

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

B E T W E E N:

**ALINE BOULANGER**

Plaintiff

- and -

**JOHNSON & JOHNSON CORPORATION, JOHNSON & JOHNSON  
MEDICAL PRODUCTS INC./PRODUITS MEDICAUX JOHNSON & JOHNSON  
INC., JANSSEN-ORTHO INC. and  
THE ATTORNEY GENERAL OF CANADA**

Defendants

Proceeding under the *Class Proceedings Act, 1992*

**AMENDED AMENDED FRESH AS AMENDED STATEMENT OF CLAIM**

TO THE DEFENDANTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff(s). The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiff(s) lawyer or, where the plaintiff(s) do(es) not have a lawyer, serve it on the plaintiff(s), and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date:  
registrar

Issued by \_\_\_\_\_

Local

Address of court office:  
393 University Avenue  
Toronto, Ontario M5G 2E6

**TO:** JOHNSON & JOHNSON CORPORATION  
One Johnson & Johnson Plaza  
New Brunswick NJ 08933  
United States of America

**AND TO:** JOHNSON & JOHNSON MEDICAL PRODUCTS INC./  
PRODUITS MEDICAUX JOHNSON & JOHNSON INC.  
1421 Lansdowne ST W  
Peterborough ON K9J 7B5  
Canada

**AND TO:** JANSSEN-ORTHO INC.  
19 Green Belt DR  
North York ON M3C 1L9  
Canada

**AND TO:** THE ATTORNEY GENERAL OF CANADA  
Justice Canada Ottawa  
Civil Litigation Branch, East Memorial Bldg.  
284 Wellington ST  
Ottawa ON K1A 0H8  
Canada

### CLAIM

1. The Plaintiff claims, on behalf of herself and all Class members,:
  - (a) for an Order certifying this proceeding as a Class Proceeding and appointing Aline Boulanger as Representative Plaintiff;
  - (b) general damages in the amount of \$500,000,000.00;

- (c) special damages in an amount to be proven at the trial of this action and, without limiting the generality of the foregoing, special damages to include, on behalf of the Plaintiff, the subrogated interest of the Ontario Health Insurance Plan pursuant to ss. 30 and 31 of the *Health Insurance Act*, R.S.O. 1990, c.H.6 (*Health Insurance Act*) as amended, and, on behalf of the Class members, the subrogated interest of their respective provincial Health Insurance Plans where they may happen to reside, pursuant to similar provincial legislation in their respective provinces related to the Ontario *Health Insurance Act*, and, furthermore, special damages for past and future medical, screening and diagnostic examinations and other medical expenses;
- (d) class-wide punitive, aggravated and/or exemplary damages in the amount of \$100,000,000.00;
- (e) for purchase price reimbursement, which includes specifically the return to the Plaintiff and Class members the full value of the purchase price of Prepulsid;
- (f) costs of the within proceeding on a solicitor-client basis together with applicable Goods and Services Tax;
- (g) pre-judgment and post-judgment interest on the aforesaid sums in accordance with the *Courts of Justice Act*, R.S.O. 1990, c.C.43, as amended;
- (h) such further and other relief as this Honourable Court deems just.

## **INTRODUCTION**

2. Cisapride, more commonly known by its brand name "Prepulsid", is a prescription drug which was authorized for sale in Canada to treat specific gastrointestinal motility disorders. Since the drug's approval in Canada in 1990, Prepulsid has been associated with at least 44 reports of heart rhythm abnormalities and 10 reports of death. The cardiotoxicity of the drug has resulted in the withdrawal of the drug from the Canadian marketplace effective August 7, 2000 from general distribution and is only available under a restricted access program. Less than 1% of Prepulsid users have requested access to the drug under this program.
3. The Defendants, Johnson & Johnson Corporation, Johnson and Johnson Medical Products Inc./Produits Medicaux, and Janssen-Ortho Inc. (the "Corporate Defendants"), have manufactured, promoted, marketed and regulated Prepulsid in Canada with false promises of

safety and efficacy, and misrepresentations regarding risks. Prepulsid was unreasonably unsafe and ineffective for over 99% of Canadians who took it.

4. The Corporate Defendants also promoted the drug to physicians as safe and effective for medical conditions for which the drug was not approved by Health Canada, including pediatric use, which resulted in Prepulsid being prescribed for uses for which the drug was not approved (“off-label” usage). Contrary to the Corporate Defendants’ promotion, consumers were not prescribed a safe drug but instead were exposed to a drug that causes potentially life-threatening heart problems including cardiac arrest, arrhythmia, ventricular tachycardia and fibrillation, prolonged QT interval, heart disease, and other adverse medical conditions. Furthermore, the drug was not effective for the treatment of conditions for which it was approved and/or prescribed. The drug was also less effective and/or more hazardous than other available treatments for the same conditions.
5. Notwithstanding that the information reviewed by Health Canada prior to issuing a Notice of Compliance (“NoC”) to the Corporate Defendants for Prepulsid was insufficient to satisfy its own standards for safety and efficacy, Health Canada approved Prepulsid for sale in Canada for certain enumerated conditions in the NoC. Health Canada was also aware that Prepulsid was going to be prescribed throughout Canada for conditions not indicated in the NoC (“off-label” usage) but did not, contrary to its own requirements, require evidence of its safety and efficacy from the Corporate Defendants.

