SUPREME COURT
OF BRITISH COLUMBIA
VANCOUVER REGISTRY

SEP 20 2021

S 218270

ACTION NO.
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

PHIL DAVIS

PLAINTIFF

AND:

PFIZER CANADA ULC / PFIZER CANADA SRI AND PFIZER CANADA INC.

DEFENDANTS

Brought under the *Class Proceedings Act*, R.S.B.C. 1996, c. 50

NOTICE OF CIVIL CLAIM

This action has been started by the plaintiff for the relief set out in Part 2 below.

If you intend to respond to this action, you or your lawyer must

(a) file a response to civil claim in Form 2 in the above-named registry of this court within the time for response to civil claim described below, and

(b) serve a copy of the filed response to civil claim on the plaintiff.

If you intend to make a counterclaim, you or your lawyer must

(a) file a response to civil claim in Form 2 and a counterclaim in Form 3 in the above-named registry of this court within the time for response to civil claim described below, and

(b) serve a copy of the filed response to civil claim and counterclaim on the plaintiff and on any new parties named in the counterclaim.

JUDGMENT MAY BE PRONOUNCED AGAINST YOU IF YOU FAIL to file the response to civil claim within the time for response to civil claim described below.

Time for response to civil claim

A response to civil claim must be filed and served on the plaintiff,

(a) if you were served with the notice of civil claim anywhere in Canada, within 21 days after that service,

(b) if you were served with the notice of civil claim anywhere in the United States of America, within 35 days after that service,

(c) if you were served with the notice of civil claim anywhere else, within 49 days after that service, or

(d) if the time for response to civil claim has been set by order of the court, within that time.

CLAIM OF THE PLAINTIFF

Part 1: STATEMENT OF FACTS

Parties and Overview

1. This action concerns the prescription medication Champix (active ingredient varenicline), which is used for smoking-cessation treatment in adults.

2. The Plaintiff, Phil Davis (the "Plaintiff"), has an address for service of Suite 820 – 980 Howe Street, in the City of Vancouver, in the Province of British Columbia. The Plaintiff was prescribed, purchased and ingested Champix.

3. The Plaintiff brings this action on his own behalf and on behalf of all persons resident in Canada who were prescribed, purchased and/or ingested certain Champix medications manufactured and/or packaged by the Defendant that have been recalled due to the presence of a nitrosamine impurity, N-nitrosovarenicline, above the acceptable intake limit, and their beneficiaries (the "Class Members") pursuant to the *Family Compensation Act,* R.S.B.C. 1996, c. 126, to be further defined in the Plaintiff's application for class certification.

Defendant Manufacturers

4. The Defendants, Pfizer Canada ULC/Pfizer Canada SRI and Pfizer Canada Inc., have their head office at 17300 Trans-Canada Highway, in the City of Kirkland, in the Province of Quebec. Their local office is at Suite 1800 - 510 West Georgia Street, in the City of Vancouver, in the Province of British Columbia.

5. At all material times, the above-named Defendants manufactured and distributed Champix for sale in Canada.

6. A nitrosamine impurity, (N-nitrosovarenicline) has been detected in certain Champix medications manufactured, distributed and sold by the Defendants at levels higher than recommended by Health Canada. The nitrosamine impurity has been shown to cause gene mutations in an *in vitro* study, indicating that its presence in Champix is associated with a potential increased cancer risk in humans.

