficacy and safety of Avandia;
- (e) concealed and mislead the Plaintiffs, Class Members and their physicians with inadequate and incomplete warning of the risks associated with ingesting Avandia;

- (f) provided the Plaintiffs, Class Members and their physicians with inadequate or incomplete or no information and warnings respecting the correct usage of Avandia;
- (g) provided inadequate or incomplete or no updated and current information to the Plaintiffs, Class Members and their physicians respecting the risks and efficacy of Avandia as it came available from time to time;
- (h) chose not to provide warnings of the potential hazards of ingesting Avandia on package labels and by other means;
- (i) chose not to provide warnings of the risks associated with Avandia on the customer information pamphlets in Canada;
- (j) chose not to warn the Plaintiffs, Class Members and their physicians about the need for comprehensive regular medical monitoring to ensure early discovery of serious problems from the use of Avandia;
- (k) after noticing problems with Avandia chose not to issue adequate warnings, recall the drug in a timely manner, publicize the problem and otherwise act properly and in a timely manner to alert the public, including warning the Plaintiffs, Class Members and their physicians of the drug's inherent dangers;
- (l) engaged in a system of improper and inadequate direction to their sales representatives and prescribing physicians respecting the correct usage of Avandia and the risks associated with the drug;
- (m) represented that Avandia was safe and fit for its intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;
- (n) misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of Avandia and its associated risks;

- (o) the misrepresentations made by the Defendants were unreasonable in the face of the risks that were known or ought to have been known to the Defendants;
- (p) continued to manufacture, market and promote the selling and/or distribution of Avandia when they knew or ought to have known that this drug caused or could cause serious problems;
- (q) actively encouraged aggressive dispensation of Avandia;
- (r) breached other duties of care to the Plaintiffs and the Class Members, details of which breaches are known only to the Defendants.

**(c) Strict Liability**

58. ~~69.~~ The Defendants are strictly liable for some or all of the damages suffered by the Plaintiffs and other Class Members in that:

- (a) the Defendants manufactured Avandia;
- (b) Avandia is a prescription drug that is considered to be inherently dangerous;
- (c) the Plaintiffs and other Class Members had no opportunity to inspect or test Avandia to ensure its safety; and
- (d) Avandia was used by the Plaintiffs and other Class Members.

**(d) Breach of Warranty**

59. ~~70.~~ The Defendants warranted to the Plaintiffs and the Class Members that Avandia was of merchantable quality and fit for use and safe for human consumption. The Defendants breached the warranty to the Plaintiffs and the Class Members by designing, testing, researching, formulating, developing, manufacturing, producing, labeling, advertising, promoting, distributing and/or selling Avandia which was inherently dangerous to users and which the Defendants knew or ought to have known would lead to serious complications.

**(e) Waiver of Tort**

60. ~~71.~~ As a result of the Defendants' conduct described herein, the Plaintiffs and Class Members reserve the right to elect at the trial of the common issues to waive the torts and to have damages assessed in an amount equal to the gross revenues earned by the Defendants, or the net income received by the Defendants or a percent of the proceeds from the sale of Avandia as a result of the Defendants' conduct.

61. ~~72.~~ The Plaintiffs and Class Members claim that such an election is appropriate for the following reasons, among others:

- (a) revenue was acquired in a manner in which the Defendants cannot in good conscience retain it;
- (b) the integrity of the pharmaceutical regulations and marketplace would be undermined if the court did not require an accounting;
- (c) absent the Defendants' tortious conduct Avandia could not have been marketed nor would the Defendants have received any revenue from its sale in Canada; and
- (d) the Defendants engaged in wrongful conduct by putting into the marketplace a pharmaceutical product which causes or has the potential to cause serious risk of injury.

**(f) Breach of Section 52 of the *Competition Act*, R.S. 1985, c. C-34**

62. ~~73~~ GSK knowingly or recklessly made material false representations to the Plaintiffs and Class Members for the purposes of promotion the supply and use of Avandia.

**(g) Breach of the *Food and Drugs Act*, R.S. 1985, c. F-27**

63. ~~74.~~ GSK engaged in unfair trade practices and specifically declared unlawful under ss. 3 and 9 of the FDA. Such practices included making false or misleading representations or advertisements, knowingly or with reason to know, as to the characteristics of Avandia.

