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Toronto

Court File No.

ONTARIO
SUPERIOR COURT OF JUSTICE

BARRY LACROIX AND VINCENT CAMPBELL

Plaintiffs

-and-

SANOFI CONSUMER HEALTH INC.; SANOFI-AVENTIS CANADA INC.; SANOFI PASTEUR LIMITED; CHATTEM (CANADA) INC.; BOEHRINGER INGELHEIM (CANADA) LTD.; APOTEX INC.; PRO DOC LTÉE; SANDOZ CANADA INC.; SANIS HEALTH INC; SIVEM PHARMACEUTICALS ULC; SHOPPERS DRUG MART INC.; PHARMAPRIX INC.; WALMART CANADA CORP; LONDON DRUGS LIMITED; REXALL PHARMACY GROUP LTD.; REXALL PLUS PHARMACIES LTD.; MCKESSON CANADA CORPORATION; LA CORPORATION MCKESSON CANADA; MCKESSON PHARMACY SYSTEMS CANADA ULC; PHARMASAVE DRUGS (ONTARIO) LTD.; PHARMASAVE DRUGS (NATIONAL) LTD.; LOBLAW COMPANIES LIMITED and AMAZON.COM, INC.

Defendants

Proceeding under the Class Proceedings Act, 1992

STATEMENT OF CLAIM

TO THE DEFENDANTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Plaintiff. 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 does not have a lawyer, serve it on the Plaintiff, 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 WILL 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.

TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court.

Date: October 16, 2019

Issued by: _____
Local Registrar

Address of court office:
Court House
393 University Avenue
Toronto, Ontario
M5G 1E6

TO: Sanofi Consumer Health Inc.
2905 Place Louis-R. Renaud
Laval, QC, Canada H7V 0A3

TO: Sanofi-Aventis Canada Inc.
2905 Place Louis-R. Renaud
Laval, QC, Canada H7V 0A3

TO: Sanofi Pasteur Limited
Head Office, Manufacturing, R&D
1755 Steeles Ave W,
North York, ON M2R 3T4

TO: Chattem (Canada) Inc.
2220 Argentia Rd,
Mississauga, ON L5N 2K7

TO: Boehringer Ingelheim (Canada) Ltd.
5180 S Service Rd,
Burlington, ON L7L 5H4

TO: Apotex Inc.
150 Signet Drive
Toronto, ON M9L 1T9

TO: Pro Doc Ltée
2925 Boul Industriel,
Laval, Quebec, H7L 3W9

TO: Sandoz Canada Inc.
675 Huntington Ridge Dr,
Mississauga, ON L5R 4H8

TO: Sanis Health Inc.
Suite 400, 371 Phoenix Square, Queen Street
Fredericton, New Brunswick, E3B lBl

TO: Sivem Pharmaceuticals ULC
2600- 595, St. Burrard,
Vancouver, British Columbia, V7X 1L3

TO: Shoppers Drug Mart Inc.
243 Consumers Rd.,
Toronto M2J 4W8, Canada

TO: Pharmaprix Inc.
400 Ave. Ste. Croix,
St. Laurent, Québec H4N 3L4

TO: Walmart Canada Corp
1940 Argentia Rd,
Mississauga, ON L5N 1P9

TO: London Drugs Limited
12251 Horseshoe Way
Richmond, British Columbia V7A 4X5

TO: Rexall Pharmacy Group Ltd.
5965 Coopers Ave,
Mississauga, ON L4Z 1R9

TO: Rexall Plus Pharmacies Ltd.
c/o 5965 Coopers Ave,
Mississauga, ON L4Z 1R9

TO: McKesson Canada Corporation
6355 Viscount Rd,
Mississauga, ON L4V

TO: La Corporation McKesson Canada
4705, rue Dobrin,
Saint-Laurent, QC H4R 2P7

TO: McKesson Pharmacy Systems Canada ULC
c/o 6355 Viscount Rd,
Mississauga, ON L4V

TO: Pharmasave Drugs (Ontario) Ltd.
Suite 404, 3100 Steeles Avenue East
Markham, Ontario L3R 8T3

TO: Pharmasave Drugs (National) Ltd.
8411 – 200th Street, Suite 201
Langley, B.C. V2Y 0E7

TO: Loblaw Companies Limited
1 Presidents Choice Cir,
Brampton, ON L6Y 5S5

AND TO: Amazon.com, Inc.
40 King St W 47th Floor,
Toronto, ON M5H 4A9

THE DEFINITIONS

1. The following definitions apply for the purposes of this statement of claim:

(a) **"Act"** means the *Class Proceedings Act, 1992*, S.O. 1992 c. 6, as amended;

(b) **"Apotex Inc."** means the defendant Apotex;

(c) **"Boehringer"** means the defendant Boehringer Ingelheim (Canada) Ltd.;

(d) **"CCQ"** means the *Civil Code of Quebec*, SQ 1991;

(e) **"Campbell"** means the proposed representative plaintiff, Vincent Campbell;

(f) **"Chattem"** means the defendant Chattem (Canada) Inc.;

(g) **"Class Members"** means all persons defined herein in paragraph 43;

(h) **"Class Period"** means the date of the injury or losses up to the date this court hears the motion for certification of this action as a class proceeding;

(i) ***"Consumer Protection Act"*** means the *Consumer Protection Act, 2002*, S.O. 2002, Chapter 30, Schedule A;

(j) ***"Competition Act"*** means the *Competition Act*, R.S.C. 1985, c.C-34. 36;

(k) **"Contaminated product(s)"** means Zantac and/or other related product(s), generic or otherwise, prescribed or over-the-counter, placed into the stream of commerce in Ontario and elsewhere in Canada containing NDMA;

(l) **"Customer"** means a person who dealt with the defendants in relation to its contaminated products under the Zantac brand name or another trade name and purchased those products as consumers or patients;

(m) **"EPA"** means the Environmental Protection Agency;

(n) **"FDA"** means the Federal Drug Administration;