7. A product monograph for Champix tablets manufactured by the Defendants states, among other things, as follows:

> **What the medicinal ingredient is:**
> Varenicline tartrate.
>
> **What the nonmedicinal ingredients are:**
> The nonmedicinal ingredients are microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, colloidal silicon dioxide and magnesium stearate. The film-coating contains hypromellose, titanium dioxide, polyethylene glycol and triacetin. The 1 mg tablet also contains FD&C Blue #2/Indigo Carmine Aluminum Lake as a colouring agent.
>
> **Carcinogenisis:**
> Lifetime carcinogenicity studies were performed in CD-1 mice and Sprague- Dawley rats. There was no evidence of a carcinogenic effect in mice administered varenicline by oral gavage for 2 years at doses up to 20 mg/kg/day (47 times the maximum recommended human daily exposure based on the area under the curve (AUC). Rats were administered varenicline (1, 5, and 15 mg/kg/day) by oral gavage for 2 years. In male rats (n=65 per sex per dose group), incidences of hibernoma (tumor of the brown fat) was increased at the mid dose (1 tumor, 5 mg/kg/day, 23 times the maximum recommended human daily exposure based on AUC) and at the maximum dose (2 tumors, 15 mg/kg/day, 67 times the maximum recommended human daily exposure based on AUC). The clinical

relevance of this finding to humans has not been established. There was no evidence of carcinogenicity in female rats.

8. None of the Defendants' product monographs list nitrosamine impurities as a component of Champix nor do they list cancer or mutagenicity as a risk to consumers using Champix.

9. On or about June 30, 2021, Health Canada issued a recall (the "Recall") advising as follows:

> Testing results received from Pfizer Canada ULC identified 5 lots of CHAMPIX (varenicline) with levels of a nitrosamine impurity, N-nitrosovarenicline, above the acceptable intake limit established by Health Canada. As a result, Health Canada requested that Pfizer Canada ULC recall the 5 impacted lots.
>
> N-nitrosovarenicline has been shown to cause gene mutations in an in vitro study, indicating that its presence in CHAMPIX may be associated with a potential increased cancer risk in humans. There is no immediate risk to patients taking this medication as an increased cancer risk would be associated with long-term use.

10. The affected products were identified as follows by Health Canada (the "Affected Drugs"):

Strength/Dosage Form	**DIN**	**Lot #**	**Expiry Date**	**Recall Status**
0.5 mg and 1 mg Tablet, Kit	02298309	00019062 00020452 00020451	2021-08 2021-12 2022-01	Recalled Recalled Recalled
0.5 mg Tablet	02291177	ED7397	2022-05	Recalled
1 mg Tablet	**02291185**	**00020013**	**2021-12**	**Outstanding**

11. On or about September 16, 2021, Pfizer Inc. recalled all American lots of Chantix (the American version of Champix) due to the presence of the same nitrosamine impurity, N-nitrosovarenicline, at or above the FDA interim acceptable intake limit.

The Plaintiff

12. The Plaintiff was taking Champix. His prescription was for 1 mg with Drug Identification Number (DIN) 02291185 which is included on the list of Affected Drugs.

13. As a result of the defective nature of the medication that he ingested, the Plaintiff has incurred damages including:

    (a) General damages for the tort of battery;

    (b) Personal injury including mental distress;

    (c) The increased material risk of developing cancer and organ damage/failure;

    (d) Special damages for the cost of medical monitoring and medical tests incurred to the date of trial and future care costs for ongoing medical monitoring and medical tests;

    (e) The cost of purchasing a drug that was unfit for the purpose intended;

    (f) Damages in accordance with s. 36 of the *Competition Act*, RSC 1985, c. C-34 for a breach of s. 52; and

    (g) Such further and other damages as shall be proven at trial.

14. The Plaintiff would not have purchased and/or used Champix had he been informed it contained a nitrosamine impurity above the acceptable limit and if he had been provided accurate information and/or warnings, particularly since there are alternative drugs available on the Canadian market that do not contain nitrosamine impurities above the acceptable limit.

