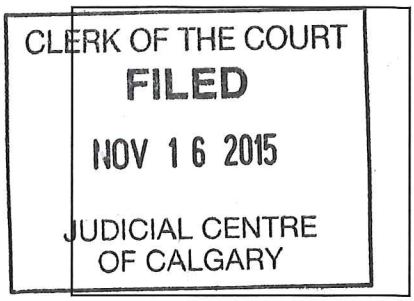
Clerk's stamp



FORM 10
[RULE 3.25]

COURT FILE NUMBER	1501-13634
COURT OF QUEEN'S BENCH OF ALBERTA JUDICIAL CENTRE	CALGARY
PLAINTIFFS	CATHERINE HOGAN on her own behalf and CATHERINE HOGAN as Litigation Representative of the ESTATE OF SARAH-FAITH HOGAN, as Representative Plaintiffs
DEFENDANTS	GLAXOSMITHKLINE INC., GLAXO WELLCOME INC., and NOVARTIS PHARMACEUTICALS CANADA INC.
DOCUMENT	**Brought under the *Class Proceedings Act*** **STATEMENT OF CLAIM**
ADDRESS FOR SERVICE AND CONTACT INFORMATION OF PARTY FILING THIS DOCUMENT	**JENSEN SHAWA SOLOMON DUGUID HAWKES LLP** Barristers 800, 304 - 8 Avenue SW Calgary, Alberta T2P 1C2 Gavin Price Erin Baker Phone: 403 571 1520 Fax: 403 571 1528 File: 11121.025
NOTICE TO DEFENDANTS	You are being sued. You are a defendant. Go to the end of this document to see what you can do and when you must do it.

Statement of facts relied on:

NATURE OF THE ACTION

1. This action arises from the risks imposed upon conceived but yet unborn children from their expectant mothers' use of the prescription drug Zofran, or its generic equivalent, during

the first trimester of pregnancy. This action involves the Defendants' unlawful, negligent, inadequate, improper, unfair and deceptive practices and misrepresentations related to, *inter alia*, their development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution and sale of Zofran.

2. The Defendants misrepresented that Zofran is a safe and effective treatment for nausea and vomiting during pregnancy, when in fact the drug was never approved for this off-label use. The drug had never been studied in pregnant women, much less shown to be safe and effective to ingest during pregnancy.

3. By contrast, the Defendants knew, or ought to have known, that Zofran was unsafe for ingestion by expectant mothers. The Defendants knew of reports of birth defects arising from the use of Zofran during pregnancy, both before and during its marketing in Canada. The Defendants never disclosed this to pregnant women or their physicians. Instead, the Defendants specifically marketed and promoted Zofran as a morning sickness drug throughout the relevant time periods discussed herein.

4. The Defendants' promotion of Zofran for use in pregnancy eventually led to a federal investigation in the United States. In 2012, the Defendants pled guilty to criminal charges laid by the US Department of Justice for its off-label promotion of Zofran for unapproved uses. At or around the same time, the Defendants also entered into civil settlements with the United States for its illegal marketing of Zofran.

5. The Defendants misled pregnant women and their physicians regarding Zofran's safety and efficacy during pregnancy, and as a result the pregnant women's offspring children suffered serious negative health consequences in utero.

THE PLAINTIFFS

6. Catherine Hogan ("Ms. Hogan"), in her capacity as Litigation Representative of the Estate of Sarah-Faith Hogan ("Sarah-Faith"), seeks to represent the following class (the "Proposed Class"):

a) Persons in Alberta, born with Birth Defects (as defined in paragraph 35), to women who ingested Zofran, or its generic form, during the first trimester of pregnancy, and any person who can claim on their behalf; and

b) Persons in Alberta, who ingested Zofran, or its generic form, during the first trimester of pregnancy and experienced a third trimester miscarriage or still birth.

7. Ms. Hogan seeks to represent the following class (the "Proposed Family Class"):

> Persons who, by reason of his or her relationship to a member of the Proposed Class, are entitled to make claims under the *Tort-feasors Act*, RSA 2000, c. T-5 or the *Fatal Accidents Act*, RSA 2000, C F-8, as a result of the death or personal injury of a member of the Proposed Class.