(o) **"GERD"** means gastroesophageal reflux disease, a digestive disorder that affects the lower esophageal sphincter, the ring of muscle between the esophagus and stomach;

(p) **"Lacroix"** means the proposed representative plaintiff, Barry Lacroix;

(q) **"MOH"** means the Ministry of Health and Long-Term Care, also known as Health Canada;

(r) **"NDMA"** means N-nitrosodimethylamine, a probable carcinogenic contaminant;

(s) **"Pro Doc"** means the defendant Pro Doc Ltée;

(t) **"Ranitidine"** means ranitidine hydrochloride, the component of Zantac and other related contaminated medications for GERD that contains NDMA;

(u) **"Sale of Goods Act"** means the *Sale of Goods Act*, R.S.O. 1990, c. S.1**;**

(v) **"Sanis"** means the defendant Sanis Health Inc.;

(w) **"Sandoz"** means the defendant Sandoz Canada Inc.;

(x) **"Sanofi"** means the Sanofi group of defendants: Sanofi Consumer Health Inc., Sanofi-Aventis Canada Inc., Sanofi Pasteur Limited;

(y) **"Sivem"** means the defendant Sivem Pharmaceuticals ULC;

(z) **"Stores"** means some of the stores that sold Zantac and generic over-the-counter Ranitidine containing NDMA, including Shoppers, Loblaw, Walmart, Rexall and the others named;

(aa) **"WHO"** means the World Health Organization; and

(bb) **"Zantac"** means the drug containing Ranitidine hydrochloride that was placed into the stream of commerce in Ontario and elsewhere in Canada.

RELIEF SOUGHT

2. The plaintiffs Campbell and Lacroix claim on their own behalf and on behalf of the Class:

(a) an order pursuant to the *Act* certifying this proceeding as a class proceeding and appointing them as representatives of the Class;

(b) damages in the amount of $500,000,000.00 for the plaintiffs and Class Members who suffered damages as a result of ingesting NDMA;

(c) damages for Provincial and Territorial Health Insurers in a subrogated claim for injuries and losses incurred as result of treatment and monitoring and for other expenses and costs;

(d) an interim fund to the benefit of the plaintiffs and Class Members and Provincial and Territorial Health Insurers, including monitoring for cancer and other injuries caused or materially contributed by NDMA including any appropriate remedies;

(e) damages for negligence as described hereunder and/or including the following declarations:

i. that the defendants negligently placed Ranitidine contaminated with NDMA into the stream of commerce in Ontario and elsewhere in Canada;

ii. that the defendants failed to warn in a timely fashion or at all when they knew or ought to have known of the contaminated products;

iii. that the defendants failed to conduct studies adequately or at all to detect NDMA;

iv. that the defendants knew or ought to have known of the risks of NDMA;

v. that the defendants failed to warn the public and alert Health Canada and other regulatory agencies as to the known risks when they knew or ought to have known of the contaminated products;

vi. that the defendants knew or ought to have known of the risks and thus disclosed same in the marketing materials and package inserts;

vii. a declaration that the damages are serious and prolonged, and go beyond the ordinary inconveniences, anxieties and fears that a person living in society can expect; and

viii. a declaration that the defendants acted deliberately and with reckless disregard to the safety and well being of the plaintiffs and Class Members.

(f) damages for breach of statute pursuant to any legislation under the *Consumer Protection Act*, including inter alia ss. 14(1), 14(2) subsections (1)(3)(6)(7) (14) (15) and 15(1), 15(2) subsections (a)(c)(d)(e)(f)(g) of the *Consumer Protection Act*; and

i. an order that the pleading issued constitutes notice under s. 92(1) of the *Consumer Protection Act* or an order waiving the requirement for notice on behalf of the plaintiffs and Class Members.

(g) damages for breach of statute pursuant to ss. 74.01 and 74.02 of the *Competition Act.*

(h) damages for breach of statute pursuant to ss. 13, 15 and 51 of the *Sale of Goods Act*.

(i) damages for breach of contract in relation to any persons who were subjected to NDMA after purchasing Zantac and/or another contaminated product;

(j) an order that the defendants are strictly liable to the plaintiffs and Class Members;

(k) an order for the aggregate assessment of monetary relief and distribution;

(l) special damages, including time lost for precautionary steps in monitoring the health of the plaintiffs and Class Members.

(m) costs of administering the plan of distribution of the recovery in this action in the sum of $10,000,000.00 or such other sum as this Honourable Court finds appropriate;

(n) an accounting of all profits received by the defendants directly or indirectly related to the profits earned, and an order requiring the defendants to disgorge these amounts;

(o) an order that the defendants hold all proceeds received from the profits realized, and any other profits or income received relating directly or indirectly to profits, in a constructive trust for the benefit of the Class Members;

(p) aggravated damages, exemplary damages and punitive damages in the amount of $20,000,000.00, or such other sum as the Honourable Court finds appropriate;

(q) an order directing a reference or giving such other directions as may be necessary to determine issues not determined in the trial of the common issues;

(r) prejudgment interest pursuant to the *Courts of Justice Act*, R.S.O. 1990, c. C.43, s. 128;

(s) postjudgment interest pursuant to the *Courts of Justice Act*, R.S.O. 1990, c. C.43, s. 129;

(t) costs of this action pursuant to the *Act*, and s. 131(1) of the *Courts of Justice Act* on a substantial indemnity basis plus applicable taxes; and

(u) such further and other relief as to this court seems just.

THE NATURE OF THE ACTION

3. This action concerns the contamination of Zantac (Ranitidine) and other contaminated products with NDMA placed into the stream of commerce in Ontario and elsewhere in Canada. The carcinogen in Zantac and the other products is NDMA. Zantac was placed into the stream of commerce by Sanofi. Some of the products are over-the-counter and generic, and others by prescription only.