Part 2: RELIEF SOUGHT

15. The Plaintiff claims, on his own behalf, and on behalf of the Class Members, as follows:

    (a) An order certifying this action as a class proceeding and appointing the Plaintiff as the representative Plaintiff under the *Class Proceeding Act*;

(b) A declaration that it is not in the interests of justice to require that notice be given pursuant to section 18(15) of the *Consumer Protection Act*, RSO 1990, c. C.31 (and any parallel provisions of other provincial consumer protection legislation) and waiving any such notice requirements;

(c) General damages;

(d) Special damages;

(e) Punitive damages;

(f) Relief pursuant to the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2, and comparable legislation in the other provinces and territories;

(g) Relief pursuant to the *Competition Act,* R.S.C. 1985, c. C-34;

(h) Relief pursuant to s. 219 of the Quebec *Consumer Protection Act,* C.Q.L.R. c. P-40.1;

(i) Recovery of health care costs incurred by the Ministry of Health Services on their behalf pursuant to the *Health Care Cost Recovery Act*, S.B.C. 2008, c.27, and comparable legislation in the other provinces and territories;

(j) Costs;

(k) Interest pursuant to the *Court Order Interest Act*, R.S.B.C. 1996, c. 79; and

(l) Such further and other relief this Honourable Court may deem just.

Part 3: LEGAL BASIS

Negligence and Failure to Warn

16. As the manufacturers, marketers, developers, distributors, labelers and/or importers of the Affected Drugs, and/or their components, the Defendants were in such a close and proximate relationship to the Plaintiff, and other Class Members, as to owe them a duty of care. The Defendants caused the Affected Drugs to be introduced into the stream of commerce in Canada, and knew that any dangers or adverse effects related to the Affected Drugs would cause foreseeable injury to the Plaintiff and Class Members.

17. The Defendants owed a duty to the Plaintiff and Class Members to exercise reasonable care when designing, testing, manufacturing, marketing, labeling, promoting, and selling the Affected Drugs.

18. The Defendants owed a duty of care to the Plaintiff and Class Members to ensure that the Affected Drugs were safe and effective for their intended use. Particulars of the Defendants' breaches of its duty of care include:

    (a) Failing to ensure that the Affected Drugs and/or their components were manufactured to product standards;

    (b) Supplying contaminated drugs to consumers;

    (c) Failing to implement appropriate quality control testing for the raw materials they manufactured, or in the alternative when they received raw materials from their supplier;

    (d) Employing inadequately trained personnel in the design, manufacturing, and/or quality control of the Affected Drugs;

    (e) Placing the Affected Drugs on the market when they knew or ought to have known that the drugs had potential risks that outweighed their potential benefits;

(f) Manufacturing and/or marketing a product that they knew, or ought to have known, had an unreasonably high risk of causing illness and/or harm to consumers;

(g) Failing to implement a timely recall of the Affected Drugs once the risks were known to them;

(h) Manufacturing and/or marketing a product that was not fit for the purposes for which they were intended;

(i) Failing to manufacture and/or market products in a good and workmanlike manner and in accordance with generally accepted standards; and

(j) Such further and other particulars as will be alleged at trial.

Unjust Enrichment

19. Further, and in the alternative, the Plaintiff pleads that he and the Class Members are entitled to claim and recover based on equitable and restitutionary principles.

20. As an expected and intended result of the unlawful conduct, the Defendants have profited and benefited from purchases of the Affected Drugs which would not have been made but for the unlawful conduct.

21. By illegally and deceptively promoting the Affected Drugs, directly, through their control of third parties, and by acting in concert with third parties, the Defendants have been unjustly enriched by the receipt of the revenue from the sale of the Affected Drugs:

(a) Revenue was acquired in a manner in which the Defendants cannot in good conscience retain;

(b) The integrity of the pharmaceutical regulations and marketplace would be undermined if the court did not require an accounting;

(c) Absent the Defendants' tortious conduct, the Affected Drugs could not have been marketed nor would the Defendants have received any revenue from their sale in Canada; and

(d) The Defendants engaged in wrongful conduct by putting into the marketplace pharmaceutical products which cause or have the potential to cause serious risk of injury.

22. The Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and provide restitution to the Plaintiff and the Class Members.

Battery

23. By ingesting the Affected Drugs, the Plaintiff and the Class Members were exposed to toxic carcinogens, constituting a harmful and offensive contact to the person.

