IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation: *MacKinnon v. Pfizer Canada Inc.,*
2021 BCSC 1093

Date: 20210607
Docket: S187485
Registry: Vancouver

Between:

Taylor Janet MacKinnon and
Alysa McIntosh

Plaintiffs

And

Pfizer Canada Inc. and Wyeth Canada

Defendants

Before: The Honourable Madam Justice Horsman

Reasons for Judgment on Certification Application

Counsel for the Plaintiffs:	John M. Rice Anthony Leoni E.F. Anthony Merchant, Q.C. Anthony Tibbs
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Place and Date of Hearing:	Vancouver, B.C. April 6-8, 2021
Place and Date of Judgment:	Vancouver, B.C. June 7, 2021

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OVERVIEW

[1] The plaintiffs apply to certify this action as a multi-jurisdictional class proceeding under the *Class Proceedings Act*, R.S.B.C. 1996, c. 50 [*CPA*], on behalf of all persons resident in Canada who were prescribed and ingested the oral contraceptive Alesse 21 or Alesse 28 (collectively, "Alesse") between January 1, 2017 and April 30, 2019 (the "Class Period"). The plaintiffs say there were manufacturing defects in Alesse during the Class Period that reduced its efficacy in preventing pregnancy. Both plaintiffs became pregnant while taking Alesse.

[2] A focus of the plaintiffs' case is an advisory issued by Health Canada in December 2017 warning consumers that complaints had been received about undersized and broken pills in packages of Alesse 21 and Alesse 28. The plaintiffs say that testing of Alesse pills has disclosed a further defect in that even normal sized pills sold during the class period contain a lower quantity of the hormone estrogen than Alesse's own Product Monograph suggests is necessary for the pills to be effective in preventing pregnancy.

[3] In this action, the plaintiffs allege that the defendants, Pfizer Canada Inc. ("Pfizer") and Wyeth Canada ("Wyeth"), negligently failed to take reasonable steps to ensure that Alesse was safe and effective for its intended use. The plaintiffs seek to certify common issues in negligence, and under consumer protection and health care costs recovery legislation.

[4] The defendants say the plaintiffs have not established any of the requirements for certification under s. 4 of the *CPA*. A central focus of the defendants' submissions is the requirement in s. 4(1)(c) of the *CPA* that the claims of class members disclose common issues. The defendants argue that the plaintiffs have not met their onus of showing some basis in fact that common issues exist, and that there is a workable methodology for determining the question of general causation that would be addressed at a common issues trial. The defendants'

submissions on these issues highlight a contest between the parties as to the limits of the Court's role on a certification hearing in resolving merits-based disputes.

[5] For the reasons that follow, I conclude that the plaintiffs have established all of the requirements for certification under s. 4 of the *CPA*, and therefore this action must be certified as a class proceeding.

BACKGROUND FACTS

Alesse

[6] Alesse is a type of combined oral contraceptive ("COC"), which contain the hormones progestin (a synthetic form of the body's naturally-occurring hormone progesterone) and estrogen. The principal mechanism of a COC is to suppress ovulation by inhibiting the gonadotropin-releasing hormone (GnRH), luteinizing hormone (LH), follicle-stimulating hormone (FSH), and the mid-cycle LH surge. The progestin component of the COC also alters the cervical mucus to make it sticky and impenetrable to sperm, and alters the endometrium (the uterine lining) to make it inhospitable to sperm migration and implantation.

[7] The two active pharmaceutical ingredients in Alesse are levonorgestrel (a synthetic derivative of progesterone) and ethinyl estradiol (a semisynthetic estrogen). For ease of reference, I will refer to levonorgestrel as "progestin", and ethinyl estradiol as "estrogen".

[8] A package of of Alesse 21 contains 21 active pink tablets, one of which is to be taken per day. Packages of Alesse 28 contain 21 pink tablets and 7 white "reminder" tablets that contain no hormones. Individuals using Alesse 21 are directed to take no pills for seven days after completing a package, while those using Alesse 28 take the reminder pills for seven days after taking the 21 active pills.

[9] As required by Health Canada, the defendants have developed a Product Monograph for Alesse that contains information for health professionals (in Part I), scientific information (in Part II), and information for consumers (in Part III).

According to its Product Monograph, revised as of June 26, 2018, each Alesse pink tablet contains 100 micrograms (mcg) of progestin and 20 mcg of estrogen. Part III of the Alesse Product Monograph ("Consumer Information"), states as follows:

> **ALESSE® 21 AND ALESSE® 28**
>
> **100 mcg Levonorgestrel and 20 mcg Ethinyl Estradiol Tablets**
>
> . . .
>
> **Effectiveness of Birth Control Pills**
>
> 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.
>
> The chance of becoming pregnant increases with incorrect use.
>
> [Emphasis in the original]

[10] There is a conflict in the expert evidence tendered on the certification application regarding the relative importance of progestin and estrogen in preventing pregnancy in individuals using a COC. I will address that dispute in addressing the defendants' argument that there is no basis in fact to suggest there is a common issue relating to the efficacy of Alesse.

The Health Canada Advisory

[11] On December 1, 2017, Health Canada issued an advisory in respect of Alesse (the "Advisory"). The Advisory related to reports that blister packages from two lots of Alesse contained an active (pink) pill that was roughly half the proper size. One of the lots expired in August 2018, while the other expired in April 2019. It was not known at the time of the Advisory whether the issue was isolated to the Advisory Lots. The Advisory stated:

> Broken or smaller-than-normal birth control pills may deliver a smaller dose of the active drug ingredient, which could reduce its effectiveness in preventing pregnancy.

[12] Alesse consumers were advised to check their pill packages, and return the package to the pharmacy if an unusual pill was observed. Consumers were also advised to continue to take Alesse pills that did not appear unusual so as to avoid the risk of an increased chance of a pregnancy. Under the heading “What Health Canada is Doing”, the Advisory stated:

> Health Canada is working with the company, Pfizer Canada, to determine the nature and scope of the issue. We will continue to monitor the situation and assess the need for further action. Health Canada will update consumers and health care professionals as appropriate.

[13] On December 9, 2017, Health Canada issued a follow up advisory to provide further information to assist health care professionals in advising patients using Alesse. Health care professionals were advised to remind patients to check tablets before taking them and to return blister packs containing broken or split pills.

[14] On April 16, 2018, Health Canada issued a general advisory to all individuals taking birth control pills, reminding them to return and replace their packages of pills if any of them were missing or included unusual looking pills. The advisory was said to be prompted by “quality issues” involving certain prescription birth control pills. The advisory included the following “background”:

> Health Canada has recently communicated about instances of quality concerns involving Alesse and Alysena birth control pills (see links below). Health Canada continues to receive complaints of quality issues and is reminding women to always check their pills before taking them.
>
> This communication is prompted by two recent complaints involving Alesse 28. In one complaint, two active pills were missing from their slots and a third slot in the blister package contained a pill fragment where a whole pill should have been (see image below). In the second complaint, a pill shifted from one slot to another, causing two pills to be found in one slot and a second slot to have no pill in it (see image below).
>
> Health Canada is providing this advice as a general reminder and is not suggesting that there are issues with all birth control pills.

The plaintiff Taylor MacKinnon

[15] The plaintiff Taylor MacKinnon deposes that she has been taking Alesse 21 as an oral contraceptive since January 2014. She says she has always taken Alesse

as directed in the manufacturer's instructions. Ms. McKinnon was taking Alesse to prevent pregnancy.

[16] Ms. MacKinnon says that on or about December 6, 2017, she was notified by her pharmacist that Alesse was the subject of a Health Canada advisory. She was advised to check her remaining pills for any abnormalities. At the time, Ms. MacKinnon was taking Alesse 21 pills from a package she had purchased on October 22, 2017. The package is not from one of the Advisory Lots.

[17] On or about December 16, 2017, Ms. McKinnon received a positive result on a pregnancy test. She visited her family doctor on December 17, 2017, and was told that she was just over five weeks pregnant. Ms. McKinnon says she subsequently telephoned Health Canada, as directed on the Health Canada website for "adverse reactions", and left her name and phone number, along with a brief description of her situation. This call was not returned. Ms. McKinnon says she also telephoned Pfizer and spoke with an agent from the Product Side Effects department. She was not provided with any further information from Pfizer.

[18] Ms. McKinnon gave birth to a daughter on August 4, 2018. She was 24 years old at the time. Ms. McKinnon says she wished to have children someday but not at such a young age. She would have preferred that she and her partner were more established in their careers and financially stable before having children. The plaintiff says she has not been able to find work as a certified dental assistant following the birth of her daughter.

The plaintiff Alysa McIntosh

[19] The plaintiff Alyssa McIntosh deposes that she has been taking Alesse 21 since January 2017 for the purpose of preventing pregnancy. She says she has always taken Alesse 21 as directed in the manufacturer's instructions.

[20] On or about October 31, 2017, Ms. McIntosh discovered she was pregnant. In or around late November or early December 2017, she suffered a miscarriage. The

gestational age of the foetus at the time of the miscarriage was between eight and nine weeks.

[21] The plaintiff purchased the Alesse 21 package that she was taking at the time of her pregnancy on or about June 23, 2017. The package came from a lot that is one of the Advisory Lots.

The plaintiffs' test results

[22] On May 31, 2018, putative class member Jenelle Hamilton provided plaintiffs' counsel with a package of Alesse 21 pills, in their original package, from one of the Advisory Lots. The pills had an expiry date of August 2018. The package was secured in a locked cabinet at the law firm of Rice Harbut Elliott LLP ("RHE").

[23] On March 5, 2019, RHE retained Emery Pharma to test the pills to determine their levels of progestin and estrogen. On March 29, 2019, the package that Ms. Hamilton had provided to RHE was sent to Emery Pharma for testing (the "First Test Package").

[24] In April 2019, Ms. Hamilton provided RHE with a package of Alesse 28 pills, in their original package, that was not from one of the Advisory Lots. This package had an expiry date of August 2020. On May 27, 2019, RHE sent this second package to Emery Pharma for testing (the "Second Test Package").

[25] On June 27, 2019, Emery Pharma provided RHE with its testing results. In relation to the First Package, Emery Pharma found that the level of estrogen in the pills ranged from 17.9954955 mcg to 18.70213964 mcg. In relation to the Second Package, the testing showed that estrogen levels in the pills ranged from 18.00675676 mcg to 19.20326577 mcg. None of the pills tested contained 20 mcg of estrogen, as represented in the Alesse Product Monograph.

[26] Neither package of Alesse that was tested by Emery Pharma contained any broken or chipped pills, which was the issue identified in the Advisory. The plaintiffs say that an inference can be drawn that estrogen levels would be even lower in

chipped or broken pills. However, they say that the Emery Pharma testing demonstrates issues with estrogen levels that go beyond broken or chipped pills.

THE ACTION

[27] The plaintiffs filed their original notice of civil claim on July 5, 2018, and an amended notice of civil claim on February 20, 2019. The current version of the pleading is the second amended notice of civil claim ("Second Amended NOCC"), filed on January 21, 2021. The current version of the pleading was intended to address some of the criticisms raised by the defendants in their response to the certification application.