8. Ms. Hogan resides in Ardmore, Alberta. She was the mother of Sarah-Faith.

9. While pregnant with Sara-Faith, Ms. Hogan was prescribed and ingested Zofran during her first trimester.

10. Sarah-Faith was born on November 8, 2004. At birth, it was determined that she suffered from multiple serious birth defects. In her two years of life, Sarah-Faith underwent more than 15 surgeries. On January 22, 2006, Sarah-Faith succumbed to her conditions and passed away.

11. Ms. Hogan, acting personally and in her capacity as Litigation Representative of the estate of Sarah-Faith, is referred to herein as the "Plaintiffs."

THE DEFENDANTS

12. GlaxoSmithKline Inc., Glaxo Wellcome Inc., Glaxo Canada Inc., and Novartis Pharmaceuticals Canada Inc. (collectively, the "Defendants" or "GSK") were involved in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling and/or selling Zofran in Canada.

13. The Defendant, GlaxoSmithKline Inc. is a federal corporation incorporated pursuant to the laws of Canada, with its head office situated in Mississauga, Ontario, and its Bureau

D'Affaires du Quebec situated in Laval, Quebec. GSK also has regional offices in Montreal, Halifax, Ottawa, Winnipeg, Calgary, and Vancouver. GSK is a subsidiary of GlaxoSmithKline PLC, incorporated under the laws of Great Britain.

14. The Defendant, Glaxo Wellcome Inc., is a federal corporation incorporated pursuant to the laws of Canada, with its head office situated in Mississauga, Ontario. Glaxo Wellcome Inc. amalgamated into GlaxoSmithKline Inc. in 2001. Glaxo Wellcome Inc. is currently inactive.

15. Glaxo Canada Inc. was a federal corporation incorporated pursuant to the laws of Canada. Glaxo Canada Inc. was dissolved by the corporation in 2011, under its most recent corporate name ViiV Healthcare Shire Canada Inc. Glaxo Canada Inc. was a subsidiary of GlaxoSmithKline Inc.

16. The Defendant, Novartis Pharmaceuticals Canada Inc., is a federal corporation incorporated pursuant to the laws of Canada, with its head office situated in Dorval, Quebec. Novartis Pharmaceuticals Canada Inc. has regional offices in Mississauga, Ontario and Boucherville, Quebec.

17. The parent companies of Novartis Pharmaceuticals Canada Inc. and GlaxoSmithKline Inc., Novartis AG and GlaxoSmithKline PLC, respectively, engaged in major business transactions in 2015. The corporations came together in the creation of a consumer healthcare joint venture, where GSK acquired Novartis AG's vaccine business, and Novartis AG acquired GSK's oncology business, including Zofran.

18. At all material times, the Defendants were engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling and/or selling Zofran in Canada. The development of Zofran for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Zofran and other actions central to the allegations of this lawsuit, were undertaken by the Defendants in Alberta and elsewhere.

THE DRUG

A. Background

(i) Zofran

19. Zofran is a prescription drug indicated for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and vomiting and post-operative nausea and/or vomiting. Zofran is available as an injection (2mg/mL), oral tablets (4mg and 8 mg), orally disintegrating sublingual tablets (4 mg and 8 mg), and an oral solution (4mg/ 5mL).

20. The medical term for nausea and vomiting is emesis, and drugs that prevent or treat nausea and vomiting are called anti-emetics.

21. Zofran is part of a class of anti-emetics called "selective serotonin 5HT3 receptor antagonists". The active ingredient in Zofran is ondansetron hydrochloride. Zofran antagonizes, or inhibits, the body's serotonin activity, which triggers nausea and vomiting.

22. Zofran was approved for use by Health Canada on November 13, 1996.

23. Zofran was approved to treat nausea and vomiting in oncology and surgery patients. Zofran was never approved for the treatment of nausea and vomiting during pregnancy. This is known as an "off-label use" for a condition that Health Canada does not approve.

24. The Defendants have not performed any clinical studies demonstrating the safety or efficacy of Zofran for treating nausea and vomiting during pregnancy. However, the Defendants had the resources and knowledge to perform such studies. Instead, the Defendants circumvented Health Canada's approval process by marketing Zofran for treating nausea and vomiting during pregnancy without applying to market Zofran for this condition or any other condition in pregnant women. This practice is known as "off-label promotion".

25. Alternatively, the Defendants knew or ought to have known that Zofran was being prescribed to treat nausea and vomiting during pregnancy.