24. Despite the fact that the Plaintiff and the Class Members willingly ingested the Affected Drugs, they were unaware that the Affected Drugs contained carcinogens. The Plaintiff and the Class Members would not have ingested the Affected Drugs if they knew they were also ingesting carcinogens, and as such, did not consent.

25. By distributing the Affected Drugs, the Defendants intended the drugs to be ingested and thereby exposed the Class Members to the toxic carcinogens.

26. Since a time that is presently not known to the Plaintiff, the Defendants knew that the Affected Drugs contained the contaminants and therefore intended Class Members be exposed to the carcinogens.

27. Alternatively, the tort of battery is made out because the Defendants were willfully blind or recklessly indifferent to whether the Affected Drugs contained heightened levels of the nitrosamine impurities. The Defendants took no steps to investigate and address the lack of quality controls at their manufacturing facilities and the impact of changes to the manufacturing process when it knew

there was a risk or likelihood that the Affected Drugs would or could be contaminated - either as a result of the lack of quality controls or because the changes in the manufacturing process would or could result in an increase in the level of nitrosamine impurities. In this context of knowing of the risk, the Defendants took no steps or insufficient steps to determine whether the carcinogens were in the drugs, therefore amounting to reckless indifference.

Breach of GMP Regulations

28. As pleaded, the Defendants were required to demonstrate that the active ingredients in the Affected Drugs were accurately described. Implicit in this is that the Defendants were obligated to ensure that the drugs they were offering did not contain any other ingredients that would alter the efficacy of the drug. The contaminants in the Affected Drugs changed the quality, safety and effectiveness of the Affected Drugs and the Defendants were required to inform users and Health Canada.

29. Similarly, the Defendants had obligations under the *Food and Drug Regulations* (C.R.C., c. 870), Part C, Division 2 – Good Manufacturing Practices (the "GMP Regulations"). No distributor or importer can sell a drug unless it has been fabricated, packaged/labelled, tested and stored in accordance with the requirements set out in the GMP Regulations. These regulations require an importer to test all lots or batches of a drug before they are sold in Canada. Had the Defendants done so, the high levels of nitrosamine impurities likely would have been discovered.

30. As set out in the GMP Regulations, the Defendants had obligations to ensure that the drugs manufactured at their facilities or suppliers met all required specifications. The Defendants also had direct, or alternatively, constructive, knowledge that the manufacturing facilities had several deviations that were not compliant with the GMP Regulations and that changes in manufacturing practices introduced the contaminants to the Affected Drugs.

31. If the Defendants had complied with the GMP Regulations that required them to ensure that all drugs that were imported were fabricated, packaged/labelled,

tested and stored in accordance with the requirements set out in the GMP Regulations in order to ensure quality, safety and effectiveness, the Defendants likely would have discovered the impurities and contaminants in the Affected Drugs at an earlier point, when the contaminants were likely first introduced into the Affected Drugs.

32. The Defendants knew, or should have known on the basis of their own monitoring of their manufacturing facilities, that the Affected Drugs did, or could contain serious contaminants which could (and did) cause harm and yet did not recall the Affected Drugs until June 30, 2021, after regulators including Health Canada published concerns with the Affected Drugs.

33. Further, the harm to the Plaintiff and the Class Members fell within the ambit of risk that the Defendants' enterprise created or exacerbated through failing to implement appropriate quality control processes, as required by the GMP Regulations. The Defendants introduced the risk of wrongs by manufacturing the Affected Drugs, particularly when they were aware of their shortcomings and thus should have managed and minimized the risk, especially when the Plaintiff and the Class Members had no control over the ingestion of contaminants and carcinogens.

34. The Defendants acted with reckless indifference to the consequences of failing to implement appropriate quality control processes, in the face of their duty to do so, and knew that they were consequently placing the Plaintiff and the Class Members at significant risk.