4. When only one 150 mg tablet of Zantac is ingested, it undergoes a chemical reaction in the stomach to create more than 3,100 times the FDA approved limit of NDMA and both the

FDA and MOH have warned that it is carcinogenic, along with the EPA and WHO. The FDA has established a permissible daily intake limit of 96ng of NDMA, but recent testing using FDA-approved methods detected more than 2,500,000ng of NDMA per 150mg tablet of Zantac, meaning that each tablet contains thousands of times higher than the FDA-approved amount of NDMA that can be ingested daily. NDMA is extremely toxic and carcinogenic and also causes organ damage, including damage to the kidneys and liver damage and failure.

5. On September 13, 2019 the MOH put out a statement for Canadians that "NDMA is classified as a probable human carcinogen." In addition, the dangers of NDMA have been publicly known for more than 40 years. The WHO has described NDMA as "clearly carcinogenic," and the EPA refers to the chemicals as "potent carcinogens." The level to which the plaintiffs and Class Members have been exposed is high, and the defendants did not disclose the risk.

6. The plaintiffs plead and rely, on behalf of themselves and the Class Members, upon competition, consumer protection, trade legislation, and common law as it exists in this jurisdiction, and the equivalent/similar legislation and common law in all Canadian provinces and territories.

THE PARTIES

i. The proposed representative plaintiffs

7. The plaintiff, Barry Lacroix resides in Sarnia, Ontario. Mr. Lacroix suffers from GERD. He has used Zantac for much of his life. He has also suffered from cancer, a known side effect of NDMA which is the contaminant in Zantac.

8. The plaintiff, Vincent Campbell resides in Burlington, Ontario. He has used Zantac for approximately 3 years. He has suffered from pain in his kidneys, low immunity, and is currently being further assessed. He was informed of the NDMA contamination in Zantac by the pharmacy on or about October 6, 2019.

ii. The defendant drug manufacturers

9. The defendant, Sanofi Consumer Health Inc. is a company established pursuant to the laws of Canada with its registered office located in Laval, QC, Canada and sells Zantac.

10. The defendant, Sanofi-Aventis Canada Inc. is a pharmaceutical company established pursuant to the laws in Canada with its registered office located in Laval, Quebec.

11. The defendant, Sanofi Pasteur Limited is a pharmaceutical company established pursuant to the laws of Canada with its registered office located in North York, Ontario.

12. The defendant, Chattem (Canada) Inc. is a pharmaceutical company established pursuant to the laws of Canada with its registered office located in Mississauga, Ontario. Chattem, along with its parent company, produced over-the-counter Zantac. It is a subsidiary of the French company Sanofi, which along with Chattem, Inc. in Tennessee, controlled the US rights to over the counter Zantac from January 2017 to the present, and manufactured and distributed the drug in North America during that time period.

13. The defendant, Boehringer Ingelheim (Canada) Ltd. is a pharmaceutical company established pursuant to the laws of Canada with its registered office located in Burlington, Ontario. Its US counterpart is Boehringer Ingelheim Pharmaceuticals Inc., a Delaware Corporation which itself is a subsidiary of Boehringer Ingelheim located in Germany. Boehringer owned the US rights to over-the-counter Zantac from October 2006 to January 2107, and distributed the drug in North America during that time period.

14. The defendant, Apotex Inc. is a corporation established pursuant to the laws of Canada with its registered office located in Toronto, Ontario. It produced a generic version of the drug sold by Walmart and other stores.

15. The Defendant, Pro Doc Ltée is a corporation established pursuant to the laws of Canada with its registered office located in Laval, Quebec.

16. The defendant, Sanis Health Inc. is a corporation established pursuant to the laws of Canada with its registered office located in Fredericton, New Brunswick.

17. The defendant, Sivem Pharmaceuticals ULC is a corporation established pursuant to the laws of Canada with its registered office located in Vancouver, British Columbia.

ii. **The defendant Stores**

18. The contaminated product was available at drug stores and other locations and online as well.

19. The defendant, Shoppers Shoppers Drug Mart Inc. is a corporation established pursuant of the laws of Canada with its registered office located in Toronto, Ontario. It is the wholly owned subsidiary of Loblaw Companies Limited.

20. The defendant, Walmart is a corporation established pursuant to the laws of Canada with its registered office located in Mississauga, Ontario.

21. The defendant, Pharmaprix Inc. is a corporation established pursuant to the laws of Canada with its registered office located in St. Laurent, Québec. It is a wholly owned subsidiary of Loblaw Companies Limited.

22. The defendant, London Drugs Limited is a corporation established pursuant to the laws of Canada with its registered office located in Richmond, British Columbia.

23. The defendant, Rexall Pharmacy Group Ltd. is a corporation established

pursuant to the laws of Canada with its registered office located in Mississauga, Ontario.

24. The defendant, Rexall Plus Pharmacies Ltd. is a corporation established pursuant to the laws of Canada with its registered office located in Mississauga, Ontario.

25. The defendant, McKesson Canada Corporation is a corporation established pursuant to the laws of Canada with its registered office located in Mississauga, Ontario. Rexall™ is a member of the Rexall Pharmacy Group Ltd, which is a wholly owned subsidiary of McKesson Canada Corporation.

26. The defendant, McKesson Canada Corporation is a corporation established pursuant to the laws of Canada with its registered office located in Mississauga, Ontario. Rexall™ is a member of the Rexall Pharmacy Group Ltd, which is a wholly owned subsidiary of McKesson Canada Corporation.

27. The defendant, La Corporation McKesson Canada is a corporation established pursuant to the laws of Canada with its registered office located in Saint-Laurent, Quebec.

28. The defendant, McKesson Pharmacy Systems Canada ULC is a corporation established pursuant to the laws of Canada with its registered office located in Saint-Laurent, Quebec.

29. The defendant, Pharmasave Drugs (Ontario) Ltd. is a corporation established pursuant to the laws of Canada with its registered office located in Markham, Ontario.

30. The defendant, Pharmasave Drugs (National) Ltd. is a corporation established pursuant to the laws of Canada with its registered office located in Langley, British Columbia.