6. From 1990 until March 2000, Health Canada continued to accumulate information that Prepulsid was neither safe nor effective but did not, contrary to its own policies, take any adequate steps to limit the use of Prepulsid or revoke the NoC it had previously issued. Having adopted a policy of warning physicians and the ultimate consumers of prescription drugs about hazards of prescription drugs, Health Canada took no effective steps to warn consumers of the hazards of Prepulsid. Throughout the period, Health Canada unlawfully delegated its obligations under Statute and Common Law to regulate Prepulsid to the Corporate Defendants.

### **DEFINITION OF CLASS**

7. This Class Action is brought on behalf of a Class consisting of:
  - (a) all persons in Canada, including infants, who have ingested Prepulsid, manufactured, developed, designed, fabricated, sold, imported, distributed, marketed, or otherwise placed into the stream of commerce by the Defendants;
  - (b) claimants, pursuant to the *Family Law Act* of Ontario and other similar provincial legislation elsewhere in Canada, who have sustained a loss of care, guidance and companionship and/or suffered pecuniary and other losses as a result of the ingestion of Prepulsid by their family members;
  - (c) the personal representatives of the estates of persons who have died, or who will die after the filing of this Statement of Claim, as a result of taking Prepulsid; and
  - (d) the Plaintiff, Aline Boulanger, who is representative of the Class, and seeks to represent all residents of Canada who have ingested Prepulsid;

### **PARTIES**

8. The Plaintiff, Aline Boulanger, is a resident of the City of Timmins, in the District of Cochrane, in the Province of Ontario. Commencing in 1994 until September 1996, the Plaintiff was prescribed and thereafter ingested Prepulsid to treat heartburn associated with gastroesophageal reflux disease.

9. In the time period before and during the Plaintiff's and Class members' ingestion of Prepulsid, they received no warnings or insufficient warnings from the Defendants or from their physicians or pharmacists about the risk of adverse, and potentially lethal, cardiac events and other harm resulting from the ingestion of Prepulsid.
10. Although the exact size of the Class is unknown at present, membership in the Class is ascertainable through appropriate discovery. The Plaintiff believes that the Class number totals approximately 350,000 persons since it is estimated that between 7 and 8 million prescriptions for Prepulsid were filled in Canada.
11. The damages sustained by the Plaintiff and the members of the Class were caused directly by the Defendants' wrongful conduct.
12. The Defendant Johnson & Johnson Corporation is an incorporated business and has its principal place of business in City of New Brunswick, in the state of New Jersey, in the United States of America. At all material times herein, Johnson & Johnson Corporation was in the business of designing, developing, exporting, selling, promoting, manufacturing, marketing, distributing or otherwise placing into the stream of commerce, pharmaceuticals and other products including Prepulsid. Johnson & Johnson Corporation does, and at all material times did, through its subsidiaries, which are controlled directly and/or indirectly by Johnson & Johnson Corporation, transact business in Canada, through the designing, developing, exporting, sale, manufacturing, production, promotion, advertising and placing into the stream of commerce consumer products, prescription drugs, and non-prescription medications, including Prepulsid.
13. The Defendant, Johnson & Johnson Medical Products Inc./Produits Medicaux Johnson & Johnson Inc. is a subsidiary of and is controlled directly and/or indirectly by Johnson & Johnson Corporation with a registered business address in the City of Peterborough, in the

Province of Ontario. At all times relevant hereto, Johnson & Johnson Medical Products Inc./Produits Medicaux Johnson & Johnson Inc. was in the business of developing, designing, importing, formulating, promoting, manufacturing, packaging, labeling, marketing, advertising, distributing, selling and placing into the stream of commerce prescription drugs, including Prepulsid, and at all material times developed, marketed, promoted, sold, manufactured and placed into the stream of commerce Prepulsid in Canada.

14. The Defendant Janssen-Ortho Inc. is a subsidiary of and is controlled directly and/or indirectly by Johnson & Johnson Corporation, and has its principal place of business in the Regional Municipality of Metropolitan Toronto, in the Province of Ontario. At all times relevant hereto, Janssen-Ortho Inc. was in the business of developing, designing, importing, formulating, manufacturing, packaging, labeling, promoting, marketing, advertising, distributing, selling and placing into the stream of commerce prescription drugs, including Prepulsid. Janssen-Ortho Inc. at all material times developed, promoted, sold, marketed, manufactured and placed into the stream of commerce Prepulsid in Canada.
15. The Defendants, Johnson & Johnson Corporation, Johnson & Johnson Medical Products Inc./Produits Medicaux Johnson & Johnson Inc. and Janssen-Ortho Inc. will hereinafter be referred to collectively as the "Corporate Defendants".
16. The Defendant, Attorney General of Canada ("Canada"), is responsible through Health Canada for the regulation of prescription drugs in Canada and through this department, tests, approves and regulates pharmaceutical products in Canada, including Prepulsid, collects, reviews and disseminates adverse drug reaction reports, provides warnings to the medical community and the general public concern hazards relating to prescription drugs, and administers the Food and Drugs Act, R.S.C. 1985, c. F-27 (the "Food and Drugs Act").

