S-100961

No._____
Vancouver Registry

IN THE SUPREME COURT OF BRITISH COLUMBIA

Between:

PATRICIA CLOW, PERSONAL REPRESENTATIVE OF THE ESTATE OF HEIDI MEGAN CLOW, DECEASED, ALICIA PICKERING and NICOLE MCIVOR

Plaintiffs

and:

PFIZER CANADA INC. and PFIZER, INC.

Defendants

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

WRIT OF SUMMONS

NAME & ADDRESS OF EACH PLAINTIFF:

Patricia Clow, personal representative of the estate of Heidi Megan Clow, deceased
207 Meade Ave
Victoria, B.C.
V9A 1C8

Alicia Pickering
6067 South Gale Ave
Sechelt, B.C.
V0N 3A5

Nicole McIvor
1000 Memorial Park
Princeton, B.C.
V0X 1W0

NAME & ADDRESS OF EACH DEFENDANT:

Pfizer Canada Inc.
2700 700 West Georgia Street

Vancouver, B.C.
V7Y 1B8

-and-

Pfizer, Inc.
235 East 42nd Street, New York, New York 10017.

ELIZABETH THE SECOND, by the Grace of God, of the United Kingdom, Canada and Her other Realms and Territories, Queen, Head of the Commonwealth, Defender of the Faith.

TO THE DEFENDANTS: Pfizer Canada Inc.
Pfizer, Inc.

TAKE NOTICE that this action has been commenced against you by the Plaintiffs for the claim set out in this Writ.

IF YOU INTEND TO DEFEND this action, or if you have a set off or counterclaim which you wish to have taken into account at the Trial, YOU MUST

(a) GIVE NOTICE of your intention by filing a form entitled "Appearance" in the above Registry of this court, at the address shown below, within the Time for Appearance provided for below and YOU MUST ALSO DELIVER a copy of the Appearance to the Plaintiffs' address for delivery, which is set out in this Writ, and

(b) if a statement of claim is provided with this writ of summons or is later served on or delivered to you, FILE a Statement of Defence in the above registry of this court within the Time for Defence provided for below and DELIVER a copy of the Statement of Defence to the Plaintiffs' address for delivery.

YOU OR YOUR SOLICITOR may file the Appearance and the Statement of Defence. You may obtain a form of Appearance at the registry.

JUDGMENT MAY BE TAKEN AGAINST YOU IF

(a) YOU FAIL to file the Appearance within the Time for Appearance provided for below, or

(b) YOU FAIL to file the Statement of Defence within the Time for Defence provided for below.

TIME FOR APPEARANCE

If this writ is served on a person in British Columbia, the time for appearance by that person is 7 days from the service (not including the day of service).

If this writ is served on a person outside British Columbia, the time for appearance by that person after service, is 21 days in the case of a person residing anywhere within Canada, 28 days in the case of a person residing in the United States of America, and 42 days in the case of a person residing elsewhere. [or, if the time for appearance has been set by order of the court, within that time].

TIME FOR DEFENCE

A Statement of Defence must be filed and delivered to the plaintiffs within 14 days after the later of

(a) the time that the Statement of Claim is served on you (whether with this writ of summons or otherwise) or is delivered to you in accordance with the Rules of Court, and

(b) the end of the Time for Appearance provided for above.
[or, if the time for defence has been set by order of the court, within that time.]

(1) The address of the Registry is:
800 Smithe Street
Vancouver, BC V6Z 2E1

(2) The ADDRESS FOR DELIVERY is:
Klein Lyons
1100- 1333 West Broadway
Vancouver, BC V6H 4C1
Fax Number for delivery: (604) 874-7180

(3) Name and office address of Plaintiff's solicitor (if any):
David A. Klein
Klein Lyons
1100- 1333 West Broadway
Vancouver, BC V6H 4C1

SERVICE OUTSIDE OF BRITISH COLUMBIA WITHOUT LEAVE

The plaintiff claims the right to serve the defendants who are outside British Columbia without leave on the grounds that the proceeding is founded on a tort committed in British Columbia and a

business carried on by the defendants in British Columbia pursuant to Rule 13(1) of the Rules of Court and Section 10 of the *Court Jurisdiction and Proceedings Transfer Act*, R.SB.C. 2003, Chapter 28, and amendments thereto.