31. The defendant, Loblaw Companies Limited is a corporation established pursuant to the laws of Canada with its registered office located in Brampton, Ontario.

32. The defendant, Amazon.com Inc. is a corporation established pursuant to the laws of Canada with its corporate hub located in Toronto, Ontario and Vancouver, British Columbia.

RELATIONSHIP AMONG THE DEFENDANTS

33. At all material times, the group of Sanofi defendants, Chattem, Boehringer, Apotex, Pro Doc, Sandoz, Sanis, Sivem, and/or their parents and subsidiaries were engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor, or subsidiary, drugs containing Ranitidine to treat customers.

34. These customers were suffering from abdominal discomfort and esophageal, intestinal and stomach pain, and among other conditions, heartburn, acid reflux, and GERD and the defendants placed drugs into the stream of commerce in Ontario and elsewhere in Canada, and engaged in marketing to promote these drugs for profit.

35. The Sanofi group of defendants, and Chattem, Boehringer, Apotex, Pro Doc, Sandoz, Sanis, and Sivem were involved in the development of Ranitidine and its related contaminated products for sale in Ontario and elsewhere in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, and the labelling and promotional activities regarding Ranitidine. Chattem and Boehringer sold over-the-counter Ranitidine, and the other defendants by prescription. The stores sold the drugs directly to the customers as over-the-counter medication, as well as online, and some stores by prescription.

36. The defendants were also engaged in other actions central to the allegations of this lawsuit, jointly and severally, and the defendants are vicariously liable:

(a) as a global partnership or common business enterprise which manufactured and distributed Ranitidine and its related contaminated products internationally, and in Ontario and elsewhere in Canada;

(b) as each was the partner or agent of the others: (i) as each company's business was and is inextricably connected with the other defendants; and (ii) as each company had a common plan to manufacture and distribute Ranitidine and its related contaminated products throughout the world, including in Canada, for profit; and

(c) as joint tortfeasers.

NDMA

37. NDMA is a chemical that is known by Health Canada to be a probable carcinogen.

38. NDMA is harmful at very minute concentrations, but is difficult to detect at those same concentration levels. The U.S. Emergency Planning and Community Right-to-Know Act classifies it as an "extremely hazardous substance." Among others, the FDA, WHO and EPA consider it as a carcinogen.

39. On September 17, 2019, Sandoz Canada recalled its NDMA contaminated Ranitidine drugs.

40. On September 25, 2019, Health Canada advised that it is requesting that companies stop distributing products containing Ranitidine, including drugs made or distributed by Apotex Inc., Pro Doc Limitée, Sanis Health Inc., and Sivem Pharmaceuticals ULC.

41. Drug lots were recalled from the following companies by MOH on September 25, 2019.

42. The following table of recalled contaminated products was provided on its website by the MOH:

The following is a list of ranitidine products being recalled in Canada at this time:					
Company	**Product Name/Active Pharmaceutical Ingredient (API)**	**DIN**	**Strength**	**Lot**	**Date added**
Apotex Inc.	Acid Reducer (ranitidine) sold under the brand names Equate and Selection	02296160	150 mg	All lots	September 25, 2019
Apotex Inc.	Apo-Ranitidine Oral Solution	02280833	15 mg/mL	All lots	September 25, 2019
Apotex Inc.	Apo-Ranitidine Tablet 150mg	00733059	150 mg	All lots	September 25, 2019
Apotex Inc.	Apo-Ranitidine Tablet 300mg	00733067	300 mg	All lots	September 25, 2019
Pro Doc Limitée	Ranitidine - 150	00740748	150 mg	All lots	September 25, 2019
Pro Doc Limitée	Ranitidine - 300	00740756	300 mg	All lots	September 25, 2019
Sandoz Canada	Sandoz Ranitidine	02243229	150 mg	All lots	September 17, 2019
Sandoz Canada	Sandoz Ranitidine	02243230	300 mg	All lots	September 17, 2019
Sanis Health Inc.	Ranitidine	02353016	150 mg	All lots	September 25, 2019
Sanis Health Inc.	Ranitidine	02353024	300 mg	All lots	September 25, 2019
Sivem Pharmaceuticals ULC	Ranitidine	02385953	150 mg	NP4179 NP4183 NP4184 NP5656 NP5657 NT2721 NT2722 NT2724 NT2757 NT2762 NT2763 NT2764 NT2765 PJ2434 PJ2435 PV6243 PV6244 PV6245	September 25, 2019
Sivem Pharmaceuticals ULC	Ranitidine	02385961	300 mg	NP4177 NP4180 NT1365 PX8854	September 25, 2019

CLASS DEFINITION

43. This action is brought on behalf of the plaintiffs and Class Members including all persons residing in Canada who ingested Zantac (Ranitidine) and related NDMA contaminated products, along with others who are entitled to bring a derivative claim by virtue of:

(a) familial relationship, including a person's spouse, children and grandchildren, parents and grandparents, and brothers and sisters, and

(b) fatal accidents legislation.

CAUSES OF ACTION

44. The plaintiffs and Class Members incorporate by this reference the assertions set forth in the paragraphs above as if fully set forth under each of the causes of action below.

NEGLIGENCE

45. The Defendants owed a duty of care to the plaintiffs and Class Members to, among other things:

(a) exercise reasonable care in formulating, manufacturing, and testing of the products;

(b) ensure the products were safe for human ingestion;

(c) market only products that are fit for human consumption;

(d) study and conduct trials on an ongoing basis to determine safety issues;

(e) rectify any problems as they arise and alert the regulatory authorities;

(f) conduct ongoing testing and analyses to determine if any impurities or risks in ingesting the products exist or arise;

(g) ascertain within a reasonable time of any impurities in the manufacture of the products;

(h) inform the public and regulatory authorities if any problems arise;

(i) warn the public and alert Health Canada; and

(j) recall the contaminated products immediately.

46. The defendants breached the standards of care required, in particular in that NDMA is a probable cause of cancer and other ailments and was present in Ranitidine.