26. The Defendants' promotion of Zofran for treating pregnant women eventually led to a federal investigation in the United States. In 2012, the Defendants pled guilty to criminal charges laid by the US Department of Justice for its off-label promotion of Zofran. At or around the same time, the Defendants also entered into civil settlements with the United States that included more than $1 billion in payments for its illegal marketing of various drugs, including Zofran.

27. The Defendants were aware of reported birth defects arising from using Zofran during pregnancy, both before and during its marketing in Canada.

(ii) The Generic

28. The first generic Zofran products were approved by Health Canada in 2006. These products are referred to as "ondansetron products".

29. At least thirteen companies market and sell ondansetron products in Canada.

30. A generic drug is a term used for drugs that contain the same medical ingredient(s) as the innovator drug. Zofran's medical ingredient is ondansetron hydrochloride.

31. A Canadian generic drug must be the pharmaceutical equivalent and bioequivalent of the innovator drug, have the same route of administration, and its uses must fall within the conditions of marketing approval for the innovator drug.

32. Generic drugs are assessed according to an abbreviated process which is intended to demonstrate that the generic drug is bioequivalent to the innovator drug, and as such, is interchangeable. In accordance with the *Food and Drug Act*, and the *Food and Drug Regulations*, a generic drug sponsor submits the required information to Health Canada as an Abbreviated New Drug Submission.

33. The clinical data requirements for an Abbreviated New Drug Submission are purposely limited. This is based on the assumption that the safety and efficacy of the innovator product demonstrated in the original submission and confirmed during the extensive period of

marketing can be extrapolated to the generic drug. Generic producers are not required to provide regulators with detailed reports to establish the safety or clinical effectiveness of their products. Meaning, producers of generic ondansetron products necessarily relied on the research and actions of the Defendants. The generic manufacturers were required to merely prove that their products were equivalent to Zofran, in order to obtain regulatory approval for sale in the Canadian market.

34. GSK knew, or ought to have known, that doctors and other medical professionals would prescribe the generic in any circumstance in which they would prescribe Zofran. Therefore, by marketing Zofran for use in treating nausea and vomiting in pregnancy, GSK assumed the risk that doctors would similarly prescribe the generic in such circumstances.

B. The Risks

35. Using Zofran during pregnancy may result in serious side effects, including birth defects. Birth defects suffered as a result of using Zofran during pregnancy include but are not limited to: congenital heart disease, including septal defects, dimorphism, intrauterine death, stillbirth, kidney malformation, congenital diaphragmatic anomalies, congenital musculoskeletal anomalies, and orofacial anomalies, including cleft lip and cleft palate (the "Birth Defects").

36. In 2013, a study titled "Ondansetron Use in Early Pregnancy and the Risk of Congenital Malformations — A Register Based Nationwide Control Study", reported that Zofran taken during the first trimester of pregnancy was associated with an increased risk of cardiac malformations.

37. In 2014, a study titled "Ondansetron During Pregnancy and Congenital Malformations in the Infant", reported that mothers who took Zofran during early pregnancy had a 62% increased risk of having a baby with a cardiovascular defect.

38. In 2012, a study titled "Medications Used to Treat Nausea and Vomiting of Pregnancy and the Risk of Selected Birth Defects", reported that there is a positive association between using Zofran during the first trimester of pregnancy and facial clefts.

39. At least as early as 1992, the Defendants began receiving reports of Birth Defects associated with the use of Zofran by pregnant women in the United States. From 1992 to the present, the Defendants received more than 200 reports of Birth Defects in children who were exposed to Zofran during pregnancy in the United States.

40. In 2012, at least 20 Canadian women treated with Zofran during the first trimester of pregnancy experienced serious suspected side-effects, including two infant deaths and multiple cases of newborns with heart defects and kidney malformations.

41. Notwithstanding the important findings of serious birth defects in numerous studies, and other data and information that was being collected worldwide by the Defendants, the Defendants concealed the risks of using Zofran during pregnancy.

42. Despite the publicity surrounding reports by third parties, the Defendants continued to market and distribute Zofran as being safe and effective in the treatment of nausea and vomiting in pregnant women, without undertaking their own studies in order to either confirm or dispute the findings reported by others.

