NO.:
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN

ROBYN KLIMEK

PLAINTIFF

AND

PFIZER INC., PFIZER CANADA ULC / PFIZER CANADA SRI, PHARMACIA & UPJOHN COMPANY LLC, and PHARMACIA & UPJOHN LLC

DEFENDANTS

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

NOTICE OF CIVIL CLAIM

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

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

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

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

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

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

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

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

Time for response to civil claim

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

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

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

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

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

PART 1: STATEMENT OF FACTS

Nature of the Action

1. This action concerns the Defendants' medroxyprogesterone acetate-based drug product marketed in Canada under the trade name "**Depo-Provera**". Depo-Provera plays a substantial and causal role in the development of meningiomas—a type of tumour that forms in the meninges of the brain and spinal cord.

2. The Plaintiff brings this proposed class proceeding for damages arising from the Defendants' negligent and wrongful conduct related to, *inter alia*, the design, research, development, testing, labelling, marketing, distribution, supply and sale of Depo-Provera. The Defendants knew or ought to have known that Depo-Provera was defective, but failed to ensure that it was safe for its ordinary use. They failed to adequately warn consumers and healthcare professionals that there was a significant risk of developing meningiomas arising from Depo-Provera use, and misrepresented Depo-Provera as safe when it in fact had a propensity to cause serious injury.

3. Ultimately, consumers like the Plaintiff have been harmed and suffered loss as a result of the Defendants' negligence and wrongdoing.

Defined Terms

4. In addition to terms defined elsewhere herein, this Notice of Civil Claim uses the term "**Depo-Provera**" to refer collectively to all drug products that have the active ingredient medroxyprogesterone acetate as an injectable suspension and were marketed, sold, imported, supplied and/or otherwise distributed in Canada by the Defendants under the brand name "Depo-Provera".

Parties

The Plaintiff

5. The Plaintiff, Robyn Klimek, has an address for service of 820-980 Howe Street, Vancouver, BC V6Z 2Z8. The Plaintiff resides in Houston, British Columbia.

6. Starting in approximately 2000, the Plaintiff was prescribed and began receiving injections of the Defendants' Depo-Provera product. She continued receiving Depo-Provera on a periodic basis until 2018. In 2020, the Plaintiff was diagnosed with two intracranial meningiomas.

7. The Plaintiff brings this action on her own behalf and on behalf of a class of persons in Canada who are similarly situated, to be further defined on the application for certification (the "**Class**" or "**Class Members**"). The Class includes persons in Canada entitled to claim by virtue of a personal, familial or beneficiary relationship.

The Defendants

i. Pfizer Inc. and Pharmacia Defendants

8. The Defendant, Pfizer Inc., is a corporation incorporated pursuant to the laws of Delaware and has a place of business at 235 E 42nd Street, New York, NY 10017, United States. All references in this Notice of Civil Claim to Pfizer Inc. include all of its predecessor corporations and all of their divisions.

9. Initially, Depo-Provera was designed and developed by Pfizer Inc. predecessors. In 2003, Pfizer Inc. acquired Pharmacia Corp., including its subsidiary Pharmacia

and Upjohn Company, and is now responsible for all liabilities which result from any acts or omissions of these entities which occurred prior to its acquisition.

10. At present, Defendant Pharmacia & Upjohn Company LLC ("**P&UC**") is a wholly owned subsidiary of Defendant Pharmacia & Upjohn LLC ("**P&U**" and collectively, "**Pharmacia Defendants**"). P&U is a wholly owned subsidiary of Pfizer Inc. These entities share a registered office with Pfizer Inc. at 235 E 42nd Street, New York, NY 10017, United States. At times relevant to this action, Pfizer Inc. had responsibility for the operations of the Pharmacia Defendants with respect to Depo-Provera.

11. Pfizer Inc. was a sponsor or market authorization holder for Depo-Provera in the United States during the times relevant to this proceeding.

12. P&UC has held the Canadian trademark to "Depo-Provera" during the times relevant to this proceeding.

13. Pfizer Inc. operates a manufacturing facility in Kalamazoo, Michigan which was first established through a predecessor entity, The Upjohn Company, in 1948. At times relevant to this action, the Kalamazoo manufacturing site served as one of the primary facilities globally for the manufacturing of Depo-Provera.