**(h) Unjust enrichment**

64. 75. GSK voluntarily accepted and retained profits and benefits, derived from the Plaintiffs and Class Members, with full knowledge and awareness that, as a result of its conscious and intentional wrongdoings, Plaintiffs and Class Members did not receive a product of the quality, nature or fitness that had been represented by GSK or that Plaintiffs and Class Members, as a reasonable consumer, expected.

65. 76. By virtue of the conscious wrongdoings alleged, GSK has been unjustly enriched at the expense of the Plaintiffs and Class Members.

**VIII. DAMAGES**

66. 77. The Plaintiffs' and Class Members' injuries and damages were caused by the Defendants, their servants and agents.

67. 78. The Defendants have caused injury to the Plaintiffs and to the Class Members including:

- (a) death and/or a reduced standard of living as a result of illness;
- (b) the cost of treatment to combat the adverse health effects caused by their use of Avandia; and
- (c) an enhanced risk of future problems attributable to the use of Avandia.

68. 79. As a result of the conduct of the Defendants as hereinbefore set out, the Plaintiffs and Class Members have been placed in a position where they have sustained or will sustain serious personal injuries and damages.

69. 80. As a result of the conduct of the Defendants, the Plaintiffs and Class Members suffered and continue to suffer expenses and special damages of a nature and an amount to be particularized prior to trial.

70. 81. Some of the expenses related to the medical treatment that the Plaintiffs and Class Members have undergone, and will continue to undergo have been borne by provincial health insurer including the Nova Scotia Medical Services Insurance Plan.

As a result of the negligence of the Defendants, the provincial health insurer have suffered and will continue to suffer damages.

**(A) Manifest Harm and Injuries:**

~~71.~~ ~~82.~~ In addition, the past and ongoing use of Avandia has resulted in the Plaintiffs and Class Members' physical and mental health injuries pleaded above, and have further led to pain and suffering, loss of income, impairment of earning ability, loss of valuable services, future care costs, medical costs, loss of amenities and enjoyment of life, anxiety, nervous shock, mental distress, emotional upset, and out of pocket expenses.

~~72.~~ ~~83.~~ The Plaintiffs and Class Members assert a claim for each of the types of damages listed above.

**(B) Medical Monitoring: Responding to Material Risk of Illness**

~~73.~~ ~~84.~~ Further, the past and ongoing use of Avandia have also caused or materially contributed to increased health risks to the Plaintiffs and other Class Members. As a result of the use, the Plaintiffs and Class Members have already and will continue to experience illness, anxiety, loss of amenities and enjoyment of life.

~~74.~~ ~~85.~~ There are medically accepted tests and diagnostic tools which, if used properly and on a timely basis, will detect at an early stage the serious problems which may result from the use of Avandia by the Class Members. However, not all of these tests are generally available or being administered to the Class Members despite their elevated risk. The early detection of these conditions will significantly reduce the harm and risk of death therefrom.

~~75.~~ ~~86.~~ The Class Members seek to recover damages in the form of the total funds required to establish a 'medical monitoring' process to be made available to the Class Members. Such damages include the costs of medical screening and treatment incurred by or on behalf of the Class Members.

~~76.~~ ~~87.~~ The damages referred to above may have been incurred directly by the Plaintiffs and Class Members, or may constitute subrogated claims owed to provincial health insurers, or to private health, disability, or group benefit insurers.

~~77.~~ ~~88.~~ The Plaintiffs further allege that the establishment of a medical monitoring process is a necessary and appropriate step for all of the Defendants to take in the course of fulfilling their obligation to minimize the damages suffered by Class Members.

#### **IX. AGGRAVATED, PUNITIVE AND EXEMPLARY DAMAGES**

~~78.~~ ~~89.~~ The Defendants manufactured, marketed, promoted and sold Avandia with full knowledge of the fact that they were adversely impacting the physical and psychological health of the Plaintiffs and the Class Members. Knowledge of the risks associated with the use of Avandia was not released to the Plaintiffs and Class Members. Despite having specific information that the Plaintiffs and Class Members were at risk of serious problems associated with the use of Avandia, the Defendants continued or permitted the continuation of the manufacturing, marketing, promoting and selling of Avandia without any or reasonable controls.