Dated at Vancouver, British Columbia on February 9, 2010.

DAVID A. KLEIN
Solicitor for the Plaintiff

No._____
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STATEMENT OF CLAIM

Parties and Overview

1. This action concerns Champix (generic name: varenicline). It is a prescription drug sold as a smoking cessation aid. It has been linked to reports of neuropsychiatric adverse events, including depression and suicide.

2. The Plaintiffs allege that the Defendants negligently designed, tested, labeled, manufactured and marketed this drug to Canadians. In particular, the Defendants failed to provide adequate and timely warning to Canadians about the risk of neuropsychiatric adverse events caused by this drug.

3. The Plaintiff, Heidi Megan Clow ("Heidi"), died in Victoria, British Columbia, on October 4, 2009, at the age of 22. She is represented in this action by her mother, Patricia Clow ("Patricia") who is the executrix of Heidi's estate.

4. Heidi was prescribed Champix beginning in or about June 2009. She took it regularly as directed. She committed suicide on October 4, 2009. Her death was a result of taking Champix.

5. The Plaintiff, Alicia Pickering ("Alicia"), resides in Sechelt, British Columbia. She was prescribed Champix beginning in or about June 2008. She took the drug regularly as directed. Shortly after taking the drug Alicia had a severe neuropsychiatric adverse reaction. She became deeply depressed and catatonic. It became necessary for her to take a leave of absence from her employment. Her mental health worsened, she contemplated suicide, and she was ultimately hospitalized. Her injury was a result of taking Champix.

6. The Plaintiff, Nicole McIvor ("Nicole"), resides in Princeton, British Columbia. She was prescribed Champix on December 6, 2007. She took the drug regularly as directed. Shortly after taking the drug Nicole became depressed and contemplated suicide. She sought counseling for depression and was prescribed anti-depressants. In May 2008, she attempted suicide by deliberately trying to smash her car into an oncoming logging truck. Nicole suffered personal injury as a result of taking Champix.

7. The Plaintiffs bring this action on their own behalf, and on behalf of a class of similarly situated persons resident in British Columbia. This class of persons will be more fully defined in the Plaintiffs' application for class certification.

8. The Defendant, Pfizer Canada, Inc. ("Pfizer Canada") is incorporated pursuant to the laws of Canada, and is registered as an extra-provincial company in British Columbia with an address for service at 2700 700 West Georgia Street, Vancouver, British Columbia, V7Y 1B8.

9. The Defendant, Pfizer, Inc. ("Pfizer") is a Delaware corporation whose address and principal place of business is 235 East 42nd Street, New York, New York 10017.

10. Pfizer Canada is a subsidiary of Pfizer.

Facts Regarding Champix

11. The Defendants individually and collectively participated in one or more of the following: the manufacture, development, distribution, marketing, labeling, promotion

and importation of Champix for sale to Canadians, including residents of British Columbia.

12. The Defendants obtained regulatory approval to sell Champix in Canada under the *Food and Drugs Act*, R.S.C. 1985, c.F-27 from Health Canada by Notice of Compliance, dated January 24, 2007, with sales beginning in April 2007 in this country.

13. Pfizer also marketed the drug in the United States and Europe, (U.S. brand name: Chantix) obtaining approval of the U.S. Food and Drug Administration ("FDA") through an accelerated review process on May 11, 2006, and from the European Medicines Agency of the European Union ("EMEA") on September 29, 2006. Sales of the drug in these jurisdictions preceded sales in Canada by about a year.

14. Champix is designed to work by specifically inhibiting nicotine receptors in the brain. It employs a somewhat novel mechanism of action that is intended to operate as both an "agonist" and "antagonist" to decrease nicotine craving and psychological rewards associated with smokers. As an agonist, Champix is supposed to reduce nicotine craving and withdrawal symptoms. As an antagonist, Champix is supposed to reduce the psychological reward associated with smoking.