14. At all times relevant to this action, Pfizer Inc. and the Pharmacia Defendants were involved in and responsible for the research, development, design, testing, manufacture, labelling, marketing, distribution, supply and importing of Depo-Provera products which were sold in Canada, either directly or indirectly through their current or predecessor subsidiaries. Particulars of these responsibilities include, *inter alia*: the research related to Depo-Provera, the development and design of Depo-Provera, the preparation of regulatory applications, the maintenance of regulatory records, activities respecting intellectual property rights for Depo-Provera products, the manufacturing of Depo-Provera, labelling and promotional activities, and other actions central to the allegations of this lawsuit.

ii. Pfizer Canada ULC / Pfizer Canada SRI

15. The Defendant, Pfizer Canada ULC / Pfizer Canada SRI ("**Pfizer Canada**"), is a corporation incorporated pursuant to the laws of Nova Scotia, with a registered office in Vancouver, BC and a place of business at 17300 Trans-Canada Hwy, Kirkland, QC H9J 2M5. All references in this Notice of Civil Claim to Pfizer Canada include all of its predecessor corporations, including, without limitation, Pfizer Canada Inc., and all of their divisions.

16. Pfizer Canada is a wholly owned subsidiary of Pfizer Inc. At times relevant to this action, Pfizer Inc. had responsibility for the operations of Pfizer Canada.

17. Pfizer Canada is the sponsor or market authorization holder for Depo-Provera in Canada, meaning that it is an entity authorized by Health Canada to sell Depo-Provera within Canada. Pfizer Canada is listed on the product information documents for Depo-Provera in Canada.

18. Pfizer Canada licenses the "Depo-Provera" Canadian trademark from P&UC in marketing Depo-Provera in Canada.

19. At times relevant to this action, Pfizer Canada was involved in the research, development, design, testing, manufacture, labelling, marketing, distribution and sale of Depo-Provera across Canada, including in British Columbia. Particulars of these activities include, *inter alia*: the development of Depo-Provera for sale in Canada, the preparation of regulatory applications for submission to Health Canada, the maintenance of regulatory records, labelling and promotional activities, distribution and sale of Depo-Provera across Canada, and other actions central to the allegations of this lawsuit.

iii. Common Design

20. This Notice of Civil Claim uses the term "**Defendants**" to refer collectively to Pfizer Inc., Pfizer Canada, the Pharmacia Defendants, and all of their related and/or

predecessor corporations that were involved with the research, development, design, testing, labelling, marketing, distribution and sale of Depo-Provera.

21. At all material times, the Defendants were engaged in the business of researching, developing, designing, manufacturing, testing, labelling, packaging, promoting, marketing, importing, distributing, supply, and/or selling Depo-Provera in Canada, including in British Columbia. They did so either directly, or indirectly through agents, subsidiaries, affiliates, representatives or predecessors.

22. If and to the extent that any related corporations designed, developed, researched, tested, manufactured, imported, labelled, packaged, marketed, distributed, supplied or sold Depo-Provera in Canada, one or more of the Defendants is responsible for their conduct as master, employer, partner, joint venturer or alter ego. To the extent that any predecessor corporations designed, developed, researched, tested, manufactured, imported, labelled, packaged, marketed, distributed, supplied or sold Depo-Provera in Canada, one or more of the Defendants is responsible for their conduct as successor.

23. At all times relevant to this case, the Defendants acted pursuant to a common design in, *inter alia*, researching, developing, designing, testing, labelling, marketing, distributing and selling Depo-Provera in Canada, the particulars of which include, but are not limited to:

    (a) assistance in obtaining regulatory authorization for the marketing of Depo-Provera globally and in Canada;

    (b) licencing of trademarks to permit Pfizer Canada to market “Depo-Provera” in Canada;

    (c) cooperation in developing and maintaining product information, websites and other marketing material as sources of information regarding the use and safety of Depo-Provera that are used by consumers worldwide, including in Canada;

    (d) cooperation in conducting research, including clinical trials;

(e) sharing of data and information relevant to this proceeding, including results of scientific studies, sales and market data, safety information, and adverse reaction data; and

(f) adhering to global standards established by Pfizer Inc. for the conduct of its pharmaceutical business, including standards for monitoring and management of the risks associated with Depo-Provera, which applied to Pfizer Canada and all other subsidiaries that are or may be relevant to this proceeding.

24. The arrangement ensured that all parties to the common design had an incentive to maximize profit from the supply of Depo-Provera in Canada.