[28] The Second Amended NOCC pleads that the defendants, "[a]s the manufacturers, marketers, developers, distributors, labelers and/or importers of Alesse 21 and Alesse 28", owed a duty of care to the plaintiffs and other class members. The defendants are alleged to have been negligent in failing to ensure that Alesse was safe and effective for its intended use. Particulars of the alleged negligence are set out in Part 3, para. 32(a)-(h).

[29] The plaintiffs both allege that they became pregnant as a result of the defendants' negligence. They seek general damages, damages for income loss, and special damages in the form of the cost of purchasing Alesse when the product was defective.

[30] The Second Amended NOCC also pleads that the defendants' solicitations, offers, advertisements, promotions, sales and supply of Alesse for personal use by the plaintiffs and by class members were "consumer transactions" within the meaning of the *Business Practices and Consumer Protect Act*, S.B.C. 2004, c. 2 [*BPCPA*]. It is alleged that the defendants' conduct in their solicitation, offers, advertisements, promotions, sales and supply of Alesse had the capability, tendency or effect of deceiving or misleading consumers regarding the efficacy of Alesse. It is further alleged that the defendants engaged in deceptive acts and practices contrary to s. 4 of the *BPCPA* in failing to properly disclose all risks associated with Alesse.

[31] The plaintiffs seek injunctive and declaratory relief, damages, and statutory compensation pursuant to ss. 171 and 172 of the *BPCPA*.

[32] The plaintiffs also seek recovery of health care costs incurred on their behalf by the British Columbia Ministry of Health Services, and on behalf of class members by other provincial and territorial governments. The plaintiffs rely on the *Health Care Costs Recovery Act*, S.B.C. 2008, c.27 [*HCCRA*], and comparable legislation from other provinces and territories.

[33] Finally, the plaintiffs plead that the conduct of the defendants was high-handed, wanton, and reckless, warranting an award of punitive damages.

[34] It is not clear from the record whether the defendants have filed a response to civil claim. If so, it was not included in the application record.

THE CERTIFICATION APPLICATION

[35] The plaintiffs filed a certification application on November 28, 2019. They seek to certify the action as a class proceeding under the *CPA*, and to represent a class of individuals comprised of:

> All persons resident in Canada who were prescribed Alesse 21 or Alesse 28 (collectively, “Alesse”) and ingested said medications between January 1, 2017 and April 30, 2019 (the “Class Period”).

[36] At the time of the filing of the plaintiffs’ certification application, a proposed class action had been filed in Québec by Merchant Law Group covering similar claims against the manufacturers of Alesse: *Hakim v. Pfizer Inc. et al.*, No. 500-06-00916-185 [*Hakim*]. Plaintiffs’ counsel in the two proceedings subsequently agreed to collaborate on a joint prosecution of the proposed class proceeding in British Columbia. I am advised that the plaintiff in the *Hakim* action has applied to discontinue that action.

[37] The plaintiffs seek to have common issues certified in relation to the claims in negligence, under consumer protection legislation, and under health care cost

recovery legislation. The plaintiffs also propose common issues in relation to their claims for punitive damages. A complete list of the plaintiffs' proposed common issues is included at Appendix A to this judgment.

[38] The evidence tendered by the plaintiff in support of certification includes the affidavits of three expert witnesses: Dr. Michael Freeman, a forensic epidemiologist and Associate Professor of Forensic Medicine at Maastricht University in the Netherlands; Dr. Sid Katz, a Professor Emeritus of Pharmaceutical Sciences at the University of British Columbia; and, Jennifer Mosher, a pharmacist and investigator with the Alberta College of Pharmacy. In general terms, the plaintiff's experts opine that lower levels of estrogen likely reduces the efficacy of Alesse, and that any chipped or broken pills are likely to contain even less estrogen than that measured by Emery Pharma in the unchipped and unbroken pills they tested. Dr. Freeman and Professor Katz propose methodologies for determining the impact of any defects on the effectiveness of Alesse in preventing pregnancy. The plaintiffs say that their expert evidence establishes that there is some basis in fact for the proposed common issues, and outlines plausible methodologies to determine whether there is a causal link between lower estrogen levels and a higher risk of pregnancy.

[39] The defendants' evidence on the certification application includes the affidavit of Dr. Robert Reid, a Professor Emeritus of Obstetrics and Gynecology at Queen's University in Kingston, Ontario. The thrust of Dr. Reid's evidence is that the measured levels of estrogen in the Emery Pharma testing results are within an acceptable range of deviation, and the noted deviations would have no impact on pregnancy rates. Dr. Reid also questions the practical and ethical feasibility of Dr. Freeman's proposed methodology for determining causation.

[40] While the defendants dispute that the plaintiff has established any of the criteria for certification under the *CPA*, a key battleground between the parties is the dispute between the expert witnesses, and the propriety of the Court attempting to resolve the dispute on a certification hearing.

THE CERTIFICATION REQUIREMENTS

[41] The *CPA* sets out the procedure by which a member of a class may commence and maintain an action on behalf of all members of a class. Pursuant to s. 2 of the *CPA*, the person wishing to represent a class of persons must bring an application for an order certifying the action as a class proceeding and appointing the applicant as the representative plaintiff.

[42] A class action has three principal advantages over the pursuit of individual claims through a multiplicity of suits. First, class actions serve judicial economy by avoiding unnecessary duplication in fact-finding and legal analysis. Second, class actions promote access to justice by making economical the prosecution of claims that would be prohibitively costly for any individual class member. Third, class actions ensure that actual and potential wrongdoers modify their behaviour to take full account of the harm they have caused, or may cause, to the public: *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 15 [*Hollick*].

[43] In order to have an action certified as a class proceeding in British Columbia, the proposed representative plaintiff must meet the criteria set out in s. 4(1) of the *CPA*. Section 4(1) requires the court to certify a proceeding as a class proceeding if all of the following requirements are met:

> (a) the pleadings disclose a cause of action;
>
> (b) there is an identifiable class of 2 or more persons;
>
> (c) the claims of the class members raise common issues, whether or not those common issues predominate over issues affecting only individual members;
>
> (d) a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues;
>
> (e) there is a representative plaintiff who
>
> (i) would fairly and adequately represent the interests of the class,
>
> (ii) has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding, and

> (iii) does not have, on the common issues, an interest that is in conflict with the interests of other class members.

[44] The requirement in s. 4(1)(a) that the pleadings disclose a cause of action is assessed on the same test applicable on a motion to strike pleadings under R. 9-5(1) of the *Supreme Court Civil Rules*, B.C. Reg. 168/2009 [*SCCR*]. The question is whether, assuming the facts pleaded are true, it is plain and obvious that the plaintiff's claim has no reasonable prospect of success: *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at para. 63 [*Microsoft*].

[45] In relation to the remaining criteria in s. 4(b)-(e), the plaintiff must show "some basis in fact" that the requirements for certification are met: *Hollick* at para. 25. This does not involve an assessment of the merits. The question is not whether there is some basis in fact for the claim itself, but rather whether there is some basis in fact to establish each of the individual requirements for certification. The certification stage is not concerned with the merits of the action but rather with its form and whether the action can properly proceed as a class action: *Hollick* at paras. 16 and 25; *Microsoft* at paras. 99-105.

SECTION 4(1)(a): CAUSE OF ACTION

The claims in negligence

[46] The defendants say that the Second Amended NOCC fails to disclose a cause of action in negligence. In brief, the defendants argue:

a) the Second Amended NOCC fails to distinguish between Pfizer and Wyeth, and lumps them together as a group;

b) the Second Amended NOCC fails to delineate between three distinct causes of action alleged: (i) negligent design, development and testing; (ii) negligent manufacturing; and, (iii) negligent distribution, importation, marketing and sale;

c) the Second Amended NOCC fails to set out material facts to support each of the three alleged causes of action in negligence.

[47] I begin with the observation that it cannot be disputed that pharmaceutical manufacturers in Canada owe a duty of care to consumers to take reasonable steps to ensure there are no defects in their product that are likely to give rise to injury on ordinary use. As stated by the Supreme Court of Canada in *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634:

> [23] … Medical products are often designed for bodily ingestion or implantation, and the risks created by their improper use are obviously substantial. The courts in this country have long recognized that manufacturers of products that are ingested, consumed or otherwise placed in the body, and thereby have a great capacity to cause injury to consumers, are subject to a correspondingly high standard of care under the law of negligence; see *Shandloff v. City Dairy*, [1936] 4 D.L.R. 712 (Ont. C.A.), at p. 719; *Arendale v. Canada Bread Co.*, [1941] 2 D.L.R. 41 (Ont. C.A.), at pp. 41-42; *Zeppa v. Coca-Cola Ltd.*, [1955] 5 D.L.R. 187 (Ont. C.A.), at pp. 191-93; *Rae and Rae v. T. Eaton Co. (Maritimes) Ltd.* (1961), 28 D.L.R. (2d) 522 (N.S.S.C.), at p. 535; *Heimler v. Calvert Caterers Ltd.* (1975), 8 O.R. (2d) 1 (C.A.), at p. 2. Given the intimate relationship between medical products and the consumer's body, and the resulting risk created to the consumer, there will almost always be a heavy onus on manufacturers of medical products to provide clear, complete and current information concerning the dangers inherent in the ordinary use of their product.

[48] It is, of course, necessary for a plaintiff to plead a concise statement of the material facts giving rise to a claim: *SCCR*, R. 3-1(2). However, a notice of civil claim is to be interpreted generously for the purpose of determining if a cause of action is disclosed: *R. v. Imperial Tobacco Canada Ltd.*, 2011 SCC 42 at para. 21. If the Second Amended NOCC were deficient in the manner suggested by the defendants, it would be necessary to consider whether the deficiencies could be cured by way of further amendment. It is very difficult to see how the defendants can maintain that the Second Amended NOCC discloses no cause of action in negligence whatsoever in the circumstances of this case, and that an action in negligence is doomed to fail.

[49] In my view, it is not necessary to require the plaintiffs to amend their Second Amended NOCC to provide further particulars of the negligence claims. The plaintiffs

have pleaded their causes of action in negligence with as much precision as can reasonably be expected at this stage of the proceeding.

[50] I will begin with the defendants' criticism that the Second Amended NOCC fails to disclose a cause of action because the plaintiffs have not distinguished between the two defendants. The Second Amended NOCC pleads as follows:

> 6. Alesse 21 and Alesse 28 are manufactured by Pfizer at its facility located at 300 Trans-Canada Highway, Kirkland, Quebec, under licence from Wyeth.
>
> . . .
>
> 30. 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.

[51] The defendants say that these paragraphs are inconsistent. It is not apparent to me that this is so. The alleged licence agreement between Pfizer and Wyeth is not before the Court. The plaintiffs' factual allegation is that Pfizer and Wyeth are both manufacturers, marketers, developers, distributors, labelers and/or importers of Alesse. The allegation may, or may not, prove to be accurate. However, for the purpose of the certification criteria, I must assume it to be true.

[52] It may be that with the benefit of discovery, the plaintiffs will revise their pleading to accord with information disclosed by the defendants about the relationship between Pfizer and Wyeth, and their respective responsibilities for the manufacturing and marketing of Alesse. At this stage, and without the benefit of discovery, they have necessarily cast a wide net: *Bartram (Litigation guardian of) v. GlaxoSmithKline Inc.*, 2012 BCSC 1804 at para. 21, aff'd 2013 BCCA 462.