~~79.~~ ~~90.~~ These activities were carried out with reckless, callous and wanton disregard for the health, safety and pecuniary interests of the Plaintiffs and other Class Members. The Defendants knowingly compromised the interests of the Plaintiffs and Class Members, solely for the purpose of monetary gain and profit. Furthermore, once the Defendants knew of the extraordinary dangers that Avandia posed to the Plaintiffs and Class Members, the Defendants failed to advise them in a timely fashion, or fully, or at all.

~~80.~~ ~~91.~~ The Defendants' negligence was callous and arrogant and offends the ordinary community standards of moral and decent conduct. The actions, omissions, or both, of the Defendants involved such want of care as could only have resulted from actual conscious indifference to the rights, safety or welfare of the Plaintiffs and Class Members.

~~81.~~ ~~92.~~ Consequently, the Plaintiffs and Class Members are entitled to aggravated damages, and an award of punitive and exemplary damages commensurate with the outrageous behaviour of the Defendants.

~~82.~~ ~~93.~~ The Plaintiffs and Class Members plead that, by virtue of the acts described herein, the Defendants are liable to them in damages. Each of the Defendants is vicariously liable for the acts and omissions of the others for the following reasons:

- (a) each was the agent of the other;
- (b) each Defendants' business was operated so that it was inextricably interwoven with the business of the other;
- (c) each Defendant entered into a common advertising and business plan with the other to distribute and sell Avandia;
- (d) each Defendant owed a duty to the other and to the Plaintiffs and Class Member by virtue of the common business plan to distribute and sell Avandia; and
- (e) each Defendant intended that the businesses be run as one global business organization.

## **X. GENERAL PROVISIONS**

83. 94. The Plaintiffs states that the Defendants are responsible, jointly and severally, for the injuries and damages suffered by the Plaintiffs and other Class Members.

84. 95. The Plaintiffs pleads the doctrine of *respondeat superior* and state that the Defendants are vicariously liable to the Plaintiffs and Class Members for the acts, omissions, deeds, misdeeds and liabilities of their contractors, sub-contractors, agents, servants, employees, assigns, appointees and partners.

85. 96. The Plaintiffs pleads and relies on the *Canada Food and Drugs Act*, R.S. 1985, c. F-27, the *Canada Competition Act*, R.S., 1985, c. C-34, s. 1; R.S., 1985, c. 19 (2nd Supp.), s. 19, the *Nova Scotia Tortfeasors Act*, R.S.N.S., c. 471, the *Nova Scotia Sale of Goods Act*, R.S., c. 408, s. 1, the *Nova Scotia Consumer Protection Act*, R.S., c. 92, s. 1 and the *Nova Scotia Fatal Injuries Act*, R. S. N. S. 1989, c. 163 as amended.

## **XI. RELIEF SOUGHT**

86. 97. The Plaintiffs repeats the foregoing paragraphs and states that the Defendants are jointly and severally liable for the following:

- (a) an Order certifying this proceeding as a class proceeding and appointing the Plaintiffs as Representative Plaintiffs for the Class;
- (b) general damages, including aggravated damages for personal injuries;
- (c) special damages for medical expenses and other expenses related to the use of Avandia;
- (d) aggravated, punitive and exemplary damages;
- (e) further or alternatively the Plaintiffs claims, on her own behalf and on behalf of the Class Members:
  - (i) a declaration that the benefits which accrued to the Defendants as a result of their wrongful acts unjustly enriched the Defendants;
  - (ii) an accounting of the benefits which accrued to the Defendants as a result of their wrongful acts;
  - (iii) a declaration that the Defendants hold in trust for the Class the benefits which accrued to the Defendants as a result of their wrongful acts;
  - (iv) disgorgement of the benefits which accrued to the Defendants as a result of their wrongful acts;
- (f) damages for the funding of a “Medical Monitoring Program”, supervised by the Court, for the purpose of retaining appropriate health and other experts to review and monitor the health of the Class Members, and to make recommendations about their treatment;
- (g) subrogated claims on behalf of the Provincial providers of medical services;
- (h) interest pursuant to the *Judicature Act*;
- (i) costs; and
- (j) such further and other relief as this Honourable Court deems just.

PLACE OF TRIAL: Halifax, Nova Scotia.

DATED at Halifax, Nova Scotia this 27 day of July, 2010.



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