17. As regulator of pharmaceuticals in Canada, including Prepulsid, Canada, through Health Canada, owed the ultimate consumers of Prepulsid, including the Plaintiff and Class members, a duty of care to ensure that any negligence in the performance of their duties did not expose these consumers to any undue or unnecessary risk or harm.

### **FACTUAL BACKGROUND**

18. At all material times, the Corporate Defendants manufactured, created, designed, tested, labeled, sterilized, packaged, distributed, supplied, marketed, sold, advertised, promoted, distributed and placed into the stream of commerce the drug Cisapride under the brand name Prepulsid throughout Ontario and Canada. Prepulsid is sold under the brand name "Propulsid" in the United States and was manufactured, created, designed, tested, labeled, sterilized, packaged, distributed, supplied, marketed, sold, advertised, promoted, distributed and placed into the United States stream of commerce by the Defendant, Johnson and Johnson Corporation and its other associated subsidiary corporations in the United States and elsewhere.
19. On or about January 1990, Health Canada approved the distribution of Prepulsid in Canada for the treatment of certain gastrointestinal disorders as set out in the NoC issued by Health Canada.
20. Prepulsid was launched in Canada by the Corporate Defendants in 1990. It was approved for the treatment of gastroparesis, intestinal pseudo obstruction and gastroesophageal reflux disease. The Corporate Defendants received a Notice of Compliance ("NoC") from Health Canada based on the Corporate Defendants' submissions to Health Canada, which the Plaintiff states were fraudulently and/or negligently prepared and in violation of the provisions of the *Food and Drug Act*, following which the Corporate Defendants aggressively marketed and promoted Prepulsid as safe and effective in the treatment of both approved and non-approved uses to physicians and the use of detail men to induce the widespread use of the drug.

21. The Corporate Defendants' aggressive and relentless efforts were an astonishing success. The drug became available in 89 countries. The Corporate Defendants have reaped enormous financial rewards from the drug with gross annual revenue exceeding one billion dollars. By way of example, in the United States, in 1999 Propulsid (called "Propulsid" in the United States) ranked 63<sup>rd</sup> in prescriptions filled among all prescription drugs.
22. The Corporate Defendants aggressively sought to create demand for Propulsid, marketing and promoting Propulsid as safe and effective, despite knowing as early as 1986 that there were published scientific reports that Propulsid was cardiotoxic. In 1995, reports of serious adverse events including death from heart rhythm disorders and sudden cardiac arrest prompted Health Canada to issue a warning about the drug. Subsequently, as consumers continued to suffer adverse consequences from Propulsid, Health Canada in February 2000 issued more severe warnings, including a recommendation that patients be given echocardiograms and certain blood tests blood prior to being prescribed Propulsid.
23. During this period, the Defendants had knowledge of the widespread prescription of Propulsid for off-label use.
24. As of December 31, 1999, the United States Food & Drug Administration ("F.D.A.") reported more than 270 cases of serious cardiac arrhythmia, including 70 deaths, since its introduction into the market in 1993. In Canada, as of the same date, 44 cases of serious cardiac arrhythmia, including 10 deaths, in association with the use of Propulsid were reported. Combined with these statistics is the fact that only a small portion of suspected adverse reactions are usually reported.
25. Despite these reports of death and cardiotoxicity, the Corporate Defendants failed to conduct sufficient study, clinical investigation, or other inquiry concerning the potential relationship between the use of Propulsid and heart rhythm abnormalities. Furthermore, the Corporate

Defendants did not provide adequate warning to consumers of the potential relationship between heart disease and the use of Prepulsid, and the Corporate Defendants continued to actively and aggressively market Prepulsid.

26. Since Prepulsid's introduction to Canada in 1990, the warning label has been revised at least 5 times to make the warnings of possible life threatening reactions progressively stronger. The Corporate Defendants and Health Canada were aware, however, that the ultimate consumers of the drugs did not receive these warnings.
27. Furthermore, the product warnings were wholly inadequate to alert prescribing physicians and consumer patients, including the Plaintiff and Class members, of the actual risk of serious adverse cardiac events associated with the use of Prepulsid which was then known or ought to have been known by the Corporate Defendants and Health Canada.
28. Despite Prepulsid having caused many instances of serious adverse reaction, including death, the Corporate Defendants did not immediately withdraw the drug from the marketplace. Finally, on August 7, 2000, Health Canada announced that the risks associated with Prepulsid were not manageable and the drug would no longer be available on the Canadian market except through special access.

### **CAUSES OF ACTION**

29. The Plaintiff and Class members plead that the Corporate Defendants are liable to the Plaintiff and Class members for damages under the doctrines of failure to adequately warn, negligence, breach of fiduciary duty, and breach of implied and/or express warranties as to merchantability, quality and fitness of Prepulsid for a particular purpose, breach of collateral contract and warranty, purchase price reimbursement and/or unjust enrichment, and for damages resulting from the fraudulent and/or negligent filings with Health Canada to obtain its approval for Prepulsid and failure to comply with the provisions of the Food and Drug Act.