[53] I note that while the defendants object that they have been "lumped together as a group" in the Second Amended NOCC, the defendants do not offer any assistance to the plaintiffs in narrowing their claims. There is no concession, for example, that Pfizer assumes responsibility for any liability in the manufacture and

marketing of Alesse, and thus Wyeth is not a necessary defendant. Instead, the defendants insist that the plaintiff's negligence claims are doomed to fail because the plaintiffs cannot, at this early stage, particularize the precise responsibilities each defendant performed in relation to the manufacture and marketing of Alesse. The law does not impose such a burden on the plaintiffs: *SCCR*, R. 3-7(20).

[54] I am similarly not persuaded that the Second Amended NOCC is deficient in failing to sufficiently delineate between the various negligence claims. The plaintiffs allege that the Health Canada Advisory and the Emery Pharma testing demonstrates that there are defects in the Alesse pills. It is alleged that there is a causal relationship between the lower levels of estrogen measured by Emery Pharma and a degree of decreased efficiency of contraceptive medication. It is alleged that the plaintiffs would not have used Alesse if they had been provided with accurate information and/or warnings by the defendants. It is alleged that the plaintiffs suffered damages as a result of their consumption of the defective product.

[55] Particulars of the defendants' negligence are set out in Part 3 of the Second Amended NOCC as follows:

> 32. 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 standard, including failing to ensure that Alesse 21 and Alesse 28 contained 20 mcg of the API ethinyl estradiol or more;
>
> (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, including that the product is less effective than advertised in preventing pregnancy;

(g) failing to manufacture and/or market a product in a good and workmanlike manner and in accordance with generally accepted standard; and

(h) such further and other particulars of negligence as will be alleged at trial.

[56] The Second Amended NOCC thus alleges the existence of a duty of care based on a close and proximate relationship between the plaintiffs and the defendants, and provides particulars of the defendants' alleged breach of the standard of care. The particulars include a concise explanation of how the defendants are said to have been negligent in the manufacture, design, and marketing of Alesse. The plaintiffs allege that they have suffered damages that are causally related to the defendants' breach of their standard of care. Without commenting on the merits of the plaintiffs' claims, which is not the concern of the Court on a certification application, I find that the pleadings disclose a cause of action in negligence.

The consumer claims

Claims under the BPCPA

[57] The plaintiffs plead that the defendants have engaged in deceptive acts or practices contrary to s. 5 of the *BPCPA*. Section 5 prohibits a "supplier" from engaging in a deceptive act or practice in respect of a consumer transaction. Section 1 defines "supplier" as a person who in the course of business participates in a consumer transaction by (a) supplying goods or services or real property to a consumer, or (b) soliciting, offering, advertising or promoting with respect to such a transaction. Section 4(1) defines a "deceptive act or practice" as follows:

> 4(1) In this Division:
>
> **"deceptive act or practice"** means, in relation to a consumer transaction,
>
> (a) an oral, written, visual, descriptive or other representation by a supplier, or
>
> (b) any conduct by a supplier

that has the capability, tendency or effect of deceiving or misleading a consumer or guarantor;

"representation" includes any term or form of a contract, notice or other document used or relied on by a supplier in connection with a consumer transaction.

[58] The plaintiff seeks remedies under ss. 171 and 172 of the *BPCPA*. Those sections provide, in relevant terms:

> 171(1) Subject to subsection (2), if a person, other than a person referred to in paragraphs (a) to (e), has suffered damage or loss due to a contravention of this Act or the regulations, the person who suffered damage or loss may bring an action against a
>
> (a) supplier,
>
> . . .
>
> who engaged in or acquiesced in the contravention that caused the damage or loss.
>
> . . .
>
> 172(1) The director or a person other than a supplier, whether or not the person bringing the action has a special interest or any interest under this Act or is affected by a consumer transaction that gives rise to the action, may bring an action in Supreme Court for one or both of the following:
>
> (a) a declaration that an act or practice engaged in or about to be engaged in by a supplier in respect of a consumer transaction contravenes this Act or the regulations;
>
> (b) an interim or permanent injunction restraining a supplier from contravening this Act or the regulations.
>
> . . .
>
> (3) If the court grants relief under subsection (1), the court may order one or more of the following:
>
> (a) that the supplier restore to any person any money or other property or thing, in which the person has an interest, that may have been acquired because of a contravention of this Act or the regulations;
>
> (b) if the action is brought by the director, that the supplier pay to the director the actual costs, or a reasonable proportion of the costs, of the inspection of the supplier conducted under this Act;
>
> (c) that the supplier advertise to the public in a manner that will assure prompt and reasonable communication to consumers, and on terms or conditions that the court considers

> reasonable, particulars of any judgment, declaration, order or injunction granted against the supplier under this section.

[59] Pursuant to ss. 171 and 172, the plaintiffs seek declaratory and injunctive relief, damages, and statutory compensation. The relief sought includes "disgorgement of the profits or revenues" received by the defendants from the sale of Alesse in Canada. I interpret the disgorgement plea to seek the remedy of a restoration order under s. 172(3)(a) of the *BPCPA*. The plaintiffs also seek an order under s. 173(3)(c) requiring the defendants to advertise the particulars of any judgment against them.

[60] The defendants say that the plaintiffs' claims under the *BPCPA* do not disclose a cause of action because such claims can only succeed in a products liability case where it is shown that the plaintiff relied on the alleged representations that are said to constitute deceptive practices. The plaintiffs have not pleaded that they relied on any representation by the defendants, including in relation to the quantity of estrogen reported on Alesse packages and in the Product Monograph.

[61] The defendants' submission that reliance is a pre-requisite to a claim under the *BPCPA* must be placed in context. The provisions of the *BPCPA* do not, on their face, require that an individual seeking remedies for a contravention of s. 5 must prove detrimental reliance. Section 171(1) does require that, in order to obtain a remedy in damages, the person bringing an action must have suffered loss or damage "due to a contravention of this Act or the regulations". A condition of a restoration order under s. 172(3)(a) is that the money or other property was "acquired because of a contravention of this Act or the regulations". In order to obtain these remedies, therefore, the plaintiff must show a causal relationship between the alleged contravention of the *BPCPA* and the damage claimed by the consumer, or the money acquired by the supplier: *Wakelam v. Wyeth Consumer Healthcare/Wyeth Soins de Sante Inc.*, 2014 BCCA 36 at para. 49.

[62] There has been some suggestion in the case law that the causal link required by s. 171 of the *BPCPA* can only be established, in the context of an alleged breach

of s. 5, by showing detrimental reliance on the representation that is said to be deceptive and misleading. The law on this point is, at the very least, unsettled. In *Finkel v. Coast Capital Savings Credit Union*, 2017 BCCA 361, the Court of Appeal commented on the need for reliance in the context of a claim for damages under s. 171 for a contravention of s. 5:

> [83] In my view, the causal link required between a breach of s. 5 of the *BPCPA* and damages for the cause of action created by s. 171 is not equally well-settled. Nor is it equally apparent that reliance will always be necessary for causation purposes given the differing nature of the statutory breach and the potential loss. As this Court noted in *Collette v. Great Pacific Management Co. Ltd*., 2004 BCCA 110 at para. 34 in the context of a tort claim, reliance may not be required to establish a causal link between a breach of duty and a loss in all misrepresentation cases. The reason for insistence on reliance is to prove causation. They are not independent requirements. Accordingly, if a breach of duty can be adequately linked to a loss by alternate means, individual reliance need not be shown.
>
> [Emphasis in the original]

[63] (See also: *Cantlie v. Canadian Heating Products Inc.*, 2017 BCSC 286 at paras. 241-246; *Bhangu v. Honda Canada Inc.*, 2021 BCSC 794 at para. 55 [*Bhangu*].)

[64] In the present case, the plaintiffs plead that the defendants' conduct constitutes deceptive acts and practices, including the misrepresentations they made that Alesse contains 20 mcg of estrogen and that Alesse is more than 99% effective in preventing pregnancy. It is pleaded that the defendants' deceptive acts and practices also includes their failure to disclose all material facts regarding the risks of using Alesse. The non-disclosure of a material fact can, on its own, amount to a deceptive act or practice under the *BPCPA*: *Stanway v. Wyeth Canada Inc.*, 2012 BCCA 260 at para. 80 [*Stanway*]. The plaintiffs also plead causation. They say that as a result of the defendants' deceptive acts and practices, the plaintiffs and class members have suffered loss and damage, including unintended pregnancy, emotional upset, and the cost of purchasing the defective medication.

[65] In my view, the Second Amended NOCC pleads material facts that are sufficient to ground cause of action under ss. 171 and 172 of the *BPCPA*. It is not plain and obvious that the cause of action is doomed to fail.

Claims under other consumer protection legislation

[66] In the Second Amended NOCC, Part III at para. 37b, the plaintiffs plead reliance on "competition, consumer protection, and trade practices legislation in British Columbia and similar legislation elsewhere, including…". What follows is a list of 11 provincial and federal statutes from across Canada, including the *Competition Act*, R.S.C. 1985, c. C-34.

[67] As noted by Justice Iyer in her recent judgment in *Bhangu* at paras. 58 and 59, there are material differences in the elements of the statutory causes of action as between the *BPCPA* and consumer protection legislation in other jurisdictions. By way of example, the Ontario *Consumer Protection Act, 2002*, S.O. 2002, c. 30, requires contractual privity as a precondition to the advancement of an action. The Second Amended NOCC does not allege that there is privity of contract between the plaintiffs and the defendants. Section 18 of the Ontario statute also requires a consumer to provide notice within one year of entering the agreement where a remedy is sought in relation to an unfair practice, and notice is a pre-condition to bringing an action. A similar notice requirement is contained in s. 7.1(1) of Alberta's *Consumer Protection Act*, R.S.A. 2000, c. C-26.3.[1] The Second Amended NOCC does not allege that effective notice has been given under those statutes. Section 52 of the *Competition Act* prohibits a person from "knowingly or recklessly" making misrepresentations to the public about a product. The Second Amended NOCC does not allege that the defendants acted knowingly or recklessly.

[1] I note that the Second Amended NOCC cites the *Fair Trading Act*, R.S.A. 2000, c. F-2, as the relevant Alberta legislation. This is incorrect. Bill 31, which received Royal Assent in December 2017, amended the *Fair Trading Act* and changed its name to the *Consumer Protection Act*.

[68] I acknowledge the plaintiffs' submission that a court hearing a common issues trial for a national class must take into account the law of other jurisdictions: *Ravvin v. Canada Bread Company*, 2019 ABQB 686 at para. 39, aff'd 2020 ABCA 424, leave to appeal ref'd [2021] S.C.C.A. No. 35. However, that does not answer the question of whether consumer claims under other legislation have been sufficiently pleaded.

[69] The parties provided limited submissions on the issue of the existence of a cause of action under other provincial and federal consumer protection legislation. The plaintiffs simply assert, without supporting analysis, that, for the purpose of the common issues, the legislation in other jurisdictions is identical to the *BPCPA*. For the purpose of assessing the sufficiency of the pleading, I am not persuaded this is so. I have already highlighted some of the material differences in the legislation. Given those differences, I cannot find that that the Second Amended NOCC discloses a cause of action for each of the "competition, consumer, and trade practices" statutes listed in para. 37b. It may be that some of the statutes are, as the plaintiffs maintain, sufficiently similar to the *BPCPA* that the Second Amended NOCC, as presently drafted, discloses a cause of action. However, in the absence of more fulsome submissions from the parties on the elements of the causes of action under the various statutes, it is impossible to reach firm conclusions on that point.