25. The business of the Defendants is and was inextricably interwoven with that of the other and each is the agent of the other for the purposes of the research, development, design, manufacture, testing, labelling, packaging, promotion, marketing, importing, distribution, supply and sale of Depo-Provera in Canada.

The Product: Depo-Provera

Background

26. The active ingredient in Depo-Provera, medroxyprogesterone acetate ("**MPA**"), is a hormonal medication of the progestin type.

27. A progestin is a synthetic progestogen. Progestogens are a type of drug which produces effects similar to those of the natural female sex hormone progesterone in the body.

28. Depo-Provera is the Defendants' brand-name, injectable form of MPA, also known as depot-medroxyprogesterone acetate ("**DMPA**"). DMPA functions like MPA, but is administered as an intramuscular or subcutaneous injection and forms a long-lasting "depot" from which the active ingredient, MPA, is released over a period of months.

29. Currently, Depo-Provera is indicated for use as a method of birth control in Canada. Prior to February 2024, it was also indicated for treatment of endometriosis.

30. The effects of Depo-Provera usually last at least three months.

31. Depo-Provera's active ingredient, MPA, works by binding to hormone receptors in the female reproductive tract and the brain's hypothalamus and pituitary gland. In particular, MPA acts as a full agonist of progesterone, androgen, and glucocorticoid receptors in the body. This means that MPA binds to these receptors with a similar (or better) affinity and efficacy relative to the endogenous hormones.

32. By providing a constant progesterone mimic, Depo-Provera prevents ovulation from occurring.

Development and Regulatory Approval

33. MPA was first developed in 1956 and introduced for limited medicinal use in the United States in 1959 by Pfizer Inc. predecessor, The Upjohn Company ("**Upjohn**"). Subsequently, Upjohn developed DMPA.

34. Following its development, DMPA was first assessed in clinical trials for use as an injectable contraceptive in 1963.

35. In the 1960s and 1970s, DMPA was approved by the U.S. Food and Drug Administration ("**FDA**") for non-contraceptive use: the treatment of endometriosis and for palliative treatment of certain cancers. Similarly, DMPA was cleared for these uses in Canada.

36. In 1967, Upjohn first sought U.S. FDA approval of intramuscular 150 mg/mL DMPA as a contraceptive under the brand name Depo-Provera, but the application was rejected. This formulation was introduced in countries outside of North America beginning in 1969. DMPA was available in over 90 countries worldwide by the time it was approved for contraceptive use by the U.S. FDA in 1992.

37. In 1984, Upjohn applied to Health Canada for a license to market DMPA as a contraceptive in Canada under the brand name Depo-Provera. Upjohn was optimistic that Depo-Provera would be approved for use as a contraceptive more quickly in Canada than in the U.S., with an Upjohn spokesperson noting: “We do things in a more private way in Canada … Here, it is really a matter between us and [Health Canada].” Upjohn’s Health Canada application was rejected in 1988.

38. In or around 1997, Depo-Provera was finally approved for marketing and sale as a contraceptive in Canada.

39. After receiving the necessary approvals from Health Canada, the Defendants’ predecessors, Pharmacia Corp and Pharmacia Canada Inc., introduced Depo-Provera for use as a contraceptive to the Canadian market.

40. Almost immediately thereafter and continuing on at all times relevant to this action, the Defendants began heavily marketing and promoting Depo-Provera for use as a contraceptive in Canada.

Sale and Marketing in Canada

41. Currently, Pfizer Canada is the approved Health Canada sponsor of Depo-Provera.

42. At all material times to this action, Depo-Provera has been the dominant DMPA product in Canada.

43. Since its approval for use as a contraceptive in Canada, Canadians have been exposed to extensive advertisements that were created, produced, financed, procured, uploaded, published and/or monitored by the Defendants.

44. The Defendants were engaged in a joint enterprise for the promotion, marketing, packaging, labelling, and advertising of Depo-Provera in British Columbia and elsewhere in Canada. Depo-Provera was jointly promoted through a variety of media sources in Canada: online, print, and television.

The Health Risk: Meningiomas

45. Meningiomas are a type of tumor that grows from the membranes that surround the brain and spinal cord, called the meninges. Meningiomas are usually benign (noncancerous). Symptoms of meningiomas may depend on their size and location, but can include seizures, paralysis, and problems with vision, language, hearing and memory. Since they can grow and put pressure on adjacent brain tissue and structures, they often require surgical or radiation treatment.