15. The receptors in the human brain affected by Champix are controlled by dopamine. This is a neurotransmitter produced by the brain. Smokers receive bursts of nicotine when they inhale which trigger an immediate increase in dopamine, thereby creating the craving and perceived pleasure from smoking.

16. In theory, Champix is supposed to work by blocking dopamine, and thus the cravings for nicotine are diminished and psychological pleasure derived from smoking is reduced.

17. Essentially, Champix regulates and restricts dopamine and blocks pleasure sensors in the brain to depress the normal flux of emotions experienced by humans in daily life.

18. The Defendants negligently failed to properly and fully study, evaluate and examine the mechanism of action and the effects thereof associated with Champix. Neuropsychiatric harm was a foreseeable outcome of this drug, given its intended operation on the brain.

19. The Defendants' failures to conduct adequate studies of Champix include:

(a) intentionally excluding certain patients from clinical trials. For example, the Defendants excluded patients from clinical trials if they had previous history and/or diagnosis of mental/psychological disorders;

(b) intentionally ignoring any proper evaluation of depression, aggression, suicide, suicidal ideation, suicidal thoughts, or suicidal tendencies; and

(c) failure to determine what other effect Champix has on other receptors in the human brain and body.

20. The Defendants knew or should have known that Champix increased the risk of causing serious injuries and death, including suicide and attempted suicide. The active ingredient in Champix is varenicline tartrate which is derived from cytosine. Cytosine has been used in Europe for decades as a smoking cessation drug. There are reports going back to 1972 linking cytosine to cases of suicide and attempted suicide. The risk of harm with this precursor drug should have alerted the Defendants to the risk of harm with Champix.

21. The Defendants also should have known of the potential risks of serious injury and death related to Champix because of experience with other drugs with similar mechanisms of action on dopamine, including Zoloft.

22. Further, there was evidence that arose during the Defendants' clinical trials which demonstrated risk of injury due to Champix. The Defendants failed to properly consider and follow up on this evidence. In a clinical study completed by the Defendants in February 2004, one of the subjects participating in the study committed suicide. In a

second study completed by the Defendants in March 2005, there were multiple reports of adverse psychiatric effects among test subjects, including cases of acute psychosis.

23. In clinical trials, the efficacy of Champix has been shown to be limited, at best. In a head to head study comparing Champix against the nicotine patch, published on February 8, 2008, the benefits of using Champix over the patch were found to be marginal and not statistically significant. Unlike Champix however, the nicotine patch does not present a risk of serious injury, death or suicide. Given its limited benefit, and its apparent risk, the Defendants ought to have proceeded more cautiously, and to have conducted more testing before bringing the product to market in Canada and elsewhere.

24. The Defendants disregarded such concerns in favour of profits. After its launch, Champix quickly became one of the Defendants' best selling new drugs in Canada and elsewhere. The Defendants sold over 700,000 prescriptions of Champix to Canadians in the first year the product was on the market in this country, earning substantial revenues and profits.

Regulatory Events

25. Beginning in 2006, the EMEA began to receive reports of neuropsychiatric adverse events in patients taking Champix in Europe. It conducted follow up investigations into cases of suicide and suicide ideation in July, October, and November, 2007. Similar reports were received by the FDA in the United States during 2006 and 2007.

26. Thus, before the Defendants even began to sell Champix in Canada, they were already aware of reports of adverse events received by regulators in the United States and Europe.

27. In November 2007, the United States FDA issued an advisory concerning the drug, noting a possible association between suicide and attempted suicide within days to weeks of initiating treatment with the drug. On November 20, 2007, the U.S. regulator issued a directive to Pfizer requiring "Modification of the patient package insert to

address possible drug adverse effects [including] depression, agitation, suicidal thoughts..."