30. The Plaintiff and Class members plead that Health Canada is liable to the Plaintiff and Class members under the doctrines of negligence, ~~and breach of fiduciary duty, and their failure to comply with their duties under the Food and Drugs Act.~~

**BREACH OF COLLATERAL CONTRACT AND WARRANTY AND BREACH OF EXPRESS AND IMPLIED WARRANTIES**

31. The Plaintiff on her own behalf and on behalf of the other Class members, claims damages for breach of warranty as to merchantability, quality and fitness for a particular purpose.
32. Prepulsid, as purchased and ingested by the Plaintiff and Class members, was formulated, manufactured, marketed, packaged, labelled, sold and placed in the stream of commerce by the Corporate Defendants with implied warranties of merchantability and fitness for its intended purposes, namely, for the effective treatment of certain gastrointestinal motility disorders in adults, without risk of permanent damage to the purchaser's and/or consumer's body and health, including organs such as the heart and ventricles.
33. The Corporate Defendants expressly and impliedly warranted that Prepulsid was reasonably fit for its intended purpose and that it was of merchantable quality when in fact the drug, when used in a normal manner for its intended purpose, caused injury to the Plaintiff and other Class members.
34. The Corporate Defendants breached their express and implied warranties to the Plaintiff and the Class members by:
- a) placing Prepulsid into the normal stream of commerce with the knowledge and expectation that it would be sold and ultimately used without further inspection of its condition or without inspection adequate to reveal latent defects in the product;
  - b) manufacturing, marketing, packaging, labelling and selling to the Plaintiff and other Class members, Prepulsid, which failed to control the Plaintiff's and Class members' gastrointestinal motility disorders in a safe manner;

- c) manufacturing, marketing, packaging, labelling and selling to the Plaintiff and other Class members, Prepulsid, which caused them serious physical injury and pain and suffering and attendant economic loss.
35. The Plaintiff, when ingesting Prepulsid, relied upon the representations of the Corporate Defendants with respect to the drug, that it was fit for the purpose intended. The Plaintiff acted and relied upon those misrepresentations to her detriment.
36. Prepulsid contains chemical compounds which, when taken by persons, can have devastating health consequences, including cardiac arrhythmia, which can lead directly or indirectly to death or to a shortened life expectancy, and other adverse effects.
37. Prepulsid offers no therapeutic relief from gastrointestinal motility disorders and is no better than placebo treatment.
38. Prepulsid, as manufactured, labeled, and ultimately delivered to and taken by the Plaintiff and the Class members, is not reasonably safe and, thus, is a defective product.
39. Prepulsid was and is defective in that it was not properly conceived, designed, formulated, tested, researched, studied, packaged, distributed, sold and placed in the stream of commerce and particularly in that it was not accompanied by effective warnings and instructions. Additionally, Prepulsid was and is not a reasonably safe product because of, but not limited to, the following grounds:
- (a) the foreseeable risks exceeded the benefits associated with the product;
  - (b) the product is more dangerous than ordinary consumers, including the Plaintiff and Class members, would expect and more dangerous than other products marketed for the same purposes;
  - (c) the product did not have adequate, effective warnings and instructions in light of the dangers associated with its use;

- (d) the product was inadequately tested; and
  - (e) the product was not fit for the purpose for which it was intended.
40. The Corporate Defendants made changes in the prescribing information for Prepulsid, including changes to the indications for prescribing it, changes to the adverse reactions to it, changes to the contraindications to prescribing it, and changes to the boxed warnings in the prescribing information. These changes were not, however, effectively communicated by the Corporate Defendants to prescribing physicians. As a result, prescribing physicians continued to write prescriptions based on the original prescribing information provided to them by the Corporate Defendants.
41. At all material times, the Corporate Defendants expressly and/or impliedly warranted to the Plaintiff, the members of the Class, the Plaintiff's agents and physicians, by and through statements made by the Corporate Defendants or its authorized sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients, including the Plaintiff and Class members, and the general public, that Prepulsid was safe, effective, fit, and proper for its intended and foreseeable uses. In utilizing Prepulsid, the Plaintiff and members of the Class relied upon the skill and judgement and foregoing express and/or implied warranties of the Corporate Defendants. Said warranties and representations were false in that Prepulsid was not safe nor of merchantable quality and was unfit for the uses for which it was intended.
42. As a direct and proximate result of the breach of express and/or implied warranty, the Plaintiff and members of the Class suffered and will continue to suffer injury, harm, and economic loss as alleged herein.
43. The Corporate Defendants placed Prepulsid into the normal stream of commerce with the knowledge and expectation that it would be sold and ultimately used without further clinical evaluation to expose the product's latent defects.

44. The Plaintiff and Class members plead that there is a collateral contract between themselves and the Corporate Defendants. The Plaintiff and Class members further state that, notwithstanding the absence of a direct contractual relation with between themselves and the Corporate Defendants, the Corporate Defendants are liable on the basis of a collateral warranty since their product, Prepulsid, was defective and did not meet the standards regarding fitness, safety and efficacy as expressed and warranted by the Corporate Defendants.

### **NEGLIGENCE**

45. The Plaintiff and Class members plead and rely upon the *Negligence Act*, R.S.O. 1990, c.45, as amended, and other similar provincial legislation elsewhere in Canada.
46. At all material times, the Corporate Defendants owed a duty of care to the Plaintiff and Class members and had a duty to properly manufacture, design, formulate, compound, test, produce, process, inspect, research, distribute, market, label, package, prepare for use, sell, and place in the stream of commerce and adequately warn of the risks and dangers of Prepulsid.
47. At all material times, Health Canada owed a duty of care to the Plaintiff and Class members to properly perform its duties without negligence including providing sufficient warnings about the risks and dangers of Prepulsid.