43. Zofran's product monograph does not provide any meaningful precaution to health professionals or consumers about the risk of Birth Defects. Rather, the Part III Compendium of Pharmaceuticals and Specialties ("CPS") for Zofran:

(b) Between 1996 and 1997 stated:

> "The safety of ondansetron during pregnancy has not been established. Ondansetron is not teratogenic in animals. However, ondansetron should not be used during pregnancy, particularly in the first trimester unless, in the physician's opinion, the expected therapeutic benefit to the mother outweighs the possible risk to the fetus." [emphasis added]

(c) Between 1998 and 2015, was revised to state:

> "The safety of ondansetron for use in human pregnancy has not been established. Ondansetron

> is not teratogenic in animals. However, as animal studies are not always predictive of human response, the use of ondansetron in pregnancy is not recommended."

44. Even if animal studies did not reveal evidence of harm to a prenatally exposed fetus, this is not necessarily predictive of human response. For example, a drug formerly prescribed to alleviate morning sickness, thalidomide, is an infamous teratogenic in humans, but animal studies involving the drug failed to demonstrate such an increased risk of birth defects in humans. Therefore, the Defendants were aware that they could not responsibly rely on its animal studies as a basis for promoting Zofran for pregnant women.

45. No information regarding the number or incidence of Birth Defects was provided in the CPS from 1996-2015. Neither the "Adverse Reactions" section, which lists reactions observed in clinical studies pre-approval, nor the "Post-Market Adverse Reaction" section, which lists reactions report relating to post-approval use, mention Birth Defects.

46. Had Zofran's CPS entry provided meaningful precaution about the risk of Birth Defects, health professionals would have avoided prescribing Zofran to pregnant women, and would likely have screened women of childbearing age for the possibility of pregnancy.

47. From 1997-2010, in the Consumer Information section of Zofran's product monograph, the Defendants advised that Zofran should not be used if you are pregnant. This warning was immediately followed by the following statement: "However, there may be circumstances when your doctor advises you to use this medicine during pregnancy." [emphasis added]. This statement misled expectant mothers to believe that Zofran was safe and effective to use during pregnancy, and further demonstrates that the Defendants were aware of the occurrence of this off-label use.

48. In 2014, the Consumer Information was amended to read: "Before you use Zofran talk to your doctor or pharmacist if you are pregnant or likely to become pregnant." Again, this statement fails to provide any meaningful precaution about the risk of Birth Defects and misleads expectant mothers regarding the safety of Zofran during pregnancy. The statement

contains no reference to a possible increased risk of Birth Defects, nor does it explain that the Defendants had not conducted studies regarding the safety of Zofran use during pregnancy.

THE PLAINTIFFS' EXPERIENCE

49. Ms. Hogan began receiving Zofran tablets and intravenous injections on or about April 2004 to treat symptoms, including nausea and vomiting. Ms. Hogan ingested Zofran for approximately four months. During this time, Ms. Hogan was in her first and second trimesters of pregnancy.

50. After receiving the Defendants' Zofran, Ms. Hogan's daughter, Sarah-Faith, suffered debilitating Birth Defects that eventually culminated in her death at age two.

51. Ms. Hogan became aware that her unborn child suffered from Birth Defects at 20 weeks gestation. Ms. Hogan delivered Sarah-Faith on November 8, 2004, at 38 weeks gestation via scheduled caesarean section.

52. After birth, it was determined that Sarah-Faith suffered from multiple cardiac malformations, including: tetralogy of Fallot with pulmonary atresia (rare and complex combination of congenital heart defects involving enlarged right ventricle, overriding aorta, and complete pulmonary obstruction between the right ventricle and pulmonary artery), major aortopulmonary collateral arteries (when pulmonary atresia occurs, blood cannot flow through the pulmonary arteries to the lungs, instead blood must flow through multiple smaller vessels called "collateral arteries" (which typically do not exist after birth), large atrial septal defect (hole in the atrium of the heart), and ventricular septal defect (hole in the ventricle of the heart).

53. Sarah-Faith's Birth Defects required her to endure copious medical interventions. Sarah-Faith underwent more than 15 surgeries, including a heart and double lung transplant, open heart surgery, and the implantation of central lines (temporary catheter in large vein) and gastrostomy rubes (feeding tubes). Sarah-Faith's surgeries resulted in complications, including infections and blood clots.