35. The Defendants were aware of the risk that certain consequences could result from contaminants in the Affected Drugs but was indifferent to the risk. The Defendants continuously failed to establish, maintain and enforce appropriate quality control processes, despite the well-known risks associated with the manufacturing process of the Affected Drugs. The Defendants' failure to implement appropriate quality control processes was an unreasonable risk to take and constituted reckless indifference.

36. The Defendants' failure to implement appropriate quality control processes constituted either conscious wrongdoing or a marked departure from the standards by which responsible and competent pharmaceutical manufacturers govern themselves when manufacturing pharmaceutical products in Canada.

37. By failing to implement adequate quality control measures, the Defendants knew their practices were not in conformity with their obligations under GMP Regulations or industry standards, and knew it was wrong to have done nothing or to decide not to do anything with reckless indifference to the consequences.

38. As a direct result of the Defendants' wrongful acts as pleaded herein, the Plaintiff and the Class Members ingested contaminated drugs manufactured by the Defendants, which intentionally caused harmful or offensive contact with the Plaintiff to which the Plaintiff and the Class Members did not consent. As a result, the Defendants committed the tort of battery. The Plaintiff suffered damages as a result of the battery, including enhanced risk of cancer, physical bodily injury comprised of changes at a cellular or molecular level, emotional upset, prolonged mental distress, anxiety and will require therapy and extensive medical monitoring.

Business Practices and Consumer Protection Act

39. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of the Affected Drugs for personal use by the Plaintiff and by the Class Members were "consumer transactions" within the meaning of the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2 ("BPCPA"). With respect to those transactions, the Plaintiff and the Class Members who ingested Affected Drugs are "consumers" and the Defendants were "suppliers" within the meaning of the BPCPA.

40. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of Affected Drugs had the capability, tendency or effect of deceiving or misleading consumers regarding the safety and efficacy of the Affected Drugs. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Affected Drugs were deceptive

acts and practices contrary to s. 4 of the BPCPA. The Defendant's deceptive acts and practices included the failure to properly disclose all material facts regarding the risks of using the Affected Drugs, including the level of nitrosamine impurity present therein.

41. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Champix were "unconscionable acts or practices" contrary to s. 8 of the BPCPA. The Defendants' unconscionable acts or practices included inter alia the Defendants' advertisements, promotion and sale of the Affected Drugs which took advantage of the Plaintiff's and Class Members' inability or incapacity to reasonably protect their own interests because of the Plaintiff's and Class Members' ignorance, illiteracy, age and/or inability to understand the character, nature or language of the consumer transaction.

42. The Defendants knew or ought to have known the following:

    a. That the Plaintiff and Class Members were unable to protect their own interests because of ignorance, illiteracy, age and/or inability to understand the character, nature or language of the consumer transaction;
    b. That the Plaintiff and Class Members would not and could not reasonably protect their interests by conducting adequate testing of Champix prior to use;
    c. That the Plaintiff and Class Members would be unable to receive the benefit misrepresented to them from the Defendants; and
    d. That the Plaintiff and Class Members would rely on the Defendants' misrepresentations to their detriment.

43. As a result of the Defendants' deceptive acts and practices and unconscionable acts and practices, the Plaintiff and Class Members have suffered loss and damages. The Plaintiff seeks injunctive relief and declaratory relief and damages and statutory compensation pursuant to ss. 171 and 172 of the BPCPA on their own behalf and on behalf of Class Members who purchased Affected Drugs in

Canada. Such relief includes the disgorgement of the profits or revenues received by the Defendants from the sale of Affected Drugs in Canada.

44. The Defendants' deceptive acts and practices and unconscionable acts and practices were made for the purpose of promoting, directly or indirectly, the sale of Champix or for the purpose of promoting, directly or indirectly, the business interests of the Defendants. The deceptive acts and practices were made knowingly and recklessly. The deceptive acts and practices were made to the public, to the Plaintiff, and to the Class Members. The deceptive acts and practices were false and/or misleading in a material respect, namely as to the presence of a nitrosamine impurity above acceptable levels. The Defendants knowingly accepted the benefits of their deceptive conduct in the form of profits from the sale of Champix.