### **AS TO THE NEGLIGENCE OF THE CORPORATE DEFENDANTS**

48. The Corporate Defendants knew or reasonably ought to have known that Prepulsid is and was not reasonably safe as delivered to those taking it, and they knew or ought to have known that Prepulsid would cause serious harm to some of the persons who would consume it, including the Plaintiff and the Class she seeks to represent and, furthermore, knew or ought to have known that Prepulsid would be of no value to persons who consumed the drug,

including the Plaintiff and members of the Class.

49. The Corporate Defendants negligently designed, formulated, tested, manufactured, labeled, distributed, advertised, marketed, and promoted Prepulsid.
50. The Corporate Defendants negligently breached their duty to the Plaintiff and other Class members to test and to warn with respect to the risks of serious adverse cardiac events and other harm resulting from the ingestion of Prepulsid.
51. The Corporate Defendants negligently advertised Prepulsid to the physicians and pharmacists of the Plaintiff and Class members in an effort to drive up the market for Prepulsid by persuading physicians to prescribe it and pharmacists to dispense it without adequately disclosing the cardiac risks associated with Prepulsid in this marketing campaign.
52. The Corporate Defendants knew or ought to have known of the dangers of Prepulsid, and they owed a duty to provide information to physicians, pharmacists, the Plaintiff, Class members and potential consumers of Prepulsid of the dangers of the drug by means of adequate prescribing information, clearly advising of the dangers of the use of Prepulsid in and of itself, in combination with other drugs, in people with conditions predisposing them to an adverse reaction to Prepulsid, and for treatment of conditions other than gastrointestinal motility disorders.
53. The Corporate Defendants negligently withheld and/or downplayed information which they had or ought to have had in their possession, and information which they knew or ought to have known, concerning research, testing and studies which demonstrated that Prepulsid causes cardiac arrhythmia, which can lead to cardiac arrest, myocardial infarction, and other heart problems.
54. The Corporate Defendants negligently provided misleading information concerning

Prepulsid and they provided only partial information concerning its ill effects.

55. The Corporate Defendants knew or ought to have known that consumers of Prepulsid, including the Plaintiff and Class members, would foreseeably suffer injury as a result of the Corporate Defendants' failure to exercise the care required of them as manufacturers and distributors of a health product that is to be ingested by such consumers.
  
56. Particulars of the negligence of the Corporate Defendants include but are not limited to the following:
  - (a) they failed to ensure that Prepulsid was not unreasonably dangerous during the course of its use;
  - (b) they failed to provide the Plaintiff, other Class members and their doctors with any or adequate warning of potentially catastrophic risks associated with the administration of Prepulsid;
  - (c) they failed to warn the Plaintiff, other Class members and their doctors with any or any adequate warning of the risks associated with the use of Prepulsid;
  - (d) they failed to provide the Plaintiff, other Class members and their doctors with any or any adequate information and warnings respecting the correct usage of Prepulsid and, in particular, failed to adequately warn the Plaintiff and other Class members with respect to the significant health risks inherent in taking Prepulsid alone or in conjunction with other medications;
  - (e) they failed to adequately test Prepulsid in a manner that would fully disclose the serious side effects and the magnitude of the risks associated with its use;
  - (f) they failed to conduct any or adequate post-market surveillance of the safety of Prepulsid;
  - (g) they failed to properly investigate reports of harm caused by Prepulsid and they failed to bring these reports to the attention of the public, the medical and scientific community and public health regulators;
  - (h) they failed to cease the manufacture and/or distribution of Prepulsid when they knew or ought to have known that Prepulsid caused or could cause significant injury;

- (i) they failed to conduct randomized, controlled studies with long-term follow-up in order to ensure the safety and efficacy of the drug;
- (j) they failed to provide any, or any adequate, updated and current information to the Plaintiff or other Class members and their doctors respecting the risks and efficacy of Prepulsid as it became available from time to time;
- (k) they failed to establish any or adequate procedure to educate their sales representatives or prescribing physicians respecting the correct usage of Prepulsid and the risks associated with Prepulsid;
- (l) they failed to ensure that adverse reaction reports were adequately and appropriately communicated to the ultimate consumer or their treaters;
- (m) they failed to ensure that Prepulsid was fit for its intended purposes;
- (n) they negligently misrepresented the safety of the drug to Health Canada in order to obtain its approval to market the drug and failed to advise that the drug should be immediately withdrawn after having received information as to the potential of the drug to cause serious health effects;
- (o) they continued to place Prepulsid into the stream of Canadian commerce when they knew or ought to have known that published scientific studies demonstrated that the product was unsafe and unreasonably hazardous;
- (p) they failed to provide warnings of the potential hazards of ingesting Prepulsid on package labels;
- (q) they failed to discourage medical practitioners and pharmacists to prescribe and distribute Prepulsid for off-label uses;
- (r) they failed to label the drug with instructions for the consumers as to the dosage limitations, the methods of administration and a warning that safe use of Prepulsid had not been determined and that it could cause death;
- (s) they failed, after notice of problems with Prepulsid, to issue adequate warnings, recall the drug, publicize the problem and otherwise act properly and in a timely manner to alert the public, including the Plaintiff and other Class members and their physicians of the drug's inherent dangers;
- (t) they breached other duties of care to the Plaintiff and Class members, with details of such breaches only known to the Defendants.