[70] In these circumstances, I consider it appropriate, pursuant to s. 5(6) of the *CPA*, to adjourn the plaintiffs' application to certify a common issue in relation to the other consumer protection legislation. In the interim, I will also grant leave to the plaintiffs to further amend their Second Amended NOCC, as necessary, to plead material facts to support a cause of action under the other legislation. I note that a similar remedy was granted by Justice Iyer in *Bhangu* (at para. 61) to address the same problem. Both parties will have an opportunity to provide further submissions when this aspect of the certification application is rescheduled.

Health Care Costs Recovery Act

[71] The final cause of action pleaded under the Second Amended NOCC is a claim for the recovery of health care costs under the *HCCRA*, and comparable legislation in other provinces and territories. I do not understand the defendants to dispute that the plaintiffs' claim for recovery of health care costs under the *HCCRA* and related legislation in other provinces and territories discloses a cause of action. Indeed, the plaintiffs are required to advance such a claim as a matter of statutory compulsion.

Summary on *CPA* s. 4(1)(a)

[72] In summary, I conclude that the Second Amended NOCC discloses causes of action in negligence, under the *BPCPA*, and under health care cost recovery legislation. The plaintiffs' application to certify a common issue in relation to other consumer protection legislation is adjourned, with the plaintiff having leave to further amend their pleading in the interim.

SECTION 4(1)(b): CLASS DEFINITION

Legal principles

[73] Section 4(1)(b) of the *CPA* requires that there is an identifiable class of two or more persons. The principles governing this requirement were summarized by the Court of Appeal as follows in *Jiang v. Peoples Trust Company*, 2017 BCCA 119:

> [82] In sum, the principles governing the identifiable class requirement may be summarized as follows:
>
> · the purposes of the identifiable class requirement are to determine who is entitled to notice, who is entitled to relief, and who is bound by the final judgment;
>
> · the class must be defined with reference to objective criteria that do not depend on the merits of the claim;
>
> · the class definition must bear a rational relationship to the common issues — it should not be unnecessarily broad, but nor should it arbitrarily exclude potential class members; and

> · the evidence adduced by the plaintiff must be such that it establishes some basis in fact that at least two persons could self-identify as class members and could later prove they are members of the class.
>
> [Emphasis in the original]

[74] A proposed class definition is not overbroad because it may include persons who will ultimately not have a claim against the defendants: *Price v. H. Lundbeck A/S*, 2018 ONSC 4333 at para. 96, reversed on other grounds 2020 ONSC 913.

Position of the Parties

[75] For ease of reference, I will repeat the plaintiffs' proposed class definition:

> All persons resident in Canada who were prescribed Alesse 21 or Alesse 28 (collectively, "Alesse") and ingested said medications between January 1, 2017 and April 30, 2019 (the "Class Period").

[76] The plaintiffs say that the Class Period is designed to cover the period of time that the Advisory Lots would most likely have been in the stream of commerce in Canada. The end date—April 30, 2019—coincides with the last expiry date of the Advisory Lots. The class definition is not limited to class members who ingested the Advisory Lots because the Emery Pharma testing indicates that the defects in the Alesse pills at the relevant time may not be limited to the Advisory Lots. Thus, the plaintiffs say, the class definition is rationally connected to the proposed common issues, and will capture all persons who may have a claim against the defendants as a result of having ingested the allegedly defective product.

[77] Although the plaintiffs do not know the class size, they say there is reason to expect it will be comprised of at least the 138 women from across the country who have, to date, contacted RHE about their experience taking Alesse, a number of whom say they became pregnant while on Alesse. The Health Canada Adverse Reaction online database lists 38 women who provided adverse reaction reports for Alesse during the Class Period, although it is unclear whether those individuals overlap with the 138 women who have contacted RHE. In any event, the plaintiffs say there is some basis in fact to establish an identifiable class of two or more

persons. The total number of class members will only be known with reasonable certainty once notice is issued and individuals come forward.

[78] The defendants say the proposed class is overbroad, and this is indicative of a logical flaw in the plaintiffs' theory of this class action. This is because the plaintiffs' Class Period is defined by reference to the Health Canada Advisory, but the proposed class is not limited to individuals who ingested Alesse from the Advisory Lots. While the plaintiffs say the Emery Pharma testing raises issues with respect to the effectiveness of Alesse from non-Advisory lots, the defendants answer that this concern is not rationally tied to the Class Period, which is defined by reference to the expiry of the Advisory Lots. The defendants further say that any proposed class should be limited to individuals who actually became pregnant as they are the only class members who actually suffered harm.

[79] The defendants say that, even on a generous interpretation of the pleadings, a class definition in this case could only include: (a) women (not "all persons"); (b) who were prescribed Alesse for the purpose of preventing pregnancy; (c) who purchased Alesse from one of the two Advisory Lots; and, (d) who took as directed and became pregnant.

Analysis

[80] In my view, the plaintiffs' proposed class definition is not logically flawed in the manner asserted by the defendants. The plaintiffs' case is that during the Class Period, there were defects in the Alesse pills as a result of the issues with broken and undersized pills identified in the Advisory, and also the issues with reduced estrogen levels in normal-sized pills identified in the Emery Pharma testing. The potential defect identified in the Emery Pharma testing results is rationally connected to the Class Period because the testing was carried out on pills that were "in the stream of commerce", to use the plaintiffs' phrase, during the Class Period. The plaintiffs say that the testing results, combined with the Advisory, are suggestive of manufacturing defects in Alesse pills during the Class Period that may not be

confined to the Advisory Lots. In my view, again bearing in mind that the onus on the plaintiffs at this stage is not to prove their case, the proposed class definition is rationally connected to the common issues and the pleaded causes of action.

[81] The defendants' argument that the plaintiffs' proposed class definition is overbroad in failing to limit the class to individuals who became pregnant while taking Alesse presumes that an unintended pregnancy is the only type of harm that could have resulted to class members from ingesting defective Alesse pills. The plaintiffs counter that class members may have suffered other forms of harm as a result of the defects, including emotional upset on learning that Alesse was less effective than advertised in preventing pregnancy, and economic loss in the form of the cost of purchasing medication that was defective. The plaintiffs say, and have pleaded, that such loss and damage is compensable in tort and/or under consumer protection legislation.

[82] It is not plain and obvious to me that class members would be limited to damages for unintended pregnancy under the causes of action advanced in the Second NOCC. That being the case, the class should be defined in a manner that is sufficiently broad to capture class members who may have claims arising from the use of Alesse, other than damages resulting from an unintended pregnancy. The fact that some class members may ultimately be unsuccessful in establishing a claim against the defendants does not make the class overbroad. In any class action involving claims for personal injury, it is possible that the claims of some class members will be unsuccessful, and indeed such an outcome is "virtually ordained" by the jurisprudence that precludes merits-based class definitions: *Tiboni v. Merck Frosst Canada Ltd.*, 2008 CanLII 37911 (ONSC) at para. 78; see also: *Schwoob v. Bayer Inc.*, 2013 ONSC 2207 at para.s 28-29 and *Tluchak Estate v. Bayer Inc.*, 2018 SKQB 311 at paras. 102-109.

[83] Finally, I do not agree with the defendants that the plaintiffs' proposed class definition is overbroad because it includes "all persons" who used and ingested Alesse during the Class Period, rather than being limited to "all women" who used

and ingested Alesse. It is not apparent to me why it is necessary or appropriate to define class membership in terms of gender identity. The defendants' proposed definition would arbitrarily exclude potential class members, for example individuals who identify as non-binary and who may have been prescribed and ingested Alesse during the Class Period.

[84] I conclude that the proposed class definition satisfies the requirements of s. 4(1)(b) of the *CPA*. The class is defined with objective criteria that will allow potential class members to know if they are within the class. The class definition bears a rational relationship to the common issues, and the pleaded causes of action. The plaintiffs' evidence establishes some basis in fact that there are at least two persons who fall within the class.

SECTION 4(1)(c): COMMON ISSUES

Legal principles

[85] To satisfy the requirement in s. 4(1)(c) of the *CPA*, the plaintiff must show some basis in fact that "the claims of the class members raise common issues, whether or not those common issues predominate over issues affecting only individual members". Section 1 of the *CPA* defines common issues as "(a) common but not necessarily identical issues of fact, or (b) common but not necessarily identical issues of law that arise from common but not necessarily identical facts".

[86] Given the arguments advanced on the present certification hearing, it deserves emphasis that the requirement that the plaintiff show "some basis in fact" for the common issues requirement does not involve an assessment of the merits of the claim, but rather its viability as a class proceeding. As explained by Rothstein J. in *Microsoft*:

> [100] The *Hollick* standard of proof asks not whether there is some basis in fact for the claim itself, but rather whether there is some basis in fact which establishes each of the individual certification requirements. …
>
> . . .

> [104] In any event, in my respectful opinion, there is limited utility in attempting to define "some basis in fact" in the abstract. Each case must be decided on its own facts. There must be sufficient facts to satisfy the applications judge that the conditions for certification have been met to a degree that should allow the matter to proceed on a class basis without foundering at the merits stage by reason of the requirements of s. 4(1) of the *CPA* not having been met.
>
> [105] Finally, I would note that Canadian courts have resisted the U.S. approach of engaging in a robust analysis of the merits at the certification stage. Consequently, the outcome of a certification application will not be predictive of the success of the action at the trial of the common issues. I think it important to emphasize that the Canadian approach at the certification stage does not allow for an extensive assessment of the complexities and challenges that a plaintiff may face in establishing its case at trial. After an action has been certified, additional information may come to light calling into question whether the requirements of s. 4(1) continue to be met. It is for this reason that enshrined in the *CPA* is the power of the court to decertify the action if at any time it is found that the conditions for certification are no longer met (s. 10(1)).

[87] The question underlying the commonality analysis is whether allowing the action to proceed as a class action will avoid duplication of fact-finding or legal analysis: *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at para. 39 [*Western Canadian*]. The commonality analysis is animated by the following principles:

> (1) The commonality question should be approached purposively.
>
> (2) An issue will be “common” only where its resolution is necessary to the resolution of each member’s claim.
>
> (3) It is not essential that the class members be identically situated vis-à-vis the opposing party.
>
> (4) It is not necessary that common issues predominate over non-common issues. However, the class members’ claims must share a substantial common ingredient to justify a class action. The court will examine the significance of the common issues in relation to the individual issues.
>
> (5) Success for one class member must mean success for all. All members of the class must benefit from the successful prosecution of the action, although not necessarily to the same extent.

Microsoft at para. 108, citing *Western Canadian* at paras. 39-40.

[88] A common issue need not dispose of the litigation. It is sufficient if it is an issue of fact or law common to all claims and its resolution will advance the litigation

for, or against, the class: *Charlton v. Abbott Laboratories Ltd.*, 2015 BCCA 26 at para. 85 [*Charlton*], quoting *Singer v. Schering-Plough Canada Inc*., 2010 ONSC 42 at para. 140. Certification of a common issue will not move the litigation forward if it is dependent on individual findings of fact that must be made for each class member, it is framed in overly broad terms, or it is not capable of benefitting all class members if successfully prosecuted: *Thorburn v. British Columbia (Public Safety and Solicitor General)*, 2013 BCCA 480 at para. 39.