47. The plaintiffs and Class claim that the aforementioned negligence was caused as a result of the joint and/or several negligence of the defendants, and/or the employees or agents of the defendants, for whose negligence each of the defendants is in law responsible, the particulars of which are as follows:

(a) they placed into the stream of commerce a contaminated product;
(b) they allowed a product to be sold for profit when they knew or ought to have known that it contained NDMA which is a probable carcinogen and causes or materially contributes to the development of cancer and other diseases;
(c) they failed to test to determine if the product was contaminated;
(a) they failed to do adequate pre-approval clinical trials;
(b) they failed to alert Health Canada, warn the public, doctors, pharmacists as to the risks;
(c) they allowed NDMA to be ingested by the plaintiffs and Class Members;
(d) they knew or ought to have known that NDMA was a risk factor when the drugs were approved and marketed, and certainly when other drugs were found to contain it previously;
(e) they failed to exercise care in designing, developing, manufacturing, marketing, and selling the products so as to avoid potential sources of contamination;
(f) they failed to identify the contaminant in a timely manner;
(g) they failed to establish any or any adequate procedures or protocols to monitor the formulation of a safe product, or in the alternative, acted with reckless disregard as to the safety of the pubic and were motivated solely by profit;
(h) they failed to establish any or any adequate procedures to monitor the formulation of the product;
(i) they allowed cross-contamination with NDMA or sources of contamination to be incorporated into the formulation of the product;
(j) they knew or ought to have known that NDMA was a probable carcinogen and health risk and was present in the product;
(k) they failed to use adequate quality control measures;
(l) they failed to conduct adequate testing;
(m) they failed to have proper or safe manufacturing, production, or processing technology;
(n) they allowed contaminated products to be offered for sale by prescription and even over-the-counter;
(o) they sought approval to have the drugs sold directly to consumers with and without a prescription on an over-the-counter basis even though the drugs were unsafe;
(p) they sold the drugs to the public over-the-counter, by prescription, online and in stores;
(q) they endangered the public by providing harmful products for sale;
(r) they failed to recall the products promptly or at all when they initially knew of the risk;
(s) they failed to train the employees, technicians and scientists who worked for them to use adequate quality control in the production of their products; and
(t) they failed to have an adequate system in place to track the side effects of their products, which might otherwise have revealed the contamination.

48. As a result of the breach of the standard of care imposed upon them, the defendants deprived the plaintiffs and the Class Members of the right to know what risks were involved in the use of the contaminated products, and therefore to make a determination of the balance of risks and to choose alternative, safe drugs. Instead, they were inflicted with a cancer causing agent.

49. The defendants knew or ought to have known that the contaminated products contained NDMA that increased the risk to consumers of serious complications, including the development of cancer and other ailments.

BREACH OF STATUTORY REQUIREMENTS

A. *Competition Act*

50. As stated previously, the plaintiffs and Class Members plead and rely upon competition, consumer protection, trade legislation, and common law as it exists in this jurisdiction, and the equivalent/similar legislation and common law in all Canadian provinces and territories.

51. The misrepresentations by the defendants as to the risks associated with the use of the contaminated products constitute unlawful, unfair, and deceptive trade practices.

52. The defendants are in breach of ss. 74.01 and 74.02 of the *Competition Act*.

B. *Sale of Goods Act*

53. The contaminated products were not of acceptable quality and were not fit for the sole and only purpose for which they were offered for sale in Canada, which constitutes a violation of s. 15 of the *Sale of Goods Act* and other equivalent provincial legislation elsewhere.

54. Pursuant to s. 51 of that the *Sale of Goods Act*, the plaintiffs and Class Members are entitled to recover the amounts they paid for the contaminated products in addition to recovering compensation for other damages.

55. The plaintiffs and Class Members plead that the defendants are strictly liable for a product intended to be ingested by the public that could not be tested by the public prior to its use.

56. Since the defendants are solely in control of the quality of the contaminated products that were placed into the stream of commerce in Ontario and elsewhere in Canada, and are engaged in the business of researching, creating, designing, testing, manufacturing, labeling, packaging, supplying, marketing, selling, advertising, and distributing the contaminated products, it was also solely in the control of the defendants to know about the serious risks.

57. The contaminated products supplied by the defendants are unaccompanied by warnings that accurately reflected the hazards.

58. As a direct result of the proximate cause of the defective condition of the contaminated products as manufactured or supplied or distributed by the defendants, and as a direct and legal result of the conduct of the defendants described herein, the plaintiffs and Class Members have been injured by ingesting NDMA.

59. The products were unreasonably dangerous. Had the plaintiffs and Class Members been aware of the risks, resulting from the defective design and manufacture of the products, in particular that the foreseeable risks exceeded the benefits associated with the design and formulation of the drug, then they would have avoided the risks and sought alternative products that did not contain NDMA.

60. The contaminated products were more dangerous than an ordinary consumer would expect and more dangerous than alternative drugs available for the treatment of the plaintiffs and Class Members.

61. There existed, at all times material hereto, safer alternative medications that did not contain harmful and hazardous chemical substances such as NDMA.

62. The defendants did not perform adequate testing. Adequate testing would have revealed that contaminated products contained NDMA.

63. Pursuant to s. 13 of the *Sale of Goods Act*, there exist implied conditions and warranties in the sale of goods, in addition to the product being of fit and merchantable quality. The plaintiffs and Class Members plead that there was a breach of warranty, in particular that the defendants made express warranties that the products were of merchantable quality and safe to be ingested for their intended use by the plaintiffs and Class Members.

64. The defendants expressly warranted to the public, including the plaintiffs and Class Members, by way of package inserts, product monographs, and advertising and marketing, that their products were safe.

65. Further, the defendants used authorized drug representatives, agents and marketing companies, to warrant orally to suppliers including to physicians, that the products are safe. This included published studies, written materials, pamphlets, summaries, websites, and other means to show that the products are safe, effective, and fit for their intended use.