45. The Plaintiff and Class Members suffered loss or damage as a result of the Defendants' conduct including (i) purchasing and using Champix when they would not have otherwise done so had they been properly advised of the risks of using Champix; and (ii) suffering economic losses consisting of the cost of purchasing Champix and/or out of pocket expenditures for investigating and treating side effects of their use of Champix.

46. The Plaintiff and Class Members claim against the Defendants for contravention of consumer protection legislation and remedies as follows:

    a. A declaration that the Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Champix were "unconscionable acts or practices" contrary to s. 8 of the BPCPA and an order pursuant to s. 172(3) of the BPCPA that the Defendants restore to the Plaintiff and Class Members the purchase price collected from them in contravention of the BPCPA or, in the alternative, damages under s. 171 of the BPCPA;
    b. A declaration that the Defendants' conduct constitutes "deceptive acts or practices" contrary to s. 4 of the BPCPA and an order pursuant to s. 172(3) of the BPCPA that the Defendants restore to the Plaintiff and Class

Members the purchase price collected from them in contravention of the BPCPA or, in the alternative, damages under s. 171 of the BPCPA;

c. Restitution to the Plaintiff and Class Members of the purchase price they paid for Champix or, in the alternative, damages pursuant to s. 13(2) or s. 142.1 of the *Alberta Consumer Protection Act*, RSA 2000, c. C-26.3;

d. Restitution to the Plaintiff and Class Members of the purchase price they paid for Champix or, in the alternative, damages pursuant to s. 93(1) of the Saskatchewan *Consumer Protection and Business Practices Act*, SS 2014, c. C-30.2;

e. Repayment to the Plaintiff and Class Members of the purchase price they paid for Champix or, in the alternative, damages pursuant to s. 23(2) of the *Manitoba Business Practices Act*, CCAM, c. B120;

f. Rescission of the sales agreements between the Defendants and the Plaintiff and Class Members and repayment of the purchase price paid by the Plaintiff and Class Members for Champix, pursuant to s. 18(1) of the *Ontario Consumer Protection Act*, 2002, SO 2002, c. 30, Sch. A, or, in the alternative, an order for damages pursuant to s. 18(2) of the *Ontario Consumer Protection Act*;

g. Repayment to the Plaintiff and Class Members of the purchase price they paid for Champix or, in the alternative, compensatory damages, pursuant to s. 272 of the *Quebec Consumer Protection Act*, CQLR c. P-40.1;

h. Repayment to the Plaintiff and Class Members of the purchase price paid for Champix pursuant to s. 17(1) of the New Brunswick *Consumer Product Warranty and Liability Act*, SBC 1978, c. C-18.1 or, in the alternative, damages under s. 15 of the New Brunswick *Consumer Product Warranty and Liability Act*;

i. Rescission of the sales agreements between the Defendants and the Plaintiff and Class Members and return of the purchase price paid by the Plaintiff and Class Members for Champix or, in the alternative, damages pursuant to s. 4(1) of the P.E.I. *Business Practices Act*, RSPEI 1988, c. B-7; and

j. Repayment to the Plaintiff and Class Members of the purchase price they paid for Champix or, in the alternative, damages pursuant to s. 10 of the

Newfoundland and Labrador Co*nsumer Protection and Business Practices Act*, SNL 2009, c. C-31.1.

(collectively, each of these acts are referred to as the "Consumer Protection Legislation")

47. By placing their trademark on the medication thereby identifying the Defendants as the manufacturer and/or distributor of Affected Drugs, the Defendants intended to convey to consumers that the drugs were of high quality and were manufactured by a reputable pharmaceutical company.