Analysis

[89] The parties' submissions on the common issues requirement focussed on the general causation question inherent in proposed common issues (b), (c), and (d):

> b. Did the Defendants, or any of them, breach a duty of care to class members, and if so, when?
>
> c. In particular, was Alesse distributed and sold within Canada during the Class Period defective or fit for its intended use of preventing pregnancy?
>
> d. If the answer to question (c) is "yes", is the defective or unfit Alesse confined to Alesse 21 from Lot 2532 and Alesse 28 from Lot A3183 (the "Recalled Lots") or was the Alesse generally distributed by the Defendants within Canada during the Class Period defective or unfit for its intended use of preventing pregnancy?

[90] The parties agree that the question of whether the Alesse pills were fit for their intended use of preventing pregnancy is one of general causation: is the product capable of causing the harm alleged in its ordinary use?: *Harrington v. Dow Corning Corp.*, 2000 BCCA 605 at para. 42; *Stanway* at para. 12. The parties disagree on whether the plaintiffs have met their onus of showing some basis in fact for the common issues.

[91] General causation is fundamental to the plaintiffs' theory of commonality. The plaintiffs say this case is well-suited to adjudication as a class proceeding because the question of whether Alesse was fit for its intended purpose—that is, for preventing pregnancy—applies commonly across the class. Establishing that Alesse was defective, and that the defect increased the risk of pregnancy, is the common first step for all class members to a successful claim: *Stanway* at para. 55.

[92] The defendants' opposition to the certification of any common issues in this case is heavily dependent on two propositions:

a) the plaintiffs have not shown some basis in fact for the existence of an identifiable risk arising from the ingestion of Alesse pills during the Class Period that would justify a class proceeding; and

b) the plaintiffs have not shown some basis in fact for the existence of a workable methodology to determine the issue of general causation that is implicit in the proposed common issues.

[93] These propositions were a focus of the argument at the certification hearing. The arguments reflected a fundamental disagreement between the parties over the extent to which the defendants' submissions invite the Court into a consideration of the merits. Given the centrality of these two propositions to the defendants' objection to all of the plaintiffs' proposed common issues, I will begin the common issues analysis by addressing this debate between the parties.

Is there a basis in fact for the common issues?

[94] The defendants say that the plaintiffs' expert evidence does not provide any basis in fact to show that the Alesse pills were rendered less effective to prevent pregnancy as a result of either the issues identified in the Advisory or the lower estrogen levels measured by Emery Pharma. The defendants say that the plaintiffs cannot rely on the Product Monograph alone to establish that an Alesse pill must contain 20 mcg of estrogen in order to be effective. This is because the defendants' evidence is that the estrogen levels measured by Emery Pharma are within variation standards permitted by Health Canada.

[95] The defendants' arguments require consideration of the expert evidence that was tendered at the certification hearing. I note that neither party raised an objection to the admissibility of any of the affidavits that were tendered in evidence. The

evidence has not yet been tested. No cross-examination on the affidavits occurred prior to the certification hearing.

The plaintiffs' expert evidence

[96] The affidavit of Dr. Freeman, the plaintiffs' expert in forensic medicine and forensic epidemiology, includes the following observations:

> Estrogen has some effect with inhibiting follicular development because of its negative feedback on the anterior pituitary which slows FSH secretion; it's just not as prominent as the progesterone's effect.
>
> . . .
>
> The lowest amount of ethinyl estradiol found in recalled Alesse 21 samples was 17.99 (mcg) and in non-recalled Alesse 28 samples was 18 (mcg) which was **10%** less than the claimed about of 20 (mcg). It is noteworthy that these results were for the pills that were not broken, chipped, or smaller than normal. It is more likely than not that the broken or smaller pills would contain even less amount of ethinyl estradiol.
>
> . . .
>
> None of the tested samples whether recalled or non-recalled were broken or chipped and yet had 10% lower than the expected amount of ethinyl estradiol which indicates that there was a manufacturing defect in the normal shaped pills resulting in a lower level of ethinyl estradiol.
>
> . . .
>
> From the currently available data on the recalled and non-recalled Alesse pills, it is not possible to estimate the relative risk of pregnancy associated with the defective Alesse pills, versus the pills described in the drug monograph.
>
> . . .
>
> [T]he defective pills cannot be assumed to meet the advertised >99% rate of efficacy as claimed by Pfizer Canada Inc.

[97] Dr. Freeman proposes a methodology for estimating the relative risk of unintended pregnancy associated with the defective Alesse pills, versus the pills described in the Product Monograph. I address his proposed methodology later in this judgment in considering the parties' arguments on the question of the existence of a workable methodology.

[98] The first affidavit of Dr. Sid Katz, the plaintiffs' expert pharmacologist, includes the following passages:

> It should be noted that the samples tested were from Alesse pills that were not broken or chipped or smaller than normal. Testing of these defective pills would most likely yield even lower amounts of ethinyl estradiol and reduce the efficacy required for effective contraception.
>
> . . .
>
> According to The Pharmacological Basis of Therapeutics, the acknowledged authority on the pharmacokinetics of drug action, 'the intensity of a drug's effect is related to its concentration above a minimum effective concentration, whereas the duration of the drug's effect reflects the length of time the drug level is above this value. In general, these considerations apply to both desired and undesired (adverse) drug effects'. For a limited number of drugs, some effects are easily measured – such as blood pressure, blood glucose or, in the case of oral contraceptives, pregnancy – and can be used to optimize dosage using a trial and error approach.
>
> In terms of long-term therapy, such as the use of oral contraceptives, similar considerations apply to determine the amount of the active ingredients and frequency of drug administration required to achieve the optimal therapeutic effect. In this case, the Alesse product monograph prepared by Pfizer Canada states that Alesse 21 and Alesse 28 were more than 99 percent effective in preventing pregnancy when the amount of ethinyl estradiol administered was 20 micrograms or more.
>
> . . .
>
> It is more likely than not that based on a literature review lower levels of ethinyl estradiol (lower than 20 (mcg)) would result in a degree of lower efficacy the extent of which would have to be determined by a controlled study.

[99] Ms. Mosher has 27 years of experience as a licensed clinical pharmacist, and nine years of experience with the Alberta College of Pharmacists. Ms. Mosher opines as follows:

> Considering that Alesse is a critical dose drug, I would conclude that the differences in the recalled lot of Alesse 21 testing are more likely than not clinically significant resulting in a higher incidence of treatment failure. You may wish to seek the opinion of a Pharmacokineticist to evaluate the results of the test supplied and how those results might compare to in vivo studies.
> …
>
> . . .
>
> I can conclude that the testing results provided for the lots of recalled and non-recalled Alesse pills demonstrate that the Alesse pills are not as advertised, with the difference in the recalled lot of Alesse 21 potentially

> leading to treatment failure. Practically, I would not recommend to my patients a package of Alesse 21/28 that contained a defective tablet (i.e., less than 20 [mcg] of ethinyl estradiol) without a back-up method to prevent pregnancy.

The defendants' expert evidence

[100] The defendants' expert in obstetrics and gynecology, Dr. Reid, opines that the reduced levels of estrogen measured by Emery Pharma would not have reduced the effectiveness of the Alesse pills. His report includes the following passages:

> Health Canada met with the manufacturer to determine the extent of the problem and learned that a single broken pill had been found in blister packs of Alesse 21 and Alesse 28.
>
> . . .
>
> [The progestin component of the pill] suppresses the pituitary hormone – LH (Luteinizing Hormone) which is responsible for triggering the release of the egg from the ovary (Black 2016). The estrogen has a much lesser contraceptive effect. It acts in synergy with the progestin to suppress development of an egg in the ovary by suppressing the other pituitary hormone – FSH. …
>
> The reduction in estrogen dosage in modern day oral contraceptives has been accomplished without loss of contraceptive effectiveness because the main contraceptive ingredient in the pill is the progestin component. …
>
> . . .
>
> [T]he most important factors determining the contraceptive efficacy for the average woman relate to characteristics of her lifestyle that result in missed pills or delayed ingestion of pills. …
>
> In the manufacturing process for contraceptive steroids it is impossible to guarantee the precise dosage of each constituent pill. Rather, a range of concentrations close to the desired dosing is considered acceptable. In its application for new drug approval to Health Canada the manufacturers indicated that "the content for each of 10 (tablets tested) should be between 85% and 115 % of the nominal value". (Health Canada Guidance Document 2018) The product was approved with this understanding.
>
> Recent additions to the oral contraceptive market (approved by Health Canada) include pills with lower estrogen levels. …
>
> …Levonorgestrel is one of the most potent progestins in oral contraceptives and the 100 (mcg) of Levonorgestrel in the Alesse formulation would be more than enough to maintain contraceptive efficacy even in the face of small deviations from the nominal ethinyl estradiol content of 20 [mcg].

[101] Dr. Reid also questions the feasibility of Dr. Freeman's proposed methodology for comparing the effectiveness of Alesse as between the tested lots and the advertised product.

The plaintiffs' expert reply evidence

[102] The plaintiffs tendered a second affidavit from Dr. Katz which responds to the affidavit of Dr. Reid. The response affidavit includes the following passages:

> Health Canada did not discuss the incident as an isolated event which involved 'a single broken pill' but as a more general quality issue which required their ongoing attention including Recall and Safety Alert communications.
>
> Broken or smaller than normal birth control pills may deliver a smaller dose of the active drug ingredients which could reduce their effectiveness in preventing pregnancy. …
>
> . . .
>
> A literature review of combined oral contraceptives (COCs) found that the efficacy in regards to contraception prevention is similar across a wide range of estrogen doses…However, an open-label, uncontrolled multicenter study concluded that the incidence of unscheduled bleeding (intracyclic bleeding or spotting) may differ according to the estrogen dosage and was higher in those taking less than 20 [mcg] ethinyl estradiol COC…There was also a high percentage of withdrawals from this study due to untoward side effects (41.7%). Untoward side effects can have negative effects on medication compliance, which in itself results in lower efficacy.

[103] Dr. Katz also responded to Dr. Freeman's criticism of the plaintiffs' proposed methodology for determining the efficacy of Alesse pills that contain less than 20 mcg of estrogen.

Discussion

[104] In my view, the defendants' arguments require the Court to go beyond an inquiry into the viability of this action as a class proceeding, and to determine the proposed common issues in the defendants' favour. The defendants do not argue that the common issues are not common to the class. Instead, they say that the evidence supports findings that: (i) the effectiveness of Alesse as a method of birth control is not adversely affected if the estrogen contained in the pills is less than advertised levels; and, (ii) in any event, the defendants met their standard of care

because the estrogen levels measured by the Emery Pharma testing are within Health Canada-approved variations. The defendants invite the Court to make these findings despite the existence of conflicting expert evidence that has not been tested through cross-examination.