54. On January 22, 2006, Sarah-Faith passed away.

55. Ms. Hogan used Zofran in accordance with the package label and consumer information pamphlet, and the instructions of her physician.

56. Ms. Hogan did not smoke cigarettes, consume alcohol, or use illicit drugs during her pregnancy. Her prenatal care included regular check-ups with her physician.

57. Ms. Hogan delivered a healthy daughter before Sarah-Faith. She did not consume Zofran during her first pregnancy.

58. Ms. Hogan has no family history of congenital heart defects or disease.

59. In the time period before and during Ms. Hogan's use of Zofran, she received no or inadequate warning about the increased risk of Birth Defects when using Zofran during her first trimester of pregnancy.

60. Had Ms. Hogan been aware of the increased risk of Birth Defects from the use of Zofran during the first trimester of pregnancy, she would never have used Zofran. But for the Defendants' wrongful conduct, the Plaintiffs would not have incurred their damages.

CAUSES OF ACTION

A. Duty of Care

61. The Defendants, at all material times, owed a duty of care to the pregnant women and their conceived but unborn children to:

(a) ensure that Zofran was fit for its intended or reasonably foreseeable use;

(b) market Zofran for approved uses only;

(c) ensure that Zofran was an effective and safe treatment for the types of uses for which it was being marketed;

(d) conduct appropriate testing to determine whether and to what extent the foreseeable use of Zofran posed serious health risks, including the risk of Birth Defects;

(e) properly, adequately, and fairly warn the Ms. Hogan and other pregnant women, and their prescribing physicians or other health care providers that use of Zofran during pregnancy carries a risk of Birth Defects;

(f) ensure that prescribing physicians and other health care providers were kept fully and completely warned and informed regarding all risks associated with Zofran;

(g) monitor, investigate, evaluate and follow up on adverse reactions to the use of Zofran, including reports of Birth Defects; and

(h) properly inform Health Canada and other regulatory agencies of the increased risks of Birth Defects associated with the use of Zofran during pregnancy.

B. Negligence

62. The Defendants negligently breached their duty of care.

63. The Plaintiffs state that their damages and the damages of other putative class members were caused by the negligence of the Defendants. Such negligence includes, but is not limited to, the following:

(a) falsely and wrongfully promoting Zofran for off-label use;

(b) actively soliciting and misleading physicians about the effectiveness of Zofran in treating off-label health complications;

(c) failing to ensure that Zofran was fit for use during pregnancy, despite actively marketing for this use and knowing that Zofran was being prescribed to pregnant women;

(d) the Defendants failed to adequately test Zofran in a manner that would fully disclose the magnitude of the risks associated with its use, including but not limited to the increased risk of Birth Defects;

(e) the Defendants failed to give Health Canada complete and accurate information as that information became available;

(f) the Defendants failed to conduct any or any adequate follow-up studies on the efficacy and safety of Zofran, specifically when used during pregnancy;

(g) the Defendants failed to properly supervise their employees, their subsidiaries and their affiliated corporations;

(h) in all of the circumstances of this case, the Defendants applied callous and reckless disregard for the health and safety of pregnant women using Zofran and their unborn children; and

(i) the Defendants breached other duties of care to pregnant women and their unborn children, the details of such breaches are known only to the Defendants.

C. Failure to Warn

64. The Defendants failed to warn of the risks associated with using Zofran during pregnancy.

65. The Plaintiffs state that their damages and the damages of other putative class members were caused by the Defendants' failure to warn, which includes, but is not limited to, the following:

(a) the Defendants failed to provide pregnant women using Zofran, their physicians or other health care providers, and Health Canada with proper, adequate, and/or fair warning of the increased risks associated with the use of Zofran, including but not limited to, the increased risk of Birth Defects;

(b) the Defendants failed to adequately monitor, evaluate and act upon reports of Birth Defects arising from the use of Zofran in Canada and elsewhere;

(c) the Defendants failed to provide any or any adequate updated and/or current information to pregnant women using Zofran, their physicians or other health care providers, and Health Canada respecting the increased risks associated with using Zofran during pregnancy as such information became available from time to time;

(d) the Defendants failed to provide adequate warnings of the potential increased risks associated with using Zofran during pregnancy on package labels;

(e) the Defendants failed to provide adequate warnings of the increased risks associated with Zofran, including the increased risk of Birth Defects, on the customer information pamphlets;

(f) the Defendants, after hearing of problems with Zofran use during pregnancy, failed to issue adequate warnings, publicize the problem and otherwise act properly and in a timely manner to alert the public, including adequately warning women using Zofran, their physicians or other health care providers, and Health Canada of the drug's inherent dangers to conceived but unborn children, including, but not limited to, the danger of developing Birth Defects;

(g) the Defendants failed to establish any adequate procedures to educate their sales representatives and prescribing physicians or other health care providers respecting the increased risk of Birth Defects associated with using Zofran during pregnancy; and

(h) the Defendants failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act*, RSC 1985, c F-27 and its associated regulations.