46. The meningioma is one of the only cerebral tumours whose predominance is female, with a sex ratio estimated at 3:1 after puberty. Studies have long described an increase in the size of known meningiomas at puberty, during pregnancy, or during the luteal phase of the menstrual cycle. Notably, Depo-Provera functions by mimicking the hormonal experience of the luteal phase of the menstrual cycle and pregnancy.

47. The use of Depo-Provera, which is genotoxic and alters the human body's natural hormonal processes, can cause and/or substantially contribute cause to meningiomas.

Independent Research

48. At all relevant times to this action, scientific evidence has demonstrated that healthy meninges and meningiomas both frequently express progesterone receptors ("**PR**"), androgen receptors ("**AR**"), and glucocorticoid receptors ("**GR**"). MPA has been known to act as an agonist of these receptors.

49. Since these hormone receptors are found on meningiomas frequently, early researchers hypothesized that manipulation of PR using MPA would be promising for meningioma *treatment*—a hypothesis that was quickly abandoned after studies using various progesterone agonists and antagonists were carried out beginning in the 1970s and 1980s.

50. Endocrine manipulation of meningiomas *in vitro* was attempted using short-term dosing with MPA in the 1980s. These studies demonstrated that MPA binds competitively to PR in meningioma cells, but the effects could not be elucidated. One study showed possible stimulation of meningioma growth. Simultaneously, studies testing other PR agonists similarly showed no effect or possible stimulation, while the use of PR *antagonists* demonstrated the opposite: promising results and marked regression in meningioma growth.

51. By the late 1980s, it was shown that MPA was a progesterone agonist that could potentially stimulate abnormal cell growth in the meninges by binding to PR, leading to tumor development. Researchers also raised concerns that MPA could alter cellular signal pathways that control cell growth and tumour formation.

52. Similarly, the genotoxicity of MPA has also been demonstrated repeatedly in a variety of cell types and animals since MPA's development.

53. At least as early as the 1990s, it has been repeatedly demonstrated in human populations that meningioma risk is increased with certain exogenous sex steroid hormone exposures and, more specifically, high-dose progestogen treatments like Depo-Provera.

54. In November 2021, independent researchers noted the risk of meningiomas associated with progestin use and described specific features of progestin-associated meningiomas in Europe.

55. In February 2023, independent researchers in the United States highlighted evidence of a progestin-dependent meningioma syndrome associated with chronic DMPA use.

56. In June 2023, independent researchers in France published a large epidemiological study confirming that the prolonged use of DMPA was found to significantly increase the risk of intracranial meningiomas in a population in France. This study was published in the *BMJ* in March 2024. The DMPA product used in

France is a lower concentration than the one typically used in Canada, with the regular dosage being 150 mg/3 mL.

57. In January 2023, the French National Agency for the Safety of Medicines and Health Products ("**NASM**") formed a committee investigating this connection. By July 2024, the NASM formally recommended implementation of risk minimisation measures for MPA-containing products due to identified meningioma risks.

58. In August 2024, the Ministry of Health of Malaysia issued a warning to healthcare professionals regarding the risk of meningiomas with prolonged use (≥ 1 year) of high-dose MPA.

59. In September 2024, the European Medicines Agency's Pharmacovigilance Risk Assessment Committee ("**PRAC**") highlighted the risk of meningioma with high doses and prolonged use of MPA and recommended measures to minimize this risk. The PRAC agreed that a direct healthcare professional communication should be issued to inform healthcare professionals of this risk. PRAC's recommendations followed a review of data from epidemiological studies, case studies from medical literature, and adverse events reported in the pharmacovigilance database of the European Union.

60. In September 2024, the Hong Kong Department of Health issued a safety alert regarding the risk of meningioma with medicines containing medroxyprogesterone acetate, and also sent letters to inform healthcare professionals of the risk.

Adverse Event Reports

61. Tumours generally, and also meningiomas specifically, have been the subject of thousands of adverse events reported in consumers using Depo-Provera. Since the early 2000s, the U.S. FDA Adverse Event Reporting system ("**FAERS**") has shown numerous reports of meningiomas in Depo-Provera users. According to FAERS, each of the reported meningioma cases has been classified as "serious" with a number leading to outcomes such as hospitalization.

Defendants' Conduct in Addressing the Risks

Inadequate Research and Development

62. At all material times to this action, the Defendants knew or ought to have known that Depo-Provera played a causal role in the development of meningiomas.