48. The declaratory and injunctive relief sought by the Plaintiff and Class Members in this case includes an order under s. 172 of the BPCPA that the Defendants advertise any judgment against them and that they properly inform consumers and their physicians of the risks of the Affected Drugs which includes sending a "Dear Doctor Letter" to alert physicians to this problem.

Competition Act

49. As a result of its representations and omissions about the Affected Drugs, the Defendants breached s. 52 of the *Competition Act*, R.S.C. c. C-34 (the "*Competition Act*") and committed an unlawful act because their representations and omissions:

(a) Were made for the purpose of promoting, directly or indirectly, the use of their drug;

(b) Were made for the purpose of promoting indirect or directly, any business interests of the Defendants;

(c) Were made to the public;

(d) Were made knowingly and recklessly; and

(e) Were false and misleading in a material respect.

50. The Plaintiff and the Class Members suffered damages as a result of the Defendants' unlawful breach of s. 52 of the *Competition Act*. Those damages include the cost of purchasing the drug.

51. The Plaintiff and the Class Members also seek their costs of investigation, pursuant to s. 36 of the *Competition Act*.

Causation and Damages

52. As a result of the Defendants' negligence and the Defendants' breach of the BPCPA and/or the *Competition Act* and/or the Consumer Protection Legislation, the Plaintiff and the Class Members have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the Defendants. Particulars of the loss and damage suffered by the Plaintiff and the Class Members which were caused or materially contributed to by the aforementioned acts of the Defendants include:

    (a) Personal injury;

    (b) Special damages for medical expenses and out of pocket expenses; including the cost of purchasing medication that was unfit for its intended purpose;

    (c) Loss of both past and prospective income; and

    (d) Cost of future care.

53. The Plaintiff and the Class Members have suffered injuries which are permanent and lasting in nature, including diminished enjoyment of life, as well as the need for lifelong medical monitoring and/or treatment.

54. The conduct of the Defendants warrants a claim for punitive damages. They have conducted themselves in a high-handed, wanton and reckless manner, and without regard to public safety.

55. This case raises issues of general deterrence. A punitive damage award in this case is necessary to express society's condemnation of conduct such as the

Defendants', to advance public safety and to achieve the goal of both specific and general deterrence.

Health Care Cost Recovery

56. The Plaintiff relies upon health and hospital insurance legislation in British Columbia and similar legislation elsewhere and claims health care costs incurred by himself and Class Members and paid by provincial and territorial governments as a result of the wrongdoing of the Defendants:

(a) On behalf of Her Majesty the Queen in right of the Province of New Brunswick, the Plaintiff claims the cost of "entitled services" under *Health Services Act*, SNB 2014, c 112, ss 1 and 3 and General Regulation, NB Reg 84-115, s 2 and Schedule II.

(b) On behalf of the government of British Columbia, the Plaintiff claims the past and future cost of providing "health care services" under *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.

(c) On behalf of Her Majesty in right of Alberta and the Minister of Health of Saskatchewan, the Plaintiff claims the direct and indirect costs of past and future "health services" under *Crown's Right of Recovery Act*, SA 2009, c C-35, ss 1, 2(1) and 38 and *Crown's Right of Recovery Regulation*, Alta Reg 87/2012, s 3; and *The Health Administration Act*, RSS 1978, c H-0.0001, s 19.

(d) On behalf of the Minister of Health of Manitoba, the Plaintiff claims the past and future cost of "insured hospital, medical, and other services under *The Health Services Insurance Act*, RSM 1987, c H35, ss 2, 97 and *The Medical Services Insurance Regulation*, Man Reg 49/93, s 1.

(e) On behalf of Her Majesty in right of the Province of Nova Scotia, the Plaintiff claims the past and future cost of "insured hospital services", and

other care, services, and benefits under *Health Services and Insurance Act*, RSNS 1989, c 197, ss 2 and 18.

(f) On behalf of the Government of Yukon, and the Ministers of Health of the Northwest Territories and Nunavut, the Plaintiff claims the cost of providing "insured services", including in-patient and out-patient services under *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*, and RSNWT 1988, c T-3, ss 1 and 19-20 and *Hospital Insurance Regulations*, RRNWT 1990, c T-12, s 1.