[105] I decline the defendants' invitation to weigh the strength of the expert evidence at this stage, and to conclude that Dr. Reid's evidence is more cogent. This is not the role of the court on a certification application, the focus of which is to determine the form an action will take and not whether it will be successful. For present purposes, it is sufficient to note that there is conflicting evidence in the record on the significance, if any, of reduced estrogen levels on the advertised efficacy of Alesse in preventing pregnancy. These conflicts in the evidence go beyond the expert affidavits. The consumer information in Part III of the Alesse Product Monograph expressly states that the pills are 99 percent effective in preventing pregnancy when "the amount of estrogen is 20 micrograms or more".

[106] There has been no documentary discovery to date. As such, it is impossible to know what testing, if any, the defendants carried out to determine that the Alesse pills are 99 percent effective when there is at least 20 mcg of estrogen. The defendants' affidavit evidence suggests an expansive testing program has been carried out in relation to Alesse. However, the testing results that have been produced are heavily redacted by the defendants. What is left unredacted are discrete passages that the defendants appear to consider helpful to their case.

[107] The defendants also rely on redacted documents in support of the contention that any deviation from 20 mcg of estrogen per Alesse pill was within the standard of variation permitted by Health Canada. The defendants rely on the evidence of Michel Provençal, a manager of regulatory affairs with Pfizer. Mr. Provençal's evidence goes into some detail about the manufacturing and testing of Alesse, generally and during the class period, and its compliance with variance standards. However, the supporting evidence exhibited to Mr. Provençal's affidavit is

extensively redacted, save the limited passages that the defendants wish to highlight.

[108] In my view, the defendants' submission regarding their compliance with Health Canada variation standards amounts to an argument that the defendants met their standard of care in the manufacture of Alesse. This is a defence that the defendants can advance on a common issues trial in arguing that they did not breach their duty of care to class members. However, for the reasons stated, I am not prepared to determine the merits of the claims of class members on a certification application. Among other concerns, it would be unfair and unsafe to resolve the claims on the basis of an evidentiary record that, at this stage, is untested and largely defined by what the defendants have elected to disclose.

[109] The plaintiffs have provided some evidence to show a basis in fact to support the existence of an issue that is common to the class about the quality of the Alesse pills during the class period. The plaintiffs have tendered expert evidence from three expert witnesses to the effect that the Emery Pharma test results, in conjunction with the issues identified in the Advisory, suggest the Alesse pills may not have been as effective in preventing pregnancy as was advertised in the Alesse label and Product Monograph.

[110] This action may well prove to be a challenging one for the plaintiffs, and class members, including on the difficult issues of causation that arise. The plaintiffs may not succeed at the end of the day. However, the prospect that the plaintiffs may not ultimately succeed does not defeat a certification application.

Is there some basis in fact for a workable methodology?

[111] The defendants' second proposition is that the plaintiffs have not shown some basis in fact that a plausible and workable methodology exists to determine the issue of general causation that is fundamental to their proposed common issues. The "general" causation question is concerned with whether a particular substance is capable of causing a particular harm. The "specific" or "individual" causation

question is concerned whether the substance in fact caused harm to a particular plaintiff: *Charlton* at para. 95. In *Charlton*, the Court of Appeal held as follows:

> [84] Where the applicants seek to address questions of causation on a class-wide basis and where causation is said to give rise to the commonality of interests, there must be some evidence of a methodology that will enable them to prove causation on a class-wide basis. While that rule is most clearly evident in cases brought by indirect purchasers, such as the claims considered in the 2013 Supreme Court trilogy, there is in my view no basis in principle to distinguish such claims insofar as this requirement is concerned. The evidence at the certification hearing must support the conclusion that certification of the common issue will advance the claim as pleaded. Where the proposed common issue is causation, there must be some evidence that issue may be resolved on a class-wide basis. Seeking evidence of a methodology of addressing causation for the class serves the objective of class proceedings and the *Act* must be applied with a purposive approach.

[112] The plaintiffs in *Charlton* sought to certify a class action on behalf of individuals who used or purchased the drug sibutramine, which Health Canada had approved for use as part of weight loss regimes. The drug was voluntarily withdrawn from the Canadian market after a clinical trial suggested an increased risk of serious cardiovascular events was associated with sibutramine use by patients with pre-existing heart problems. The plaintiffs alleged that the ingestion of sibutramine caused or contributed to a risk of adverse cardiovascular events in all consumers of the drug, whether or not they had pre-existing heart problems.

[113] The plaintiffs in *Charlton* tendered affidavits in support of certification by an expert cardiologist, Dr. Fitchett. Dr. Fitchett opined that sibutramine caused an increased risk of a cardiovascular event even in patients without a known history of cardiovascular disease. Dr. Fitchett acknowledged he was unable to quantify the risk. He did not propose a method of quantifying the risk. The statistical evidence that was available suggested there was no measurable increase in the risk for patients without a diagnosed history of cardiovascular events. In the absence of any evidence of a methodology that could plausibly assess the increased risk, the Court of Appeal found that the plaintiffs had not met their burden of showing some basis in fact that the general causation issue could be resolved at a common issues trial:

> [112] The evidence before the certification judge was that the question whether sibutramine causes or contributes to heart attacks, strokes, and arrhythmia on a class-wide basis is incapable of resolution. There was no evidence of a methodology for establishing that the class as a whole, as opposed to those who were wrongly prescribed sibutramine despite a history of disease, was affected or put at risk by its use of sibutramine. The appellants say the trial judge did not properly exercise his gatekeeping function; he is said to have erred by failing to consider whether the class had adduced some evidence of a method of proving the claim. I agree with that submission.
>
> [113] This cannot be said to be a case like *Stanway*, where the increased risk of a certain result to the class as a whole can be quantified. While there is no dispute that those with pre-existing cardiopulmonary disease are at a statistically increased risk of adverse cardiac events, this is not a case where the experts disagree on the extent of the risk, but rather, a case where the experts are uncertain whether there is a risk to the class as a whole and cannot describe a methodology for addressing that question. Further, there is no reason to believe that the certification of the question whether sibutramine posed a risk to those with pre-existing undiagnosed cardiac disease, an undefined segment of the class, will move the litigation forward.
>
> [Emphasis added]

[114] The plaintiffs are not required to provide evidence of a specific type of methodology; rather the plaintiffs must establish that there is realistic way to test the common issues at trial: *Miller v. Merck Frosst Canada Ltd.*, 2015 BCCA 353 at para. 46 [*Merck Frosst*].

[115] The issue of whether the plaintiffs have, in the present case, established some basis in fact that a workable and plausible methodology exists to establish general causation requires a further review of the expert evidence.

The plaintiffs' expert evidence on methodology

[116] Dr. Freeman opines that the "gold standard" approach to calculating the relative risk of pregnancy associated with Alesse pills containing less than 20 mcg of estrogen would be a randomized controlled study. One group of participants would take Alesse pills containing 20 mcg of estrogen, and the second group would take Alesse pills containing less than 20 mcg of estrogen. After adjusting for potentially confounding factors, the incidence of pregnancy in the two groups would be compared. Dr. Freeman acknowledges that it is highly unlikely that such a controlled

study could be conducted because it is not practically or ethically possible to randomize individuals to exposure to a defective drug.

[117] Dr. Freeman describes a second approach that he considers more feasible:

> Another approach would be conducting a case-control study following disclosure from provincial pharmacy regulators of data for women who were prescribed Alesse from recalled lots and non-recalled lots, which will permit a large sample-size statistical analysis of the efficacy of Alesse and a comparison with the defendants' efficacy claims. In this study, women taking OCPs [oral contraceptive pills] who have unintended pregnancies will be compared with a control group of women taking OCPs who do not have an unintended pregnancy, and the frequency of the use of defective pills will be examined in both groups. Such an approach is less reliable than an RCT [randomized controlled trial] but it's the best that can be done and sufficient to prove general causation on a balance of probabilities (as distinguished from scientific certainty).

[118] Dr. Katz sets out an alternative methodology for determining general causation in his affidavit, which is to conduct a study measuring plasma hormone levels associated with the process of reproduction in subjects exposed to defective Alesse pills as compared to those taking non-defective Alesse pills. As the progestin and estrogen in COCs work together to suppress ovulation by suppressing hormone levels, Dr. Katz posits that measuring the luteinizing hormone (LH) and follicle-stimulating hormone (FSH) levels in individuals taking Alesse pills with different levels of estrogen would indicate the relative suppression of hormone levels, which would in turn be indicative of the efficacy of the pills.

The defendants' expert evidence of methodology

[119] Dr. Reid opines that Dr. Freeman's proposed case control study is not feasible for ethical and practical reasons. He states:

> In Canada there is no way to collect accurate information about who was prescribed Alesse and whether the prescription was ever filled. Confidential medical records cannot be accessed to determine whether, and for how long, Alesse was actually used by individual women of if it was taken properly as prescribed.

[120] Even if it were possible to collect such information, Dr. Reid's view is that there are too many confounding factors to permit inferences to be drawn about the

cause of unintended pregnancies. The confounding factors include the reality that many women take COCs for non-contraceptive reasons (e.g. reduction and regulation of menstrual bleeding), and the possibility of inaccurate recall and reporting of whether the product was taken as prescribed many years ago.

[121] Dr. Reid does not comment on Dr. Katz's alternative proposed methodology for determining general causation by measuring plasma hormone levels.

The plaintiffs' reply expert evidence on methodology

[122] In his response affidavit, Dr. Katz addresses Dr. Reid's critique of the methodology proposed by Dr. Freeman. In response to Dr. Reid's suggestion that there is no way to collect accurate information about who was prescribed Alesse, Dr. Katz states:

> Information on who was prescribed Alesse, whether the prescription was filled and whether these records are accessible, depends on where you live in Canada. In British Columbia, the collation and recording of prescribed medications, including oral contraceptives, is the purview of the Ministry of Health of B.C. These PharmaNet records list the date, DIN [drug identification number], the quantity and strength of the medication prescribed as well as the prescribing physician. The appearance of the medication on the list indicates that the prescription has been filed. The records do not follow whether the medications were taken as prescribed or taken at all. The review of these records, though, would allow tracking of the history of medication purchase, renewal, possible switch to other medications, or discontinuation of treatment.

[123] In relation to Dr. Reid's concern about confounding factors, Dr. Katz notes that the clinical trials referenced in the Alesse Product Monograph, which presumably ground the "99 percent effective" estimate, would have involved similar confounding factors. Dr. Katz suggests that once the study design for the clinical trials is known, it would be possible to address confounding factors using the same methods as was used in the studies.

[124] Also in evidence is a letter from Irene Rae, Accounting Operations Branch of the Ministry of Health. Ms. Rae confirms that the Province of British Columbia has

retained RHE to advance its claim for recovery of health care costs under the *HCCRA* in this proceeding. Ms. Rae further advises as follows:

> In British Columbia the Province maintains PharmaNet, administered by the Ministry of Health, which is a record of every prescription that is dispensed along with the manufacturer name and drug identification number ("DIN").
>
> The Ministry of Health – Health Insurance BC – also maintains the medical services plan ("MSP") registry that contains a note of all publicly funded health care visits with diagnostic codes.
>
> From data held by the Province, it is possible to gather the data, on an anonymized basis, to establish:
>
> 1. How many women in BC were dispensed Alesse during a relevant time range; and,
>
> 2. The Medical Services Plan team can then conduct a search for pregnancy related visit or lab tests within MSP records.
>
> The Ministry is unable to confirm whether a patient took the drug or took it appropriately.