66. These warranties were made directly to the public, to pharmacists, to regulators, and even to Health Canada. In using the products, the plaintiffs and Class Members rely upon the representations made by the defendants.

67. The plaintiffs and Class Members relied upon the representations and express warranties made by the defendants.

68. These warranties and representations proved to be false because the product was not safe. It contained NDMA and is unfit for the purpose for which it was intended as swallowing it causes thousands of times the daily level of NDMA to be ingested.

69. As a direct and proximate result of the defendants' warranties, made in these representations, the plaintiffs and Class Members have suffered injuries.

C. *Consumer Protection Act*

70. Pursuant to Part III, which governs unfair practices, in respect of false, misleading or deceptive representation, s. 14 provides that it is an unfair practice for a person to make a false, misleading or deceptive representation which includes a representation that the goods or services are of a particular standard, quality, grade, style or model, if they are not.

71. Pursuant to s. 14(1) and s. 14(2) subsections 1, 3, 6,7, 14,15, and s. 15(1), and s. 15(2) subsections (a), (c), (e), (f), (g) of the *Consumer Protection Act*, the defendants engaged in the following unfair practices:

(a) s. 14(2)(1). A representation that the goods or services have sponsorship, approval, performance characteristics, accessories, uses, ingredients, benefits or qualities they do not have.

(b) s. 14(2)(3). A representation that the goods or services are of a particular standard, quality, grade, style or model, if they are not;

(c) s. 14(2)(6). A representation that the goods or services are available for a reason that does not exist.

(d) s. 14(2)(7). A representation that the goods or services have been supplied in accordance with a previous representation, if they have not;

(e) s. 14(2)(14). A representation using exaggeration, innuendo or ambiguity as to a material fact or failing to state a material fact if such use or failure deceives or tends to deceive.

(f) s.14(2)(15). A representation that misrepresents the purpose or intent of any solicitation of or any communication with a consumer.

72. Further, pursuant to s. 15(1) it is an unfair practice to make an unconscionable representation, which is set out in s. 15(2), in the following subsections (a)(c)(d)(e)(f)(g) to s. 15(2):

(a) that the consumer is not reasonably able to protect his or her interests because of disability, ignorance, illiteracy, inability to understand the language of an agreement or similar factors;

(c) that the consumer is unable to receive a substantial benefit from the subject-matter of the representation;

(e) that the consumer transaction is excessively one-sided in favour of someone other than the consumer;

(f) that the terms of the consumer transaction are so adverse to the consumer as to be inequitable;

(g) that a statement of opinion is misleading and the consumer is likely to rely on it to his or her detriment.

73. The representations in regard to these defendants are in breach of these sections in that the defendants represented that the goods supplied were safe and effective. In fact, they were the opposite. They contained an impermissible contaminant which was undetectable by the average consumer. There was no way for the plaintiffs and Class Members to recognize the inherent risks of the product. The defendants relied upon the ignorance of the consumer, the one-sided nature of the contract, and the inequitable relationship between the drug company and the plaintiffs and Class Members and Canadian public.

74. The defendants also made statements that the products are safe.

75. The plaintiffs and Class Members plead that subject to s. 17 (1) of the *Consumer Protection Act*, no person shall engage in an unfair practice, and (2) A person who performs one act referred to in ss. 14, 15 or 16 shall be deemed to be engaging in an unfair practice. Subject to s. 116 (1) in respect of offences under the *Consumer Protection Act*, a person is guilty of an offence if the person, (a) fails to comply with any order, direction or other requirement under this Act and pleads that the defendant breached s. 17 (1).

76. The defendants are the manufacturers and sellers of contaminated products, and the plaintiffs and Class Members are buyers within the meaning of statutes such as the *Competition Act*, the *Sale of Goods Act*, and the *Consumer Protection Act*, and all provincial and federal equivalents. As a result of a breach of the statutory and common law warranties, the plaintiffs and Class Members are entitled to all the remedies contained in the *Competition Act*, the *Sale of Goods Act*, and the *Consumer Protection Act*, and all provincial and federal equivalents, and the common law.

INFLICTION OF MENTAL SUFFERING

77. The plaintiffs and Class Members plead that the defendants placed into the stream of commerce in Ontario and elsewhere in Canada a product that is extremely toxic. It causes cancer and organ damage and failure. The sole motivation is profit.

78. The defendants' conduct is:

(a) flagrant and outrageous;

(b) calculated to harm the plaintiffs and Class Members; and

(c) caused or materially contributed to the plaintiffs and Class Members suffering an illness, and anxiety and psychological damages.

79. Further or in the alternative, the defendants placed the drugs into the stream of commerce in Ontario and elsewhere in Canada with the sole intention of making profits.

80. The defendants' conduct is fraught with reckless disregard, and negligence, and caused or materially contributed to the plaintiffs and Class Members suffering an illness and anxiety and psychological damages. In placing the contaminated drugs into the stream of commerce, it was foreseeable that the defendant's negligent conduct would have caused the plaintiffs and Class Members to suffer physical and emotional illness and harm.

UNJUST ENRICHMENT

81. The plaintiffs and Class Members plead that the defendants placed into the stream of commerce a contaminated product for the strict purpose of profit.

82. As a result, they have ingested Zantac and contaminated products, generic, over-the-counter, by prescription and otherwise, and have suffered and will continue to suffer from the toxic effects and anxiety and psychological damage as a result of ingesting NDMA. They were not warned in which case they could have sought safe alternatives.

83. The plaintiffs and Class Members plead that the defendants:

(a) received a benefit in that they made profits;

(b) the plaintiffs and Class Members suffered a loss corresponding to the benefit in that they ingested Zantac and other contaminated products and suffer from the toxic effects and emotional distress of ingesting NDMA; and

(c) there was no juristic reason for the benefit and the loss.

84. The plaintiffs and Class Members plead that there has been an unjust enrichment and corresponding deprivation and no reason in law for the defendants to keep the benefits conferred.

