

JUL 05 2018

ACTION NO.
VANCOUVER REGISTRY



IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

**TAYLOR JANET MACKINNON AND
ALYSA MCINTOSH**

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PLAINTIFFS

AND:

PFIZER CANADA INC. and WYETH CANADA

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 drugs, Alesse 21 and Alesse 28, which are prescribed as oral contraceptive pills used to prevent pregnancy.
2. The Plaintiffs, Taylor Janet MacKinnon and Alysa McIntosh, have an address for service at 820 – 980 Howe Street, in the City of Vancouver, in the Province of British Columbia. The Plaintiffs had been prescribed Alesse 21 to prevent pregnancy. They bring this action on their own behalf and on behalf of a proposed class of similarly situated persons who were prescribed Alesse 21 or Alesse 28 in Canada, to be further defined in the Plaintiffs' application for class certification.
3. The Defendant, Pfizer Canada Inc. (hereinafter "Pfizer") is a body corporate, duly registered under the *Business Corporations Act*, SBC 2002, c. 57 and amendments thereto as an Extraprovincial Company pursuant to the laws of the Province of British Columbia and has its registered and records office at 2700 – 700 Georgia Street West, Vancouver, in the Province of British Columbia.
4. The Defendant, Wyeth Canada (hereinafter "Wyeth") is a body corporate, duly registered under the *Business Corporations Act*, SBC 2002, c. 57 and amendments thereto as an Extraprovincial Limited Partnership pursuant to the laws of the Province of British Columbia and has its registered and records office at 2700 – 700 Georgia Street West, Vancouver, in the Province of British Columbia.
5. The active ingredients in Alesse are ethinyl estradiol and levonorgestrel being a combination of female hormones that are meant to prevent ovulation for the purposes of contraception.

6. Alesse 21 and Alesse 28 are manufactured by Pfizer at its facility located at 17, 300 Trans-Canada Highway, Kirkland, Quebec, under license from Wyeth.
7. On the product monograph for Alesse 21 and Alesse 28, Pfizer states, among other things, as follows:

What the medication is used for:

- To prevent pregnancy

[...]

Combination birth control pills are more than 99 percent effective in preventing pregnancy when:

- the pill is **TAKEN AS DIRECTED**, and
- the amount of estrogen is 20 micrograms or more.

A 99 percent effectiveness rate means that if 100 women used birth control pills for one year, one woman in the group would get pregnant.

[...]

Unintended pregnancy occurred in 2 out of 349 study subjects using Alesse (0.6%)

8. On December 1, 2017, Health Canada issued a safety alert about Alesse 21 and Alesse 28 birth control pills (the "Recall") advising that certain affected packages might contain broken or smaller than normal pills which could reduce their effectiveness. According to Health Canada, the products affected included Alesse 21 from Lot A2532 and Alesse 28 from Lot A3183, and it was not known at the time of the announcement or currently whether the issue was isolated to those lots.
9. The information on the Health Canada website regarding the Recall included advice as to the following:
 - (a) Check your pills before and after taking them out of the blister

- package;
- (b) Do not consume the pill if it looked unusual. Examine both sides of each pill thoroughly for anything unusual before taking it (such as, a different (paler) colour, jagged edges, or the pill is broken or smaller than normal). It may not be immediately obvious from looking at the blister package that there is a problem with the pills, as the underside of the pill cannot be seen while in the blister pack;
 - (c) If you have a package with an unusual pill, return it to your pharmacy for a replacement package; and
 - (d) Do not stop taking your birth control pills as this may result in pregnancy. If you have any questions or concerns about your birth control product, talk to a health care professional, including about alternatives. Talk to a health care professional if you have any questions or concerns about your birth control product.

The Plaintiff MacKinnon

10. The Plaintiff MacKinnon had taken Alesse 21 since January 2014, as prescribed and had never become pregnant.
11. The Plaintiff MacKinnon had filled a prescription for Alesse 21 on October 22, 2017 and had two pills left in her pack when she became aware of the Recall. The Plaintiff was notified of the Recall on December 6, 2017 when she was notified by the pharmacy where she had filled her prescription, Shoppers Drug Mart Hillside.
12. The lot of Alesse 21 that the Plaintiff MacKinnon received (DIN 02236974, Lot A2766, expiry December 2018) was not one of the two lots mentioned in the Recall.'
13. The Plaintiff MacKinnon took Alesse 21 as prescribed until December 16, 2017.
14. On or about November 22 to November 27, 2017, the Plaintiff MacKinnon became pregnant. She discovered that she was pregnant on December 16, 2017, which was confirmed by a doctor on December 17, 2017.
15. The Plaintiff MacKinnon has elected to carry the pregnancy to term.

16. As a result of defective nature of the Alesse 21 that she received, the Plaintiff MacKinnon has incurred damages including:

- (a) unintended pregnancy;
- (b) income loss consequent on the pregnancy and maternity leave;
- (c) special damages; and
- (d) such further and other damages as shall be proven at trial.

The Plaintiff McIntosh

17. The Plaintiff McIntosh took Alesse 21 throughout 2017 as prescribed and had never become pregnant. She filled a prescription for Alesse 21 on June 23, 2017 (Lot A2532, expiry August 2018). She learned she was pregnant on October 31, 2017

18. The Plaintiff McIntosh was notified of the Recall by her pharmacist at the Shoppers Drug Mart in Sooke, B.C. in the first week of December 2017. She miscarried in the last week of November or first week of December 2017.