Discussion

[125] The defendants provide a lengthy critique of the methodologies proposed by Drs. Freeman and Katz. The defendants say that both methodologies are lacking in detail as to how the studies would be structured or conducted, how the studies will account for confounding factors, and, in the case of Dr. Freeman's proposal, how the gathering of personal information even on an anonymized basis would be consistent with provincial privacy legislation. The defendants suggest that the plaintiffs are asking the Court to act as a "laboratory" for fanciful methodological theories that have no scientific grounding.

[126] The defendants say the difficulties in the plaintiff's proposed methodologies are precisely the same as those that led the Court of Appeal in *Charlton* to conclude that the common issue requirement was not met. In my view, this case does not raise the same issue as *Charlton*. In *Charlton*, the plaintiff provided no evidence of a workable methodology to prove general causation. In the present case, the plaintiffs have provided evidence of methodologies that could be employed to determine the increased risk of pregnancy due to the alleged defects in the Alesse pills. The

defendants say that the methodologies are flawed and unworkable, however that raises a different issue than was addressed in *Charlton*.

[127] The issue in this case is whether the methodologies proposed by the plaintiffs' experts "are sufficiently credible or plausible to establish some basis in fact for the commonality requirement": *Microsoft* at para. 118. The proposed methodologies are not to be held to a "robust or rigorous standard" at this stage, and the court should not attempt to assess competing expert evidence: *Microsoft* at paras. 117-119.

[128] In my view, the methodologies proposed by Drs. Freeman and Katz are sufficiently credible or plausible to establish some basis in fact for the commonality requirement. They offer a realistic prospect of establishing general causation, which in turn would advance the individual claims of all class: *Merck Frosst* at paras. 68-72; *Microsoft* at para. 118.

[129] Dr. Freeman proposes a case-control study that would determine the efficacy of Alesse through a statistical analysis of a large sample size derived from provincial government data on individuals who have been prescribed Alesse. The proposed analysis would compare the incidence of defective pill use in a group comprised of individuals who had unintended pregnancies while taking Alesse, and a group who did not become pregnant while taking Alesse. If the analysis showed a correlation between the incidence of defective pills and the incidence of unintended pregnancies, this may support an inference of general causation. Dr. Freeman acknowledges this methodology is inferior to the "gold standard" of a randomized controlled trial, but the gold standard is not feasible here.

[130] The defendants say that Dr. Freeman's analysis is not plausible or workable because he does not explain how his analysis will account for the influence of confounding factors, for example the possibility that an unintended pregnancy may result from a failure to follow the manufacturer's instructions for oral contraceptive use rather than from a defective pill. Assuming that the failure to follow

manufacturer's instructions for use is a confounding factor, which itself is a proposition that requires some expertise to confirm, I do not agree that Dr. Freeman's failure to particularize at this stage how confounding factors will be reduced or minimized in the analysis is fatal at this stage. Statistical analysis of a type proposed by Dr. Freeman commonly requires the application of techniques to minimize confounding factors, whether in the design of the study or the gathering of data. This will no doubt have to be more fully addressed in the expert reports at trial. Dr. Freeman's failure to present a fully realized methodology at this stage does not make the proposed methodology implausible.

[131] The defendants next say that Dr. Freeman's analysis is not plausible or workable because there is no way to determine whether pills consumed in the past were in fact defective. In my view, this criticism is not responsive to the analysis that Dr. Freeman is proposing. The objective of Dr. Freeman's analysis is not to identify individual defective pills, but rather to compare the frequency of use of the allegedly defective pills in individuals who had intended pregnancies as compared to a control group of individuals who did not become pregnant. The defect may be confined to the Advisory lots, or, alternatively, may extend to other Alesse pills distributed during the Class Period. The plaintiffs' theory that Alesse pills were defective for their intended use of preventing pregnancy will be tested through Dr. Freeman's proposed analysis. If there is a statistically significant increase in the rate of unintended pregnancy in those who ingested pills from the Advisory lots, or from other Alesse pills distributed during the Class Period, the plaintiffs will argue that this establishes the pills were defective.

[132] The defendants also say that the plaintiffs have not provided some evidence of the availability of data to which the methodology is to be applied, which is required to establish commonality: *Microsoft* at para. 118. I do not agree. The plaintiffs have provided some evidence of the availability of data. The plaintiffs' evidence is that PharmaCare collects data on drug prescriptions, which includes the date of the prescription and a drug identification number, while the Medical Services Plan (MSP)

has data on the provision of pregnancy-related medical services. As I understand Ms. Rae's evidence, the two sources of information can be correlated so that it would be possible to establish when an individual who is prescribed Alesse obtained pregnancy-related medical services. There is evidence that the Province, an active participant in this litigation, will provide this information to the plaintiffs on an anonymized basis, which would then permit the statistical analysis proposed by Dr. Freeman to be conducted.

[133] The defendants say that provincial privacy legislation would prohibit the use of personal health information in this way, even if it is anonymized for the purpose of conducting a large sample size statistical analysis. The defendants do not identify the specific privacy legislation they say prohibits the use of anonymized health information. The evidence before the Court from a representative of the Ministry of Health is that the information is available and will be provided to the plaintiffs by the Province. This, in my view, is sufficient to discharge the plaintiffs' evidentiary burden on a certification application.

[134] Dr. Katz has proposed an alternative methodology for determining causation, which is to measure hormone levels in individuals taking Alesse pills with different levels of estrogen. The defendants' expert, Dr. Reid, does not comment on Dr. Katz's proposed methodology. The defendants argue that Dr. Katz's alternative methodology is also implausible and unworkable because it would not provide any information about the role of estrogen in preventing pregnancy. Further, the defendants say, it raises the same ethical issue identified by Dr. Freeman in providing some participants in the study with defective pills.

[135] It is not clear to me from the evidence that Dr. Katz's proposed methodology raises the same ethical concerns identified by Dr. Freeman. Dr. Katz's methodology does not anticipate measuring the increased risk of pregnancy by seeing how many study participants become pregnant while taking a defective pill. Rather, it anticipates measuring plasma hormone levels associated with the use of pills having different estrogen levels. Study participants who take the pills with lower estrogen

levels would presumably be warned, and advised to use alternative forms of birth control during the period of the study.

[136] The defendants object that Dr. Katz's focus on estrogen is "misplaced" because it is progestin and not estrogen that prevents pregnancy. This objection simply assumes the outcome of the analysis. The question of whether varying levels of estrogen can influence the effectiveness of Alesse in preventing pregnancy is the very question that Dr. Katz's methodology proposes to answer.

[137] In my view, Dr. Katz's proposed methodology, particularly in combination with Dr. Freeman's proposed methodology, establishes some basis in fact for the existence of a plausible methodology to determine the question of general causation on a class wide basis.

Should the proposed common issues be certified?

[138] This leads, finally, to the question of whether the plaintiffs' proposed common issues should be certified, apart from the general objections of the defendants that have already been addressed. The proposed common issues are, once again, set out in Appendix A to this judgment.

The common issues in negligence

[139] The defendants' primary objections to the certification of common issues in negligence are those that have already been addressed. The defendants did not otherwise argue that there is a lack of commonality in the proposed common issues.

[140] The proposed common issues in negligence concern the existence of a duty of care, whether there was a breach of the duty of care, and whether Alesse that was distributed and sold in Canada during the Class Period was fit for its intended purpose in preventing pregnancy. The common issues would require the resolution of issues fact and law that are common across the class. Their resolution in a common issues trial will avoid the duplicative litigation and fact-finding that would otherwise be required if class members advanced claims in negligence in individual

actions. Accordingly, I conclude it is appropriate to certify the proposed common issues in negligence (issues (a)—(d)).

The common issues under the BPCPA

[141] In respect to the common issues under the *BPCPA*, the defendants rely on the same objections that have already been addressed in relation to the common issues in negligence; that is, that there is no evidence that reduced estrogen levels lead to an increased risk in pregnancy, and no workable methodology to establish such a risk. As such, the defendants argue there was nothing deceptive in the labelling or marketing of Alesse, and therefore these issues should not be certified. The defendants argue, in the alternative, that even if liability issues under the *BPCPA* are common across the class, the entitlement to a remedy in damages under s. 171 involves individual issues of causation and damages that cannot be determined on a class basis.

[142] For the reasons already stated, I reject the defendants' arguments that the plaintiffs have not shown some basis in fact for the existence of common issues and a workable methodology for determining general causation. It is common ground between the parties that any assessment of damages under s. 171 will require the determination of individual issues. However, the plaintiffs are not seeking to certify common issues on remedies under the *BPCPA*. The common issues all relate to liability.

[143] In my view, the proposed common issues under the *BPCPA* also raise issues of fact and law that are common to the class, and their resolution on a common issues trial will avoid duplicative litigation. Depending on the outcome of the common issues trial, it may be necessary to have further individual trials on the issue of damages. However, the resolution of the liability issues will substantially advance the claims of class members. I therefore certify the common issues under the *BPCPA* (issues (e)—(h)). For the reasons already stated, I am not prepared to

certify proposed common issue (i), which concerns consumer protection legislation in other jurisdictions, at this time.

Common issues relating to punitive damages

[144] The defendants' primary opposition to the proposed common issues relating to punitive damages is that the claim for punitive damages is contingent on the assertion that Alesse was defective. The defendants say the plaintiffs have not shown a basis in fact for such an assertion, and therefore there is no basis for certifying common issues related to punitive damages. For the reasons stated, I decline the defendants' invitation to determine the merits of the plaintiffs' claims on the certification hearing.

[145] The defendants argue, in the alternative, that the question of entitlement to punitive damages is not common as it is linked to the effect of the defendants' conduct on individual plaintiffs. Further, where, as here, the plaintiffs acknowledge that there will necessarily be individual trials on liability and damages after the common issues trial, entitlement to punitive damages cannot be determined at a common issues trial. This is because punitive damages may only be awarded where other remedies are insufficient to achieve the objectives of retribution, deterrence and denunciation: *Whiten v. Pilot Insurance Co.*, 2002 SCC 18 at para. 123. The defendants thus say that at minimum, a bifurcated approach to punitive damages is necessary.

[146] Finally, the defendants say there is no basis in fact for the claim in punitive damages, in that the Second Amended NOCC consists of a bare allegation of egregious conduct on the part of the plaintiffs without a pleading of material facts to establish that conduct.

[147] In the Second Amended NOCC, the plaintiffs allege that the defendants have conducted themselves in a high-handed, wanton, and reckless manner, without regard to public safety. It is alleged that the defendants engaged in deceptive acts in failing to disclose all material facts regarding the risks of using Alesse. It is alleged

that the defendants caused the drug to be introduced in the stream of commerce in Canada, knowing that any such defects would cause foreseeable injury to the plaintiff and class members. It is alleged that the defendants failed to implement a timely recall of Alesse once the risks of unintended pregnancy were known to them.

[148] Reading the Second Amended NOCC generously, I interpret the claim for punitive damages to be based on the material facts that the defendants knew of the defects in Alesse, and engaged in a pattern of wrongdoing in continuing to sell the product in the Canadian market despite that knowledge. Assuming those facts to be true, they could arguably found a claim for punitive damages: *Rose v. British Columbia Life & Casualty Company*, 2012 BCSC 1296 at paras. 28-31.