63. Depo-Provera has been the subject of numerous research studies. At least as early as 1985, the Defendants knew or ought to have known that use of Depo-Provera, and its active ingredient, was a risk factor in development of meningiomas. At times relevant to this action, the Defendants knew or ought to have known of the multitude of scientific evidence that demonstrated, *inter alia*:

(a) the genotoxic and tumour-initiating potential of MPA;

(b) the hormone dependence of meningiomas, including the tendency for these tumours to express PR, AR and GR;

(c) that MPA was a potent agonist of PR, AR and GR;

(d) that PR agonists, including MPA, were ineffective at inhibiting meningioma growth;

(e) that MPA could alter cellular signal pathways that control cell growth and tumour formation;

(f) the development and/or growth of meningiomas during receptor agonist use, including MPA, in several case studies;

(g) associations between meningioma risk in humans and exogenous sex steroid hormone exposures, including progestogen treatments;

(h) significant associations between meningioma risk in humans and high-dose progestin treatments, including MPA and DMPA; and

(i) evidence of a progestin-dependent meningioma syndrome linked to a unique set of features in meningioma patients.

64. Defendants knew many of these facts before their Depo-Provera products were marketed in Canada for use as contraceptives. They closely monitored the scientific literature relating to MPA and meningiomas, including independent literature in the public domain.

65. As the developers and manufacturers of Depo-Provera, the Defendants were uniquely positioned to further study the propensity for meningiomas to develop as a result of Depo-Provera use.

66. Despite repeatedly being met with evidence concerning the link between meningiomas and Depo-Provera use, the Defendants failed to investigate and research to assess the safety of their medication through pre- and post-marketing studies, tests and trials.

67. At certain times, the Defendants conducted research in a grossly negligent fashion, such that their internal and external evidence was inadequate, unusable, insufficient and/or too poorly designed for assessment of the risks.

68. To the extent that the Defendants did not “know” any of these facts, it was solely due to their own willful ignorance and negligence. The Defendants had the means and wherewithal to conduct tests to investigate Depo-Provera’s meningioma risk since the 1960s. The Defendants did not investigate further; instead, they consistently and flagrantly ignored obvious indicators of Depo-Provera’s meningioma risk for decades.

69. A reasonable pharmaceutical manufacturer should have recognized the obvious red flags pointing to a causal role of MPA in meningioma development, and should have conducted further testing, research and investigation to determine the extent of the risk relevant to the users of their products.

70. Further, the Defendants did not provide adequate safety and adverse reaction data to regulators with respect to Depo-Provera. The Defendants’ lack of reasonable investigation and transparency is the cause for any regulatory ignorance that may exist with respect to the risk of meningiomas arising from Depo-Provera use.

71. The Defendants adopted an unreasonable, careless and/or defective product design for Depo-Provera that resulted in an increased risk of meningiomas. During the period of time that the Defendants’ Depo-Provera products have been marketed and sold to Canadians, there have existed safer and economically

feasible alternative options for both contraception and endometriosis treatment, including long-term and estrogen-free options which do not have the propensity to cause meningiomas. The Defendants' conduct hindered, delayed and/or prevented the adoption and use of these alternatives.

72. The Defendants knew or should have known that Depo-Provera posed a serious risk of harm to consumers. By failing to adequately research, design, develop and conduct surveillance of Depo-Provera, the Defendants showed a flagrant indifference to public safety and to the health of the Plaintiff and Class Members.

Inadequate Warning of the Meningioma Risk Linked to Depo-Provera

73. The Defendants are and have been responsible for ensuring that Canadian consumers and their health care providers are fully and adequately warned of the foreseeable risks and adverse side effects associated with Depo-Provera use.

74. Due to the way Depo-Provera is administered, adequate warnings are of a heightened importance relative to other forms of contraception. Once outside the immediate context of an encounter with a healthcare professional, consumers can choose whether or not to take oral contraceptive pills on a daily basis. Depo-Provera, on the other hand, is given by injection and its effects last several months; noncompliance is not an option. From the perspective of a patient taking on the attendant long-term risks of the product, there is a significant power imbalance in favour of the product manufacturers.

75. At all material times, the Defendants failed to warn or failed to adequately warn consumers and healthcare professionals, including the Plaintiff and other putative Class Members, of the risk of meningiomas arising from the use of Depo-Provera.