19. The lot of Alesse 21 that the Plaintiff McIntosh was taking (Lot A2532) was one of the two lots mentioned in the Recall.

20. As a result of defective nature of the Alesse 21 that she received, the Plaintiff McIntosh has incurred damages including:

- (a) unintended pregnancy;
- (b) income loss consequent to the miscarriage and recuperation;
- (c) special damages; and
- (d) such further and other damages as shall be proven at trial.

21. The Defendants posted an update to the Health Canada advisory on December 11, 2017.

22. The Plaintiffs would not have used Alesse 21 had they been provided accurate information and/or warnings. The Plaintiffs did not want to become pregnant and Alesse was their plan to avoid pregnancy.

Part 2: RELIEF SOUGHT

23. The Plaintiffs claim, on their own behalf, and on behalf of a class of similarly situated persons resident in Canada, as follows:

- (a) an order certifying this action as a class proceeding and appointing the Plaintiffs as the representative Plaintiffs under the *Class Proceeding Act*;
- (b) general damages;
- (c) special damages;
- (d) punitive damages;
- (e) relief pursuant to the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2;
- (f) 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;
- (g) costs;
- (h) interest pursuant to the *Court Order Interest Act*, R.S.B.C. 1996, c. 79; and
- (i) such further and other relief this Honourable Court may deem just.

Part 3: LEGAL BASIS***Negligence and Failure to Warn***

24. As the manufacturers, marketers, developers, distributors, labelers and/or importers of Alesse 21 and Alesse 28, 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.

25. The Defendants owed a duty to the Plaintiffs and class members to exercise reasonable care when designing, testing, manufacturing, marketing, labeling, promoting, and selling Alesse 21 and Alesse 28.
26. The Defendants owed a duty of care to the Plaintiffs and class members to ensure that Alesse 21 and Alesse 28 were safe and effective for their intended use. Particulars of the Defendants' negligence include:
- (a) failing to ensure that Alesse 21 and Alesse 28 were manufactured to product standards;
 - (b) employing inadequately trained personnel in the design and/or manufacturing of Alesse 21 and Alesse 28;
 - (c) placing Alesse 21 and Alesse 28 on the market when they knew or ought to have known that these drugs had potential risks that outweighed their potential benefits;
 - (d) manufacturing and/or marketing a product that they know, or ought to have known, had an unreasonably high risk of breaking before ingestion by consumers;
 - (e) failing to implement a timely recall of Alesse 21 and Alesse 28 once the risks of unintended pregnancy were known to them;
 - (f) manufacturing and/or marketing a product that was not fit for the purpose for which it was intended;
 - (g) failing to manufacture and/or market a product in a good and workmanlike manner and in accordance with generally accepted standards; and
 - (h) such further and other particulars of negligence as will be alleged at trial.

Business Practices and Consumer Protection Act

27. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of Alesse 21 and Alesse 28 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 ingested Alesse 21

and Alesse 28 are "consumers" and the Defendants were "suppliers" within the meaning of the BPCPA.

28. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Alesse 21 and Alesse 28 had the capability, tendency or effect of deceiving or misleading consumers regarding the safety and efficacy of Alesse 21 and Alesse 28. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of Alesse 21 and Alesse 28 were deceptive acts and practices contrary to s. 4 of the BPCPA. The Defendants' deceptive acts and practices included the failure to properly disclose all material facts regarding the risks of using Alesse 21 and Alesse 28.
29. 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 who purchased Alesse 21 and Alesse 28 in Canada. Such relief includes the disgorgement of the profits or revenues received by the Defendants from the sale of Alesse 21 and Alesse 28 in Canada.
30. The declaratory and injunctive relief sought by the Plaintiffs 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 Alesse 21 and Alesse 28 which includes sending a "Dear Doctor Letter" to alert physicians to this problem.

Causation and Damages

31. 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 Defendants. 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 medical expenses and out of pocket expenses;
- (c) loss of both past and prospective income; and
- (d) cost of future care.

32. 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.

33. 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

34. The Plaintiffs and class members have a claim for the recovery of health care costs incurred on their behalf by the British Columbia Ministry of Health Services and by other provincial and territorial governments. The Plaintiff pleads the *Health Care Cost Recovery Act*, S.B.C. 2008, c. 27 and the comparable legislation from the other provinces and territories.


Jurisdiction

35. 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 Alesse 21 and Alesse 28 in British Columbia;
- b) the Plaintiff resides in British Columbia; and
- c) the Plaintiff's damages were sustained in British Columbia.

Plaintiff's address for service:	RICE HARBUT ELLIOTT LLP Barristers and Solicitors 820 - 980 Howe Street Vancouver, BC V6Z 0C8
Fax number address for service (if any):	(604) 682-0587
E-mail address for service (if any):	Nil
Place of trial:	Vancouver
The address of the registry is:	800 Smith Street, Vancouver

Date: 04/July/2018



Signature of John M. Rice
 plaintiff lawyer for plaintiff

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

[The following information is provided for data collection purposes only and is of no legal effect.]

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

A claim for negligence and failure to warn resulting in unintended pregnancy, with injury, loss and damages to the Plaintiffs and a class of similarly situated persons resident in Canada.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

[Check one box below for the case type that best describes this case.]

A personal injury arising out of:

- a motor vehicle accident
- medical malpractice
- 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
- a matter not listed here

Part 3: THIS CLAIM INVOLVES:

[Check all boxes below that apply to this case]

- 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*