[149] The plaintiffs' proposed common issues on punitive damages track the bifurcated approach that the defendants suggest would be required "at minimum". The first question (issue (j)), asks whether the defendants were guilty of conduct that justifies punishment. The second question (issue (k)), which concerns the quantification of punitive damages, only arises for determination once the aggregate compensatory award is known. The plaintiffs' proposal therefore anticipates that the second question, quantification, will be tried as a common issue after individual damages trials. This bifurcated approach has been endorsed by British Columbia courts: *Stanway v. Wyeth Canada Inc.*, 2011 BCSC 1057 at paras. 58–60, aff'd 2012 BCCA 260, citing *Chalmers v. AMO Canada Company*, 2010 BCCA 560 at para. 31.

[150] Accordingly, I conclude that the plaintiffs' proposed common issues relating to punitive damages (issues (j) and (k)), meet the commonality requirement and should be certified as common issues.

The common issue under the HCCRA

[151] The plaintiffs' final proposed common issue concerns the conditions for recovery under the health care cost recovery legislation. The plaintiffs proposed common issues ask whether they are "beneficiaries" within the meaning of health care cost recovery legislation, and whether unintended pregnancy constitutes a

personal injury so as to give rise to a claim for the recovery of the cost of health care services.

[152] The defendants argue that the answer to the question of whether unintended pregnancy can constitute a personal injury may be answered differently depending on the particular statute in issue. The defendants do not point to specific provisions in comparable legislation in other jurisdictions that are materially different from the *HCCRA*.

[153] I am unable to discern material differences in the various statutes. They all provide for the recovery of the cost of health care services from a wrongdoer in relation to a claimant's personal injuries. To the extent that there may be uncertainty as to whether pregnancy constitutes a personal injury within the meaning of health care costs recovery legislation, that is an issue that can be decided commonly across the class.

[154] I therefore certify the plaintiffs' final proposed issue (issue (l)) as a common issue.

Summary on common issue requirement

[155] In summary, I conclude that the plaintiffs have established some basis in fact for the certification of all of their proposed common issues, with the exception of issue (i). The plaintiffs' application to certify issue (i) as a common issue is adjourned to permit the parties to provide additional submissions, and to permit the plaintiffs to make any necessary amendment to their pleading.

SECTION 4(1)(d): PREFERABLE PROCEDURE

Legal principles

[156] Section 4(1)(d) of the *CPA* requires the plaintiff to establish that a class proceeding is the preferable procedure for the fair and efficient resolution of the common issues. "Preferable" refers to two ideas: the first is that the class proceeding would be a fair, efficient, and manageable means to advance the claim; the second,

that a class proceeding would be preferable to any other reasonably available means of resolving the class members' claims: *AIC Limited v. Fischer*, 2013 SCC 69 at para. 48.

[157] Section 4(2) of the *CPA* sets out a non-exhaustive list of the matters that the court must consider in determining whether a class proceeding is the preferable procedure for the resolution of common issues:

> (a) whether questions of fact or law common to the members of the class predominate over any questions affecting only individual members;
>
> (b) whether a significant number of the members of the class have a valid interest in individually controlling the prosecution of separate actions;
>
> (c) whether the class proceeding would involve claims that are or have been the subject of any other proceedings;
>
> (d) whether other means of resolving the claims are less practical or less efficient;
>
> (e) whether the administration of the class proceeding would create greater difficulties than those likely to be experienced if relief were sought by other means.

Discussion

[158] The defendants argue that the preferability requirement is not met in this case because the individual nature of the claims overwhelm any common issues. They say that the answer to the general causation question will not sufficiently advance the claims of class members to justify a class proceeding.

[159] In my view, having regard to the factors in s. 4(2) of the *CPA* and the objectives of class actions, a class proceeding is the preferable procedure for the resolution of common issues in this case.

[160] While there are individual issues that will have to be determined in order for any class member to succeed in their claims, those issues do not predominate. A common issue trial will resolve a fundamental controversy between the parties, which is the question of general causation. The complexity of that issue is apparent from the material filed on this certification application, and that complexity would act as a barrier to any class member attempting to individually litigate their claims. If

general causation is established on a common issues trial, this would advance the claims of all class members. If it is not established, all class members would be bound by the result, which is to the defendants' advantage.

[161] There is no evidence that any prospective class member has an interest in individually controlling the prosecution of their own action. With the agreement of class counsel on the Québec and BC actions to collaborate on the action here, the claims are not the subject of any other active proceeding. There are no other more practical or efficient methods of resolving the claims, or at least none that the defendants have identified.

[162] There are no greater difficulties associated with prosecuting this claim as a class action than an individual action. The certification hearing focussed on the challenges in proving causation in a case that concerns alleged defects in an oral contraceptive that are said to have led to an increased risk of unintended pregnancy. Those challenges would be present regardless of whether the plaintiffs' claims were pursued in an individual action or in a class proceeding. The advantage of a class proceeding from the plaintiff's perspective is that it would not place the entire burden of marshalling the resources necessary to prosecute the claim on individual plaintiffs. The advantage to the defendants is the prospect that if the plaintiff's case on causation is lacking in merit, the claims of all class members will be disposed of in a single proceeding.

[163] I therefore conclude the plaintiffs have met their burden of establishing a class proceeding is the preferable procedure for the fair and efficient resolution of the common issues.

SECTION 4(1)(e): REPRESENTATIVE PLAINTIFF

[164] Section 4(1)(e) of the *CPA* requires that there is a representative plaintiff who:

> (i) would fairly and adequately represent the interests of the class,

> (ii) has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding, and
>
> (iii) does not have, on the common issues, an interest that is in conflict with the interests of other class members.

[165] The defendants say that the plaintiff Taylor MacKinnon is not a proper representative plaintiff because she had not taken Alesse from one of the Advisory Lots when she became pregnant. This is tied to the defendants' argument that the class definition must necessarily be restricted to individuals who took Alesse from one of the two Advisory Lots. I have already explained my reasons for rejecting the defendants' argument on the proposed class definition. Ms. MacKinnon falls within the plaintiffs' proposed class definition, which I have accepted. The evidence supports that she would fairly and accurately represent the interests of the class.

[166] The plaintiff Alysa McIntosh was taking Alesse from one of the Advisory Lots. The defendants nevertheless say that Ms. McIntosh is also not a proper representative plaintiff because she cannot establish that she, in fact, took a damaged pill from one of the Advisory Lots. I do not agree that the class in this case must be confined to individuals who can establish that they took an undersized or broken pill from one of the Advisory Lots. For the reasons stated, I have accepted the plaintiffs' proposed class definition. The evidence supports that Ms. McIntosh would fairly and accurately represent the interests of the class.

[167] Finally, the defendants say that the plaintiffs' proposed litigation plan is "rudimentary, vague and formulistic", and provides no insight into how the plaintiffs anticipate the common and individual issues will actually be resolved. The defendants take particular issue with the lack of detail as to how individual issues of causation and damages will be determined after a common issues trial.

[168] The plaintiffs' litigation plan is relatively minimalist. It includes provision for notice to the class, examinations for discovery, document production, the exchange of expert reports, and the conduct of a common issues trial. The defendants are correct that there is limited detail regarding the individual trials that may follow the

common issues trial. The litigation plan appears to depend on the exercise of the court's case management powers under the *CPA*.

[169] The purpose of a litigation plan is to provide a framework for the class proceeding that shows that the representative and class counsel understand the complexities of the case. It is not intended to resolve all procedural issues before certification has occurred. It can be anticipated that litigation plans will require amendment as the case proceeds: *Jiang v. Vancouver City Savings Credit Union,* 2019 BCCA 149 at paras. 57—61 [*Jiang 2019*].

[170] As observed by the Court of Appeal at para. 61 of *Jiang 2019*, ss. 12, 27 and 28 of the *CPA* provide post-certification tools to address how individual issues will be resolved. The adequacy of a litigation plan may be viewed through the lens of the case-management tools available to the court post-certification.

[171] In my view, the plaintiffs' proposed litigation plan is sufficient at this stage of the proceeding to satisfy the requirement in s. 4(1)(e)(ii) of the *CPA*.

CONCLUSION/SUMMARY

[172] In summary, I make the following orders:

a) This action is certified as a multi-jurisdictional class proceeding pursuant to the *CPA*;

b) The class is defined as all persons resident in Canada who were prescribed Alesse 21 or Alesse 28 (collectively, "Alesse") and ingested said medications between January 1, 2017 and April 30, 2019;

c) The plaintiffs' proposed common issues in Appendix A to this judgment are all certified, with the exception of issue (i);

d) The plaintiffs' application to certify common issue (i) is adjourned to permit the parties an opportunity to provide additional submissions on the

certification of common issues relating to the legislation listed in para. 37b of the Second Amended NOCC;

e) The plaintiffs have leave to amend the Second Amended NOCC, as necessary, in order to further particularize the causes of action advanced under the legislation listed in para. 37b of the Second Amended NOCC;

f) The parties shall, within 30 days of the date of this judgment, take steps to schedule a further appearance before me in order to settle the terms and manner of notice under the *CPA*.

"Horsman J."

APPENDIX A

THE PLAINTIFF'S PROPOSED COMMON ISSUES

Negligence and Failure to Warn Issues

a. Did the Defendants, or any of them, owe a duty of care to class members?

b. Did the Defendants, or any of them, breach a duty of care to class members, and if so, when?

c. In particular, was Alesse distributed and sold within Canada during the Class Period defective or fit for its intended use of preventing pregnancy?

d. If the answer to question (c) is "yes", is the defective or unfit Alesse confined to Alesse 21 from Lot 2532 and Alesse 28 from Lot A3183 (the "Recalled Lots") or was the Alesse generally distributed by the Defendants within Canada during the Class Period defective or unfit for its intended use of preventing pregnancy?

Consumer Protection Issues

e. Did the Defendants' solicitations, offers, advertisements, promotions, sales and supply of Alesse for personal, family, or household use by class members during the Class Period fall within the meaning of "consumer transaction" under the *BPCPA*?

f. With respect to the supply in British Columbia of Alesse to class members for their personal, family, or household use during the Class Period, are the Defendants, or any of them, "suppliers" as defined in the *BPCPA*?

g. Are the class members "consumers" as defined by the *BCCPA*?

h. Did the defendants, or any of them, engage in conduct that constituted "deceptive acts or practices" contrary to the *BPCPA* as alleged in the Notice of Civil Claim?

i. Did the Defendants, or any of them, breach the applicable consumer protection legislation of the other provinces and territories?

Punitive Damages Issues

j. If the Defendants, or any of them, breached a duty of care owed to class members, were the Defendants, or any of them, guilty of conduct that justifies punishment?

k. If the answer to common issue (j) is "yes" and if the aggregate compensatory damages awarded to class members does not achieve the objectives of retribution, deterrence, and denunciation in respect of such conduct, what amount of punitive damages is awarded against the Defendants, or any of them?

Health Care Cost Recovery Issues

l. Are class members “beneficiaries” who are entitled to recover from the Defendants for Health Care Services provided by Provincial Health Insurers, as defined under provincial health and territorial health care cost recovery legislation? In particular, does an unwanted pregnancy constitute “personal injury” in order to warrant such recovery?