28. In Europe, the EMEA issued a press release on December 14, 2007, in which it "concluded that updated warnings are needed to increase awareness of cases of suicidal ideation and suicide attempts reported in patients taking Champix".

29. In Canada, the label was updated in December 2007, and again on May 15, 2008. These warnings however were inadequate, and were not quickly, properly and thoroughly disseminated by the Defendants. The Defendants failed to take adequate or prompt steps to bring these changes to the attention of Canadian doctors and patients. Letters were not promptly sent to doctors and pharmacies alerting them to the change in labeling, nor did the Defendants' sales personnel immediately telephone or meet with doctors and pharmacists to advise them of this new safety information. Existing product on store shelves, which contained prior labeling, was not replaced with new product, with updated labels.

30. The 2008 edition of the *Compendium of Pharmaceutical Specialties*, the desk reference commonly used by Canadian doctors and pharmacists as an encyclopedia of drug labels, contained Champix's original product label from January 23, 2007. It did not contain updated safety information, including a warning about neuropsychiatric adverse events. The Defendants' updated warning label from May 15, 2008, was included in the 2009 edition of the *Compendium of Pharmaceutical Specialties*.

31. In April 2008, Health Canada issued an advisory that it had received 46 reports of adverse psychiatric effects in Canadians taking Champix.

32. On June 13, 2008, Pfizer Canada issued a letter to Canadian doctors advising them of the risk of psychiatric illness associated with the drug. The letter stated that between April 2007 and April 30, 2008, a total of 226 Canadian cases of neuropsychiatric adverse events had been reported.

33. On January 6, 2009, Health Canada issued a reminder of the risks of Champix, and that the label would need to be further updated and strengthened. It noted that "[t]his

update is the result of continuing reports, in Canada and internationally, of serious psychiatric symptoms associated with the use of Champix, and is intended to increase awareness of this risk."

34. The Defendants did not update or strengthen the label in accordance with this Health Canada advisory.

35. On July 2, 2009, the United States FDA required Pfizer to insert a "black box" warning into its labeling for Chantix concerning the risk of suicide and neuropsychiatric injury. This is a very prominent and stark warning to medical professionals. Such warning is bolded and appears at very beginning of the label, and is designed to convey the seriousness of the risk posed by the drug.

36. Notwithstanding Pfizer's amendment of the Chantix label to include a black box warning, the Defendants did not similarly update, strengthen or amend the Canadian label for Champix.

37. It is the obligation of a drug manufacturer to provide clear, complete and current safety information. The Defendants have failed in their obligation. The Defendants' labeling information for Champix is insufficiently clear in alerting patients and their health care providers to the risk of suicide and neuropsychiatric injury. The label seeks to minimize the risks of these adverse effects, suggesting that they are rare and that causation has not been established. Such information is neither correct nor current.

38. To this date, the Defendants' warning label for Champix remains inadequate. Given the serious risks posed by this drug, the Defendants have not acted with sufficient care to provide class members and their health care providers with complete, accurate and current safety information.

39. Further, even if the warning was adequate (which is denied), the Defendants have nevertheless been negligent in the sale of the drug. The risks of the drug outweigh its limited efficacy. A reasonably prudent drug manufacturer would not have sold the drug in the first place, or would have recalled it in the face of repeated reports of injury among those taking it.

The Plaintiffs' Particulars

40. The Plaintiff, Heidi Clow, was prescribed Champix beginning in or about June 2009. She took the drug regularly and as directed. She became depressed and her behaviour became erratic. She committed suicide on October 4, 2009.

41. Heidi's mother, Patricia, has suffered due to the loss of her daughter. She has been deprived of the guidance, care and support of her daughter and has suffered pecuniary loss.

42. The Plaintiff, Alicia Pickering, was prescribed Champix beginning in or about June 2008. She suffered a dramatic change in her behaviour within about week of her first consumption of the drug. She became depressed and unable to function. She cried constantly and for no reason. She contemplated suicide. Such behaviour was completely out of character for her.

43. In or about August 2008, Alicia took a leave of absence from her job. She sought psychiatric medical attention, and was hospitalized.