(g) On behalf of the Ontario Health Insurance Plan, the province of Quebec, the Minister of Health and Wellness of Prince Edward Island, and the Crown in right of Newfoundland and Labrador, the Plaintiff claims the cost of "insured services" under *Health Insurance Act*, RSO 1990, c H.6, ss 1, 11.2, and 30-31 and General, RRO 1990, Reg 552; *Hospital Insurance Act*, CQLR c A-28, ss 1 and 10 and Regulation respecting the application of the *Hospital Insurance Act*, CQLR c A-28, r 1, s 3 and *Health Insurance Act*, CQLR A-29, ss 1, 3, and 18; *Hospital and Diagnostic Services Insurance Act*, RSPEI 1988, c H-8, ss 1 and 14 and General Regulations, PEI Reg EC539/63, s 1; and *Medical Care and Hospital Insurance Act*, SNL 2016, c M-5.01, ss. 41-42 and 44, and *Hospital Insurance Regulations*, CNLR 742/96, s 2 and Schedule.

(collectively, the "Healthcare Cost Recovery Statutes")

Jurisdiction

57. The Plaintiff relies on ss. 13, 7 and 10 of the *Court Jurisdiction and Proceedings Transfer Act*, S.B.C. 2003, c. 28 and pleads that there is a real and substantial connection between the subject matter of this action and the Province of British Columbia for the following reasons:

(a) The Defendants marketed and sold the Affected Drugs in British Columbia;

(b) The Plaintiff resides in British Columbia; and

(c) The Plaintiff's damages were sustained in British Columbia.

Plaintiffs' address for service:	**RICE HARBUT ELLIOTT LLP** Barristers and Solicitors 820 - 980 Howe Street Vancouver, BC V6Z 0C8 **CHARNEY LAWYERS PC** 151 Bloor Street W., Suite 602 Toronto, ON M5S 1S4
Fax number address for service (if any):	Nil
E-mail address for service (if any):	service@rhelaw.com
Place of trial:	Vancouver
The address of the registry is:	800 Smithe Street, Vancouver

Date: 20/SEPT/2021

Counsel for the Plaintiff,
Anthony Leoni
Theodore P. Charney

Rule 7-1 (1) of the Supreme Court Civil Rules states:

(1) Unless all parties of record consent or the court otherwise orders, each party of record to an action must, within 35 days after the end of the pleading period,

(a) prepare a list of documents in Form 22 that lists

(i) all documents that are or have been in the party's possession or control and that could, if available, be used by any party at trial to prove or disprove a material fact, and

(ii) all other documents to which the party intends to refer at trial, and

(b) serve the list on all parties of record.

Appendix

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

A claim for negligence, failure to warn and, *inter alia*, breach of consumer protection legislation relating to prescription medications contaminated with a probable mutagen, with injury, loss and damages to the Plaintiff and a class of similarly situated persons resident in Canada.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

A personal injury arising out of:

a motor vehicle accident

medical malpractice

X another cause

A dispute concerning:

☐ contaminated sites

☐ construction defects

☐ real property (real estate)

☐ personal property

☐ the provision of goods or services or other general commercial matters

☐ investment losses

☐ the lending of money

☐ an employment relationship

☐ a will or other issues concerning the probate of an estate

X a matter not listed here

Part 3: THIS CLAIM INVOLVES:
[*Check all boxes below that apply to this case*]

X a class action

☐ maritime law

☐ aboriginal law

☐ constitutional law

☐ conflict of laws

☐ none of the above

☐ do not know

Part 4:
[*If an enactment is being relied on, specify. Do not list more than 3 enactments.*]

1. *Class Proceedings Act*, R.S.B.C. 1996, c. 50

2. *Health Care Cost Recovery Act*, S.B.C. 2008, c. 27
3. *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2