RESTITUTION: WAIVER OF TORT

85. Further or in the alternative, the plaintiffs and Class Members plead for restitution of benefits received by the defendants as a consequence of their tortious conduct rather than damages to compensate the plaintiffs and Class Members.

DAMAGES

86. The defendants placed products containing a probable carcinogen into the stream of commerce in Ontario and elsewhere in Canada. The defendants manufactured, marketed, and distributed contaminated products that are defective and unfit for their intended purpose.

87. The defendants acted in a manner that is unlawful, unfair, deceptive, and causes injury to the plaintiffs and Class Members who ingested a known carcinogen, a toxic substance, in doses that are thousands of times above the daily limit.

88. The effects of NDMA have been known for decades. The defendants simply preferred profit and were motivated solely by sales and not by providing a safe product. The defendants caused the plaintiffs and Class Members to purchase and ingest contaminated products.

89. Mr. Lacroix suffered from heartburn for most of his life. He used Zantac for a good portion of his life and used over-the-counter drugs as well. He had no idea that these drugs contained NDMA. As a result he has suffered significant health effects including cancer. He is about to undergo further testing.

90. In addition to the toxic effects and disease, Mr. Campbell and Mr. Lacroix are suffering from anxiety, psychological damages and emotional distress and mental suffering as a result of ingesting NDMA, an extremely toxic substance that results in an uncertain future.

91. Mr. Campbell was prescribed drugs containing Ranitidine. He is also suffering from pain in his kidneys and low immunity. Mr. Campbell also had no idea that the drugs contained NDMA. The plaintiffs both have serious health conditions as a result of the drugs in addition to the uncertainty, and will require further testing and diagnosis on an ongoing basis.

92. The plaintiffs and the Class Members have suffered economic damages, personal injuries, and endangerment, and are entitled to damages.

93. The plaintiffs and Class Members have suffered general, special, and aggravated damages. The injuries that have occurred as a result of the defendants' acts and omissions involve personal injury including but not limited to the development of cancers, and organ damage and failure, infliction of mental suffering, anxiety and emotional distress, direct or indirect economic losses including but not limited to out-of-pocket expenses for treatment, monitoring, replacement medications, cost of future care, and loss of employment income; and other pain, suffering, or loss, stemming from illness of the plaintiffs and Class Members as a result of the use of contaminated products containing NDMA.

94. The plaintiffs and Class Members have experienced anxiety and significant worry about the fact that they been exposed to a chemical that is known to be so harmful to humans. The acts and omissions and reckless disregard for the safety of the plaintiffs and Class Members have caused and/or materially contributed to the ongoing health detriments and deficits of the plaintiffs and Class Members.

95. Along with this wrongdoing, the statutory breaches of the defendants have also caused or materially contributed to the plaintiffs and Class Members suffering injury, economic loss, and damages. The acts and omissions of the defendants are as set forth above.

96. The defendants demonstrated a cavalier and arbitrary approach with respect to their obligations to the plaintiffs and Class Members, and pursued conduct which constitutes unfair business practices and dealings with their customers and the public.

97. The defendants' conduct as described in the aforementioned was high-handed, outrageous, reckless, willful, in contumelious disregard of the interests of the plaintiffs and Class Members, indifferent to the consequences and motivated by economic considerations, and in complete disregard to the security of the plaintiffs and Class Members, and as such renders the defendants liable to pay aggravated, exemplary and punitive damages in the amount of $20,000,000.00. In these circumstances punitive or exemplary damages and aggravated damages should be awarded.

SUBROGAGED DAMAGES: PROVINCIAL/TERRORITORIAL HEALTH INSURERS

98. The plaintiffs and Class Members rely upon health and hospital insurance legislation in Ontario and similar legislation elsewhere and hereby claims health care costs incurred by the plaintiffs and Class Members and paid by provincial and territorial governments, including the additional costs of doctors for new prescriptions and the monitoring of risks caused by NDMA, and the cost of the additional prescriptions. The past costs and future costs are claimed. The costs for in- patient and outpatient procedures and treatment are claimed. Insured costs are also claimed.

99. On behalf of Her Majesty the Queen in right of the Province of New Brunswick, the plaintiffs and Class Members claim the cost of "entitled services" pursuant to the *Health Services Act*, SNB 2014, c 112, ss I and 3 and *General Regulation*, NB Reg 84- I l 5, s 2 and Schedule II.

100. On behalf of the government of British Columbia, the plaintiffs and Class Members claim the past and future cost of providing "health care services" pursuant to the *Health Care Costs Recovery Act*, SBC 2008, c 27, ss 1-3 and 7 and *Health Care Costs Recovery Regulation*, BC Reg 397/2008, s 3.

101. On behalf of Her Majesty in right of Alberta and the Minister of Health of Saskatchewan, the plaintiffs and Class Members claim the direct and indirect costs of past and future "health services" pursuant to *Crown's Right of Recovery Act*, SA 2009, c C-35, ss I and 38 and *Crown's Right of Recovery Regulation*, Alta Reg 87/20 12, s 3 and *The Health Administration Act*, RSS 1978, c H-0.0001, s 19.

102. On behalf of the Minister of Health of Manitoba, the plaintiffs and Class Members claim the past and future cost of "insured hospital, medical, and other services" pursuant to *The Health Services Insurance Act*, RSM 1987, c H35, ss 2, 97 and *The Medical Services Insurance Regulation*, Man Reg 49/93, s I.

103. On behalf of Her Majesty in right of the Province of Nova Scotia, the plaintiffs and Class Members claim the past and future cost of "insured hospital services" and other care, services, and benefits, pursuant to *Health Services and Insurance Act*, RSNS 1989, c 197, ss 2 and 18.