76. At all material times, the product monographs, labels, prescribing information and other packaging and marketing materials did not warn or did not adequately warned consumers of the risk of meningiomas arising from the use of Depo-Provera. The Defendants negligently, recklessly and/or carelessly marketed,

distributed and/or sold Depo-Provera without adequate warnings of the products' dangerous risk.

77. Currently, and at all relevant times, none of the information directed at Canadian users of Depo-Provera explains the seriousness or severity of the risk of meningioma development linked to the drug. It does not, among other things, discuss specific meningioma symptoms that patients and healthcare professionals should be aware of, recommend risk management measures such as imaging and monitoring, or describe the potential subsequent medical treatment that may be required if a meningioma is diagnosed. Additionally, it does not warn of irreversible damage that may occur to the central nervous system if a meningioma is developed.

i. Canadian Product Monograph

78. One means by which the Defendants must communicate the risks and side effects is through the Canadian product monograph for Depo-Provera ("**Product Monograph**"). Product Monographs are distributed by the Defendants directly and indirectly to health care professionals and individual patients in Canada, and are also made available on Pfizer Canada's website.

79. Part I of the Product Monograph is directed at health care professionals in Canada; Part III is directed at consumers in Canada.

80. Despite all of the available information regarding the risk of meningiomas arising from Depo-Provera use, the Defendants failed to adequately or appropriately change the Product Monograph, labels, prescribing information, and other packaging materials in a timely manner or take adequate steps to warn the medical community and users of Depo-Provera of this risk. To the extent that information on meningiomas is contained in the Product Monograph, that information is inadequate, deficient, and/or misleading.

81. As of September 2024, the Defendants do not provide any meaningful or adequate warning about the risk of meningioma development in the Product Monograph. The

Product Monograph contains a black box warning section titled “Serious Warnings and Precautions” in addition to a section with general warnings. These sections contain no reference to meningiomas.

82. The current Product Monograph (Part III) warns patients not to use Depo-Provera if they have or suspect a cancer, including cancer “of the breasts, uterus or ovaries” or “a cancer that grows in response to progesterone”. It fails to make any warning of the risks associated with noncancerous tumours such as meningiomas.

83. The current Product Monograph (Part I) lists “known or suspected progestin-dependent neoplasia” as a contraindication for Depo-Provera. This is of limited utility as a warning, given that a majority of meningiomas are not known or suspected until they have already become symptomatic, by which point the patient risks irreversible and permanent injury.

84. The only time meningiomas are referenced in the Product Monograph is in passing in Part I, with a single reference within a long list of adverse reactions under the heading “Post-Market Adverse Reactions”. The section begins with a disclaimer that “the nature of post-marketing surveillance makes it difficult to determine if a reported event was actually caused by DEPO-PROVERA.”

85. In contrast, the Product Monograph provides detailed warnings about the association between breast cancer and Depo-Provera use, and directs healthcare professionals to counsel patients regarding the importance of monitoring for breast cancer.

ii. Marketing Materials

86. Similarly, the Defendants’ marketing materials to consumers for Depo-Provera failed to warn of the risk meningiomas.

87. At all material times, the Defendants’ marketing materials to consumers for Depo-Provera omitted any reference to risk of developing meningiomas. Instead of adequately informing consumers of potential risks, the Defendants’ marketing

materials to consumers for Depo-Provera were directed at attracting consumers to seek out the initiation or continuation of using Depo-Provera without sufficiently warning of the risks of developing injuries like meningiomas.

88. It was reasonably foreseeable that Canadians would receive the messages from these marketing and promotional activities and would act in reliance upon them to use Depo-Provera.

ii. Warnings in other jurisdictions

89. Despite failing to adequately warn Canadians of the risk of meningiomas associated with Depo-Provera use, the Defendants have taken action to acknowledge the meningioma risk and provide substantial warnings in other jurisdictions, including but not limited to: France, the United Kingdom, and New Zealand.

90. In France, the Depo-Provera product information for patients was revised in May 2024 to include:

(a) A black box warning at the top of the information sheet, noting the risk of meningioma with prolonged use of more than 1 year.

(b) Under the “Warnings and Precautions” section, the addition of a specific section titled “Meningiomas”. This section is placed under the “Breast Cancer” subsection which is already present in the Canadian Product Monograph. This addition provides detailed information about the risk of meningiomas associated with MPA use, meningioma symptoms that patients and healthcare professionals should be aware of, recommended guidelines for brain image monitoring, and the potential subsequent medical treatment that may be required if a meningioma is diagnosed.