## **AS TO THE NEGLIGENCE OF HEALTH CANADA**

57. Health Canada was negligent in the performance of its operational duties and responsibilities as the regulator of Prepulsid and the Corporate Defendants.
58. Health Canada negligently breached their duty to the Plaintiff and Class members to ensure that adequate testing and warnings were carried out with respect to the risks of serious adverse cardiac events and other harm resulting from the ingestion of Prepulsid.
59. Health Canada knew or ought to have known of the dangers of Prepulsid, and they owed a duty to provide information to physicians, the Plaintiff, Class members and potential consumers of Prepulsid of the dangers of the drug by means of adequate prescribing information, clearly advising of the dangers of the use of Prepulsid in and of itself, in combination with other drugs, in people with conditions predisposing them to an adverse reaction to Prepulsid, and for treatment of conditions other than gastrointestinal motility disorders.
60. Health Canada negligently failed to act on information which they had or ought to have had in their possession, and information which they knew or ought to have known, concerning research, testing, and studies which demonstrated that Prepulsid causes cardiac arrhythmia, which can lead to cardiac arrest, myocardial infarction, and other heart problems.
61. Health Canada negligently provided misleading information concerning Prepulsid and they provided only partial information concerning its ill effects.
62. Health Canada knew or ought to have known that consumers of Prepulsid, including the Plaintiff and Class members, would foreseeably suffer injury as a result of Health Canada's failure to exercise the care required of them as regulators of a health product that is to be ingested by such consumers.

63. Particulars of the negligence of Health Canada include but are not limited to the following:
- a. they failed to ensure that Prepulsid was not unreasonably dangerous during the course of its use;
  - b. they failed to provide the Plaintiff, other Class members and their doctors with any or adequate warning of potentially catastrophic risks associated with the administration of Prepulsid;
  - c. they failed to provide any or adequate warning to the Plaintiff, other Class members and their doctors of the risks associated with the use of Prepulsid;
  - d. they failed to provide the Plaintiff, other Class members and their doctors with any or any adequate information and warnings respecting the correct usage of Prepulsid and, in particular, failed to adequately warn the Plaintiff and Class members with respect to the significant health risks inherent in taking Prepulsid alone or in conjunction with other medications;
  - e. they failed to adequately test Prepulsid in a manner that would fully disclose the serious side effects and the magnitude of the risks associated with its use;
  - f. they issued a NoC for Prepulsid when they knew or ought to have know the information provided by the Corporate Defendants was incomplete, inaccurate, misleading and/or did not satisfy their own requirements to allow the sale of a prescription drug in Canada.
  - g. they failed to require the Corporate Defendants to cease the manufacture and/or distribution of Prepulsid when they knew or ought to have known that the adverse consequences of Prepulsid strongly outweighed the benefits pursuant to their own requirements;
  - h. they failed to conduct randomized, controlled studies with long-term follow-up in order to ensure the safety and efficacy of the drug or failed to ensure such studies were performed by the Corporate Defendants;
  - i. they failed to provide any, or any adequate, updated and current information to the Plaintiff or Class members and their doctors respecting the risks and efficacy of Prepulsid as it became available from time to time;
  - j. they failed to ensure that adverse reaction reports were adequately and appropriately communicated to persons within their department to ensure that the dangers of Prepulsid were known by the appropriate decision makers.

- k. they failed to ensure that Prepulsid was fit for its intended purposes;
- l. Health Canada continued to allow Prepulsid to be placed into the stream of Canadian commerce when it knew or ought to have known that published scientific studies demonstrated that the product was unsafe and unreasonably hazardous and/or ineffective.

### **NEGLIGENT OR FRAUDULENT FILINGS WITH HEALTH CANADA**

64. The Corporate Defendants knew that Health Canada, as the sole regulator of prescription drugs in Canada, had to provide regulatory approval to Prepulsid before it could be sold in Canada to the plaintiffs and class members. Consequently, the corporate defendants had to obtain and maintain regulatory approval of Prepulsid pursuant to the *Foods and Drugs Act* and regulations thereunder.
65. At the time of the corporation defendants' filings with Health Canada and subsequently, the corporate defendants knew or ought to have known that:
  - a. that Prepulsid was not an effective drug for the treatment of gastromotility disorders;
  - b. that the drug would be (and subsequently was) used substantially for off-label uses;
  - c. that Prepulsid was not safe and it had caused or contributed to serious health problems, including cardiotoxicity and deaths;
  - d. that Prepulsid had not been adequately tested; and
  - e. that other regulators in other jurisdictions, such as the F.D.A., had raised concerns about the safety and adequacy of the drug.
66. The corporate defendants had a duty to supply this information to Health Canada.