104. On behalf of the Government of Yukon, and the Ministers of Health of the Northwest Territories and Nunavut, the plaintiffs and Class Members claim the cost of providing "insured services", including in-patient and out-patient services, pursuant to *Hospital Insurance Services Act*, RSY 2002, c 112, ss 1 and 10- 11 and *Yukon Hospital Insurance Services Regulations*, YCO 1960/35, s 2; *Hospital Insurance and Health and Social Services Administration Act*, RSNWT 1988, c T-3 , ss 1 and 19-20 and *Hospital Insurance Regulations*, RRNWT 1990, c T-12, s 1; *Hospital Insurance and Health and Social Services Administration Act*, RSNWT (Nu) 1988, c T-

3 , ss 1 and 19-20 and *Hospital Insurance and Health and Social Services Administration Act*, RSNWT (Nu) 1988, c T-3, s I.

105. On behalf of the Ontario Health Insurance Plan, the province of Quebec, the Minister of Health and Wellness of Prince Edward lsland, and the Crown in right of Newfoundland and Labrador, the plaintiffs and Class Members claim the cost of "insured services," pursuant to the *Health Insurance Act*, RSO 1990, c H.6, ss I, 11.2, and 30-3 I and General, RRO 1990, Reg 552; *Hospital Insurance Act*, CNLR c A-28, ss I and 10 and Regulation respecting the application of the *Hospital insurance Act*, CNLR c A-28, r I, s 3 and *Health Insurance Act*, CQLR A-29, ss I, 3, and 18; *Hospital and Diagnostic Services Insurance Act*, RSPEI 1988, c H-8, ss I and 14 and *General Regulations*, PEI Reg EC539/63, s I; and *Hospital Insurance Agreement Act*, RSNL 1990, c H-7, s 5 and *Hospital Insurance Regulations*, CNLR 742/96, s 2 and Schedule.

106. The plaintiffs and Class Members plead and rely upon the following, together with the amendments made thereto and the regulations made thereunder:

- *Alberta Health Care Insurance Act*, R.S.A. 200, c.A-20;
- *Class Proceedings Act, 1992*, S.O. 1992, c. 6;
- *The Business Practices Act*, S.M. 1990-91, c. 6;
- *Competition Act*, R.S.C. 1985, c.C-34. 36;
- *Consumer Protection Act*, 2002, S.O. 2002, Chapter 30, Schedule A, as am, including s. 8;
- *The Consumer Protection Act*, S.S. 1996, c. C-30.1, as am., including s. 14 and Part III;
- *The Consumer Protection and Business Practices Act*, S.S. 2013, c. C-30;
- *Civil Code of Quebec*, SQ 1991;
- *Civil Code of Quebec*, L.R.Q., c. C-1991, art. 35-40;
- *Department of Health Act*, R.S.S. 1978, D-17;
- *Fair Trading Act*, R.S.A. 2000, c. F-2, as am. including s. 13;

- *Family Compensation Act*, RSBC 1996, c 126, ss 2 and 3(8)-(9);
- *Family Law Act*, RSO 1990, c F 3, ss 61(1)-(2);
- *Fatal Accidents Act*, RSY 2002, c 86, ss 2-3;
- *Fatal Accidents Act*, RSNWT 1988, c F-3, ss 2-3; Fatal Accidents Act, RSA 2000, c F-8, ss 1, 2, and 3(1);
- *The Fatal Accidents Act*, RSS 1978, c F-1 1, ss 2, 3(1), and 4(1)-(3);
- *Fatal Accidents Act*, SNu 2010, c 14, s 6, ss 2-3;
- *The Fatal Accidents Act*, CCSM c F50, ss 2-3;
- *Fatal Accidents Act*, RSNL 1990, c F-6, ss 2-4;
- *Fatal Accidents Act*, SNB 2012, c 104, ss 3, 4, and 7;
- *Fatal Injuries Act*, RSNS 1989, c 163, ss 2-3 and 5;
- *Fatal Accidents Act*, RSPEI 1988, c F-5, ss 1-2 and 6;
- *Health Care Cost Recovery Act*, S.B.C. 2008, c.27
- *Health Insurance Act*, R.S.O. 1990, c. 11-6;
- *Health Services Insurance Act*, C.C.S.M., C.1135;
- *Health Services and Insurance Act*, R.S.N.S. 1989, c.197;
- *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c. H-8;
- *Hospital Insurance Agreement Act*, R.S.N.I. 1990, c.11-7;
- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c.T-3;
- *Hospital Insurance Services Act*, R.S.Y. 2002, c.112;
- Hospital Services Act, R.S.N.B. 1973, c.11-9;
- *Hospitals Act*, R.S.A. 2000, c. 11;
- *Negligence Act*, R.S.O. 1990, c. N.1;
- *Sale of Goods Act*, R.S.O. 1990, c. S.1;
- *The Sale of Goods Act*, R.S.S. 1978, c. S-1;
- *Survival of Actions Act*, R.S.A. 2000, c. S-27, ss. 2, 5(1), 5(2);
- *The Survival of Actions Act*, S.S. 1990, c. S-66.l, ss. 3 and 6(1)-(3);
- *Survival of Actions Act*, R.S.N.S.1989, c. 453, ss. 2(1)-(2) and 5;
- *Survival of Actions Act*, R.S.N.B. 201 1, c. 227, ss. 3(1)-(2) and 6(1)-(2);

- *Survival of Actions Act*, R.S.P.E.1. 1988, c. S-11, ss. 2 and 5;
- *Survival of Actions Act*, R.S.N.L. 1990, c. S-32, ss. 2 and 4;
- *Trade Practices Act*, R.S.N.L. 1990, c. T-71, as am., including s. 14.

107. The plaintiffs and Class Members plead and rely upon the following provisions of Rule 17 of the *Rules of Civil Procedure* in support of such service: 17.02 (f) – the contract was made in Ontario; 17.02 (g) – the tort was committed in Ontario; and 17.02(p) – the defendant carries on business in Ontario, and 17.05 – service outside Ontario in relation to the defendants in the United States, if any are added.

The plaintiffs and Class Members propose that this action be tried in the City of Toronto, in the Province of Ontario.

October 16, 2019

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DEFENDANTS

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