44. Alicia has never fully recovered from her consumption of Champix, and it has caused her lasting psychiatric injury. Prior to taking the drug, she had no history of mental illness. Subsequent to taking the drug, she has developed bipolar disorder, which was caused or contributed to by her exposure to the drug.

45. Alicia has suffered personal injury as a result of taking Champix. The drug has diminished her quality of life and health, it has strained her marriage, family and personal relationships, and it has caused her family economic hardship.

46. The Plaintiff, Nicole McIvor, was prescribed Champix beginning on December 6, 2007. Within weeks of taking the drug she became depressed, and she contemplated suicide. Her behaviour became erratic and out of character. She sought counseling and was prescribed anti-depressants.

47. In May 2008, Nicole attempted suicide by trying by deliberately trying to smash her car into an oncoming logging truck.

48. Nicole has suffered personal injury as a result of taking Champix. The drug has diminished her quality and enjoyment of life and harmed her personal, marital and family relationships.

49. None of the Plaintiffs would have taken Champix if they or their health care providers had been adequately warned of the risks.

Negligence and Failure to Warn

50. As the manufacturers, marketers, developers, distributors, labellers and/or importers of Champix, the Defendants were in such a close and proximate relationship to the Plaintiffs, and other class members, as to owe them a duty of care. They caused the drug to be introduced into the stream of commerce in Canada, and they knew that any dangers or adverse effects related to the drug would cause foreseeable injury to the Plaintiffs and class members.

51. The Defendants owed a duty to the Plaintiffs and class members to exercise reasonable care when designing, testing, manufacturing, marketing, labeling, promoting, distributing, importing, and selling Champix.

52. In particular, the Defendants owed a duty to the Plaintiffs and class members to warn of dangers and adverse side effects of the product. Such warning must be prompt, clear and accurate. It must be appropriate to the seriousness of the risk of injury presented by the drug. The Defendants must take appropriate steps to ensure that such warning is actually received by the Plaintiffs, other class members, and their health care providers.

53. The Defendants failed to exercise due care expected of a reasonable pharmaceutical manufacturer under the circumstances, and they breached their duty to the Plaintiffs and class members. They failed to provide an adequate, timely warning as to the risk of serious injury and death related to their product. Particulars of their negligence are:

(a) failing to test Champix properly and thoroughly before releasing the drug to market;

(b) intentionally excluding from such testing those patients who might be vulnerable to Champix's adverse effects, thereby achieving a safety profile in clinical testing that was unrealistic;

(c) failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of Champix, including reports of suicide and neuropsychiatric adverse events in subjects on Champix during actual clinical trials;

(c) failing to consider the risks posed by Champix given reports of suicide in cytosine, the drug from which Champix is derived;

(d) failing to consider the risks posed by Champix given the clinical experience with other drugs, with similar mechanisms of action on dopamine receptors in the brain, such as Zoloft;

(e) failing to disclose to regulators, the medical community, and the general public, data from its pre- and post-marketing tests of Champix which indicated risks associated with its use;

(f) failing to conduct an adequate and timely analysis of adverse event reports;

(g) marketing the drug in Canada after already receiving sufficient reports of adverse effects among patients in the United States and Europe as to alert the Defendants to the serious risks of injury presented by Champix;

(h) failing to provide adequate and timely warning of the significant risks of injury and death presented by Champix;

(i) failing to promptly and adequately draw the attention of doctors, pharmacists and patients to changes in the product's labeling;

(j) failing to promptly call or write doctors and pharmacists to alert them to changes in labeling;

(k) failing to replace existing packaging on store shelves with updated labeling;

(l) failing to educate healthcare providers about the safest use of the drug;

(m) failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient;

(n) failing to design and implement an appropriate post-marketing surveillance system to monitor and quickly identify adverse risks among vulnerable patient populations, particularly in circumstances where the Defendants had deliberately excluded such populations from pre-clinical testing; and

(o) negligently continuing to manufacture and market Champix after the Defendants knew or should have known of the risk of serious injury and death associated with using this drug, and failing to recall the drug.