D. Negligent Distribution

66. The Defendants were negligent in the distribution, marketing and sale of Zofran to treat nausea and vomiting in pregnant women.

67. The Plaintiffs state that their damages, and the damages of other putative class members, were caused by the Defendants' negligent distribution, marketing and sale of Zofran, which includes, but is not limited to, the following:

(a) Zofran was actively marketed for an unapproved off-label use;

(b) in the alternative, the Defendants knew that Zofran was being prescribed to pregnant women and did not take active steps to prevent this;

(c) any benefit from using Zofran during pregnancy was outweighed by the serious and undisclosed risks of its use;

(d) there are no pregnant women for whom the benefits of Zofran outweigh the risks, given that there is an alternative product that is at least as effective as Zofran and carries far less and/or less serious risks than Zofran. Health Canada has approved Diclectin for the specific treatment of nausea and vomiting during pregnancy. Diclectin is also cited with approval by The Society of Obstetricians and Gynaecologists of Canada;

(e) the Defendants, when distributing the drug, failed to provide pregnant women, physicians or other health care providers, and Health Canada with proper, adequate, and/or fair warning of Zofran's propensity to injure when used during pregnancy; and

(f) the Defendants failed to timely cease the marketing and/or distribution of Zofran to pregnant women for treating nausea and vomiting, when they knew, or ought to have known, that Zofran had the propensity to injury during this off-label use.

E. Waiver of Tort

68. The Plaintiffs and other members of the Proposed Class are entitled to elect, at the end of the trial of the common issues, to waive the tort and require the Defendants to account for all or part of the revenue they received from the sale of Zofran prescribed for pregnant women in Alberta.

69. The Plaintiffs plead that such an election may be appropriate for the following reasons, among others:

(a) such revenue was acquired in such circumstances that the Defendants may not, 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) Zofran could not have been marketed, and the Defendants would not have received any or part of the revenue from its sale in Alberta, absent the Defendants' tortious conduct; and

(d) the Defendants engaged in wrongful conduct by marketing Zofran without disclosing the serious risks of Birth Defects.

DAMAGES AND SUBROGATED CLAIMS

70. The risks associated with the use of Zofran during pregnancy, including the risk of Birth Defects, were in the exclusive knowledge and control of the Defendants.

71. The extent of the risks were not known to, and could not have been known by, pregnant women, their physicians or other health care providers, or Health Canada.

72. The injuries of the Plaintiffs and other putative class members would not have occurred but for the negligence of the Defendants in marketing Zofran as safe and effective for treating nausea and vomiting during pregnancy, failing to ensure that Zofran was safe for use during pregnancy or, in the alternative, for failing to provide adequate warning of the risks associated

with using Zofran during pregnancy to women using Zofran and their physicians or other health care providers.

73. It is obvious and foreseeable, given the regulation of generic drugs in Canada, that the actions of the Defendants would continue to cause injury and consumer loss during the sale and consumption of ondansetron products. By marketing Zofran for use in treating nausea and vomiting in pregnancy, the Defendants assumed the risk that doctors would similarly prescribe the generic in such circumstances. The damages suffered from generic use of Zofran were caused by the Defendants and foreseeable by the Defendants.

74. As a result of the Defendants' conduct, putative class members have suffered and will continue to suffer damages and loss, including, but not limited to:

(a) personal injury;

(b) out-of-pocket expenses incurred, including those connected with hospital stays, medical treatment, and medication;

(c) costs of future care and future services; and

(d) loss of income and loss of future income.

75. As a result of the Defendants' conduct, putative class members suffered and will continue to suffer expenses and special damages, of a nature and amount to be particularized prior to trial.