67. The corporate defendants knew or ought to have known that Health Canada in granting regulatory approval to Prepulsid and maintaining its regulatory approval would rely almost entirely upon information provided by the Corporate Defendants. ~~Janssen-Ortho~~. The Corporate Defendants knew that by providing false or misleading information or withholding relevant information as to the true character of Prepulsid would result in receiving an NoC or maintaining its NoC. revoked.
68. The employees, servants and agents of the corporate defendants responsible for dealing with Health Canada, at the direction of the corporate defendants, deliberately or recklessly failed to provide the above information to Health Canada in their filings with Health Canada for the purpose of insuring that Prepulsid would obtain and maintain regulatory approval so that it could be marketed in Canada and that the Corporate Defendants ~~Janssen-Ortho~~ could benefit from the marketing, notwithstanding the plaintiffs and the class members would be exposed to a potentially lethal and ineffective drug. Alternatively, the conduct of the Corporate Defendants in failing to disclose this information was negligent.
69. The Corporate Defendants' sole purpose in obtaining regulatory approval was to obtain results that the plaintiffs and class members would purchase Prepulsid, which would result in the Corporation Defendants ~~Janssen-Ortho~~ obtaining profits from the sales of Prepulsid in Canada. The corporate defendants knew, and the fact is, that the plaintiffs and class members could only purchase Prepulsid in Canada if it received regulatory approval and such regulatory approval could only be based upon information provided to Health Canada by the corporate defendants.

## **REIMBURSEMENT**

70. The Plaintiff, Class members and those with subrogated interests in the claims of the Plaintiff and Class members, including provincial health insurers, and private health, disability and group benefit insurers, plead that they are entitled to the return of the full purchase price of Prepulsid.
71. The Plaintiff and Class members plead that Prepulsid is so defective that it ought never to have been on the market or sold in Canada and, furthermore, that Prepulsid provided no benefit to the Plaintiff and Class members.
72. The Plaintiff and Class members therefore plead that they are entitled to reimbursement of the purchase price of Prepulsid on the grounds that the Corporate Defendants have sold a worthless, and indeed harmful, product for which the Corporate Defendants should never have been paid. There has been a total lack of consideration.
73. In the alternative, the Plaintiff and Class members plead that they are entitled to reimbursement of the purchase price of Prepulsid as a remedy for breach by the Corporate Defendants of an implied warranty that Prepulsid was safe and fit for human consumption.
74. In the further alternative, the Corporate Defendants have been unjustly enriched in the amount of the profits they have earned as a result of the Corporate Defendants' conduct as alleged herein. The Corporate Defendants have been unjustly enriched at the expense of and to the detriment of the Plaintiff and Class members. The Corporate Defendants should be ordered to disgorge the profits they made from their wrongful sale of Prepulsid.

## **DAMAGES FOR THE PLAINTIFF AND THE CLASS**

### **PUNITIVE AND EXEMPLARY DAMAGES**

75. The conduct of the Corporate Defendants as alleged above in this claim, was reckless, intentional, wanton, and malicious. The Corporate Defendants have acted in a high-handed

manner towards the public, including the Plaintiff and Class members, and have engaged in conduct which is reprehensible. As a result, the Plaintiff and Class members seek punitive and exemplary damages.

#### **MEDICAL EXPENSES**

76. The conduct of the Corporate Defendants caused the Plaintiff and Class members to take Prepulsid. Prepulsid is a hazardous substance.
77. As a result of taking Prepulsid, the Class members have a significantly increased risk of having either a serious latent disease or undiagnosed heart damage.
78. As a result of this increased risk, otherwise unnecessary past and future medical and diagnostic examinations will be required, with attendant, medical and hospital expenses. Such expenses will be, or have been, incurred by the Plaintiff and Class members, either directly or on their behalf by provincial health insurers who hold a subrogated interest in the recovery of such expenses from the Corporate Defendants.

#### **DAMAGES FOR THE PLAINTIFF AND THE CLASS**

79. As a result of consuming Prepulsid pursuant to a prescription and the aforementioned wrongful conduct of the Defendants, the Plaintiff and Class members have suffered harm, injury and economic loss.
80. As a result of ingesting Prepulsid, the Plaintiff, Aline Boulanger, was diagnosed with ventricular tachycardia and a prolonged QT interval and she has suffered from sharp chest pains, heart palpitations, dizziness, extreme physical fatigue, shortness of breath and significant anxiety. As a result of consuming Prepulsid, the Plaintiff still suffers from heart rhythm disturbances and requires medication to help control same. She has missed time from work as a result of the above.

81. As a further result of the aforementioned wrongful conduct of the Defendants, the Plaintiff and Class members have sustained the following damages:
- (a) Past and future medical expenses;
  - (b) Temporary and permanent physical injuries;
  - (c) Significant physical pain and suffering;
  - (d) Severe and significant emotional distress, pain, and suffering;
  - (e) Humiliation, embarrassment and fear;
  - (f) Loss of enjoyment of life;
  - (g) Past and future loss of income;
  - (h) Past and future earning capacity impairment;
  - (i) Disability; and
  - (j) Lost money by purchasing Prepulsid when it was of no value whatsoever and was inherently dangerous.
82. In addition to the damages above, the personal representatives of those people who have died as a result of taking Prepulsid have incurred the following damages:
- (a) Loss of income of the deceased, services, protection, care and assistance provided by the deceased;
  - (b) Expenses for the care, treatment and hospitalization of the deceased incident to this injury;
  - (c) Reasonable funeral expenses; and
  - (d) Emotional distress and nervous shock.
83. The Class members who are personal representatives of deceased persons who ingested Prepulsid plead and rely on the provisions of Section 38 of the *Trustee Act*, R.S.O. 1990, Chapter 23, as amended, and other similar provincial legislation including:

- (a) *Fatal Accidents Act*, R.S.P.E.I. 1986 ch. F-5
- (b) *Fatal Accidents Act*, R.S.A. 2000, c. F-8
- (c) *The Fatal Accidents Act*, R.S.S. 1978 c. F-11, as amended
- (d) *Trustee Act*, C.C.S.M. 1993 c. T-160
- (e) *Fatal Accidents Act*, S.N.B. 1969 c. F-7
- (f) *Fatal Accident Act*, R.S.N.L. 1990 c. F-6
- (g) *Fatal Injuries Act*, R.S.N.S. 1989 c. 163
- (h) *Trustee Act*, R.S.N.W.T. 1988, c T-8
- (i) *Fatal Accidents Act*, R.S.Y. 2002 c. 86.

#### **FAMILY LAW ACT CLAIMS**

84. The Plaintiff and Class members plead and rely upon the *Family Law Act*, R.S.O. 1990, c. F.3., as amended, and other similar provincial legislation elsewhere in Canada, including:
- (a) *Fatal Accidents Act*, R.S.P.E.I. 1988 c. F-5, s. 6
  - (b) *Fatal Accidents Act*, R.S.A. 2000 c. F08
  - (c) *The Fatal Accidents Act*, R.S.S. 1978 c. F-11
  - (d) *The Fatal Accidents Act*, R.S.M. 1987 c. F-50
  - (e) *Fatal Accidents Act*, S.N.B. 1969 c. F-7
  - (f) *Fatal Accident Act*, R.S.N.L. 1990 c. F-6
  - (g) *Fatal Injuries Act*, R.S.N.S. 1989 c. 163
  - (h) *Fatal Accidents Act*, R.S.N.W.T. 1988 c. F-3
  - (i) *Fatal Accidents Act*, R.S.Y. 2002 c. 86.
85. "Family Law Act" claims are being advanced by those who have sustained a loss of care, guidance and companionship and/or suffered pecuniary loss as a result of Prepulsid being consumed by their family members and resultant injuries.
86. In accordance with s. 61(1) of the *Family Law Act* and other similar provincial legislation elsewhere in Canada, the F.L.A. claimant Class consists of the spouses, same-sex partners,

children, grandchildren, parents, grandparents, brothers and sisters of the Plaintiff and Class members.

87. These Class members seek to recover damages pursuant to s. 61(2) of the *Family Law Act* and other similar provincial legislation elsewhere in Canada. Specifically, such Class members seek damages for:
- (a) actual expenses reasonably incurred for the benefit of the person injured or killed;
  - (b) actual funeral expenses reasonably incurred;
  - (c) a reasonable allowance for travel expenses actually incurred in visiting the person during his or her treatment or recovery;
  - (d) where, as a result of the injury, the claimant provides housekeeping or other services for the person, a reasonable allowance for loss of income or the value of the services;
  - (e) an amount to compensate for the loss of care, guidance and companionship that the claimant might reasonably have expected to receive for the person if the injury or death had not occurred; and
  - (f) pecuniary damages.

#### **HEALTH INSURANCE ACT SUBROGATED INTEREST**

88. A claim is advanced pursuant to ss. 30 and 31 of the *Health Insurance Act*, R.S.O. 1990, c.H.6, as amended, and other similar provincial legislation elsewhere in Canada, including:
- (a) *Hospital & Diagnostic Services Insurance Act*, R.S.P.E.I. 1988 c. H-8
  - (b) *Hospitals Act*, R.S.A. 2000, c. H-12
  - (c) *Department of Health Act*, R.S.S. 1978 c.D-17, as amended
  - (d) *Health Services Insurance Act*, C.C.S.M., 1987 c. H-35
  - (e) *Hospital Services Act*, 1960 c. H-9, as amended
  - (f) *Hospital Insurance Agreement Act*, R.S.N.L. 1990 c.H-7
  - (g) *Health Services Insurance Act*, R.S.N.S. 1989 c. 197, as amended
  - (h) *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T.

1988, c T-3, as amended

(i) *Hospital Insurance Services Act*, R.S.Y. 2002, c.112

for the costs incurred by the respective provincial Health Plans for past and future insured services rendered to the plaintiff and members of the Class who suffered injury and require medical and hospital and other insured services as the result of ingesting Prepulsid. Furthermore, to the extent that the Health Insurance Plans paid for Prepulsid, the return to the Plans of the full purchase price of Prepulsid.

89. The Plaintiff and Class members plead and rely upon the *Class Proceedings Act*, 1992, S.O. 1992, c.6.
90. The Plaintiff and Class members plead rely upon the *Food and Drug Act*, R.S.C. 1985, c. F.27.
91. The Plaintiff and Class members plead and rely upon the *Crown Liability and Proceeding Act*, R.S.C. 1985, c.C.50.
92. Wherefor, the Plaintiff and Class members plead for the relief set out herein.
93. The Plaintiff and Class members propose that the trial of this action take place in the City of Toronto, in the Regional Municipality of Metropolitan Toronto, in the Province of Ontario.

Date of Issue:

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