Business Practices and Consumer Protection Act

54. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of Champix for personal use by the Plaintiffs and by 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 Plaintiffs and class members who were implanted with the Product are "consumers" and the Defendants are "suppliers" within the meaning of the BPCPA.

55. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Champix, as particularized above, had the capability, tendency or effect of deceiving or misleading consumers regarding the safety and efficacy of the Champix. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of Champix were deceptive acts and practices contrary to

s.4 of the BPCPA. The Defendants' deceptive acts and practices included the Defendants' failure to properly disclose all material facts regarding the safety and efficacy of Champix.

56. As a result of the Defendants' deceptive acts and practices, the Plaintiffs and class members have suffered loss and damages. The Plaintiffs seek 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. Such relief includes the disgorgement to class members of the profits or revenues received by the Defendants from the sale of Champix in British Columbia.

Causation and Damages

57. As a result of the Defendants' negligence and the Defendants' breach of the BPCPA, the Plaintiffs and class members have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the Defendant. Particulars of the loss and damage suffered by the Plaintiffs and class members which were caused or materially contributed to by the aforementioned acts of the Defendants include:

(a) personal injury;

(b) special damages for out of pocket expenses and loss of property;

(c) loss of income; and

(d) cost of future care.

58. 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. Particularly egregious was the Defendants' maintenance of Champix in the Canadian marketplace and continued marketing of the product as safe and effective when they knew or should have known of the risks associated with its use. 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.

Family Compensation Act

59. The Plaintiff, Heidi Clow, deceased, asserts a claim under the *Family Compensation Act*, R.S.B.C. 1996, c.126 (the "FCA") on her own behalf, and on behalf of other deceased class members. Heidi's personal claim is for the benefit of her mother, Patricia Clow, who resides at 207 Meade Ave, Victoria, British Columbia, and is an employee of the Canadian Armed Forces.

60. Damages suffered by Patricia, and by other representatives of deceased class members, include:

(a) loss of guidance and companionship;

(b) loss of support;

(c) loss of economic support;

(d) loss of household assistance;

(e) costs of the funeral; and

(f) costs associated with the administration of the deceased's estate, and settlement of the estate's financial affairs after death.

Health Care Cost Recovery Act

61. The Plaintiffs and class members have a claim for the recovery of health care costs incurred by the Ministry of Health Services on their behalf. The Plaintiffs plead the *Health Care Cost Recovery Act*, S.B.C. 2008, c.27.

Jurisdiction

62. The Plaintiffs rely upon ss.13, 7 and 10 of the *Court Jurisdiction and Proceedings Transfer Act*, S.B.C. 2003, c.28 and plead 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 Champix in British Columbia;

(b) the Plaintiffs reside in British Columbia;

(c) the Plaintiffs' damages, and those of other Class Members, were sustained in British Columbia.

Joint Enterprise

63. The Defendants functioned as a joint enterprise for the promotion and sale of Champix within Canada. The Defendants divided among themselves certain responsibilities for the manufacture and marketing of Champix, but each had an independent right and responsibility to ensure the safety of Champix. Within this joint enterprise, the Defendants individually and jointly researched, tested, developed, marketed, manufactured, imported, promoted, licensed, labeled, monitored adverse reactions to, and placed into the stream of commerce Champix for sale in Canada.

Relief Sought

64. The Plaintiffs claim, on their own behalf, and on behalf of class members:

(a) an order certifying this action as a class proceeding;

(b) general damages;

(c) special damages;

(d) punitive damages;

(e) declaratory and injunctive relief as well as damages and statutory compensation available under the BPCPA;

(f) pre-judgment interest;

(g) costs; and

(h) such further and other relief as this Honourable Court may deem just.

Dated: February 9, 2010

Solicitor for the Plaintiffs

David A. Klein
Douglas Lennox
Klein Lyons
Barristers & Solicitors
1100 – 1333 W. Broadway
Vancouver, British Columbia
V6H 4C1