76. As a further result of the Defendants' conduct, members of the Proposed Family Class have suffered and will continue to suffer damages and losses, including, but not limited to:

(a) actual expenses reasonably incurred for the benefit of members of the Proposed Class;

(b) a reasonable allowance for loss of income or the value of services provided to members of the Proposed Class;

(c) an amount to compensate for the loss of guidance, care and companionship they might reasonably have expected to receive from the members of the Proposed Class; and

(d) funeral expenses reasonably incurred for the benefit of members of the Proposed Class.

77. As a result of the Defendants' negligence, putative class members are entitled to damages pursuant to the *Tort-feasors Act*, RSA 2000 c T-5, and the *Fatal Accidents Act*, RSA 2000, c F-8, and the regulations thereunder and amendments thereto.

78. Some of the expenses related to the medical treatment that putative class members have undergone, and will continue to undergo, have been borne by the provincial health insurer and public drug benefit plans. Third Party payors have a subrogated interest in their expenditures for Zofran on behalf of the Plaintiffs and other members of the putative class, and they seek a full indemnification of those expenditures.

PUNITIVE DAMAGES

79. The Plaintiffs plead that the Defendants' conduct, as particularized above, in the development, testing, manufacturing, licensing, distribution, marketing, sale and promotion of Zofran, and the failure to warn expectant mothers of the risk of Birth Defects was high-handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, disgraceful, willful, in intentional disregard of the rights and safety of the Plaintiffs and the rights and safety of the members of the Proposed Class, indifferent to the consequences and motivated by economic considerations, such as the maintenance of profits and market share. Such conduct renders the Defendants liable to pay punitive damages to the putative class members.

80. The Plaintiffs claim on behalf of themselves and other putative class members punitive, aggravated and exemplary damages for the Defendants' reckless and unlawful conduct.

Remedy sought:

81. The Plaintiffs claim personally, as personal representatives of the Estate of Sarah-Faith Hogan, and other members of the Proposed Class (as defined in paragraphs 6 & 7):

(a) an order certifying this proceeding as a class proceeding and appointing Catherine Hogan in her capacity as personal representatives of the estate of Sarah-Faith Hogan, as the representative Plaintiffs of the Proposed Class (as defined in paragraph 6); and Catherine Hogan as the representative Plaintiffs of the Proposed Family Class (as defined in paragraph 7) (collectively, the "Class" or "Class Members");

(b) a declaration that the Defendants were negligent in the design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution and sale of Zofran (as defined in paragraph 19);

(c) a declaration that the Defendants are vicariously liable for the acts and omissions of their officers, directors, agents, employees and representatives;

(d) general damages in an amount of $10,000,000 or such other sum as this Honourable Court deems just;

(e) special damages in an amount to be assessed for each class member;

(f) alternatively, an accounting or other such restitutionary remedy disgorging the revenues realized by the Defendants from the sales of Zofran prescribed to pregnant women in Alberta;

(g) damages pursuant to the *Tort-feasors Act*, RSA 2000, c T-5 and the *Fatal Accidents Act*, RSA 2000, C F-8, in an amount to be quantified;

(h) punitive, aggravated and exemplary damages in the amount of $1,000,000;

(i) past and future care costs pursuant to the *Crown's Right of Recovery Act*, SA 2009, c C-35, and the regulations thereunder and amendments thereto;

(j) the costs of distributing all monies received to the Class;

(k) interest pursuant to the *Judgment Interest Act*, RSA 2000, c J-1 as may be allowed;

(l) costs of this action on a solicitor/client basis plus applicable taxes or, in the alternative, costs as determined by this Honourable Court; and

(m) such further and other relief as this Honourable Court deems just and appropriate having regard to the circumstances.

NOTICE TO THE DEFENDANTS

You only have a short time to do something to defend yourself against this claim:

20 days if you are served in Alberta

1 month if you are served outside Alberta but in Canada

2 months if you are served outside Canada.

You can respond by filing a statement of defence or a demand for notice in the office of the clerk of the Court of Queen's Bench at CALGARY, Alberta, AND serving your statement of defence or a demand for notice on the plaintiffs' address for service.

WARNING

If you do not file and serve a statement of defence or a demand for notice within your time period, you risk losing the law suit automatically. If you do not file, or do not serve, or are late in doing either of these things, a court may give a judgment to the plaintiffs against you.