91. Similarly, the Depo-Provera product information for healthcare professionals in France was revised to include:

(a) A black box warning noting the risk of meningioma with prolonged use of more than 1 year.

(b) A black box warning noting that the prescriber should inform the patient of the risk of meningiomas, symptoms of meningiomas, and of the monitoring information.

(c) Under the “Dosage and Administration” section, guidance directing that: (a) the patient’s age and evolution symptoms must be considered when re-prescribed after a year; and (b) warning that prolonged use at high doses should be avoided since the risk of meningiomas increases with dosage and duration of use.

(d) Under the “Special Warnings” section, the addition of a specific section titled “Meningiomas”, similar in nature to the revision to the patient information sheet. This addition provides guidelines for brain image monitoring, noting that that MRI imaging of the brain should be performed at the end of the first year of treatment with Depo-Provera if treatment is being renewed. It also directs patients with additional risk factors for meningiomas (such as a history of brain radiotherapy in childhood) to be monitored immediately.

92. In New Zealand, the Depo-Provera product information for healthcare professionals and patients was revised in February 2024 to include warnings of the risk of meningiomas. The revised NZ product information for healthcare professionals lists the association between meningiomas and long-term administration of progestogens under the heading “Special Warnings and Precautions for Use”. Similarly, the revised NZ product information for patients explicitly directs that the patient tell their doctor if they have ever had a brain or spinal cord tumour or abnormal growth.

93. In the United Kingdom, the Depo-Provera product information for patients and healthcare professionals was revised in May 2024 to include warnings of the risk of meningiomas. The revised UK product information for healthcare professionals lists the association between meningiomas and long-term administration of progestogens under the heading “Special Warnings and Precautions for Use”. Similarly, the revised UK product information for patients explicitly directs that the patient tell their doctor if they have ever had a meningioma.

94. The Canadian Product Monograph was last updated in February 2024. As of February 2024, Depo-Provera is no longer indicated for treatment of endometriosis in Canada.

95. Updates and modifications similar to the ones described above were not implemented in Canada.

Harms Suffered by the Plaintiff and Class

96. Class Members, including the Plaintiff, suffered and will continue to suffer harms, losses and damages as a result of the Defendants' negligent and wrongful conduct. Such harm, loss and damage was reasonably foreseeable by the Defendants.

97. Subsequent to using Depo-Provera, the Plaintiff and Class Members have suffered injuries which are long-lasting or permanent in nature, including physical and mental injury, diminished enjoyment of life, as well as the need for lifelong medical monitoring and/or treatment.

98. Had the Plaintiff and the Class been adequately warned of the nature and severity of the risk of meningiomas arising from the use of Depo-Provera, these harms would have been avoided. They would have explored one or more of the many other viable alternatives available to them and/or taken appropriate risk management measures to mitigate the harms suffered.

99. Particulars of the losses suffered by the Plaintiff and Class Members which were caused or materially contributed to by conduct of the Defendants alleged herein include:

(a) personal and mental injury, including meningiomas and the attendant symptoms and harms;

(b) lost past and prospective earnings and housekeeping capacity;

(c) costs of past, ongoing and future care;

(d) special damages for costs of medical and treatment expenses, out-of-pocket expenses, and other attendant services; and

(e) costs and expenses associated with medical monitoring and medical tests, including those incurred to date.

100. At all material times, the Plaintiff and Class Members were in a relationship of proximity with the Defendants. But for the Defendants' negligent and wrongful conduct, the Plaintiff and Class Members would not have incurred damages.

Plaintiff's Experience

101. Subsequent to beginning to use Depo-Provera, the Plaintiff began experiencing symptoms such as blurring vision, weakness in her limbs, memory issues, nausea and facial paralysis. Unable to work, she underwent imaging studies and other testing and was eventually diagnosed with two meningiomas in 2020.

102. Depo-Provera played a substantial and causal role in the Plaintiff's development of meningiomas.

103. The Plaintiff continues to experience pain, suffering, disability and emotional distress due to her meningiomas.

104. The Plaintiff relied on representations made by the Defendants with respect to the use, safety and efficacy of Depo-Provera. The Plaintiff was not appropriately warned by the Defendants of the risk that Depo-Provera could cause her to develop a meningioma.

105. At no time during the 18-year period over which the Plaintiff received Depo-Provera injections did the Defendants, or anyone, inform her of all potential dangers, complications and side effects from using Depo-Provera. At all material times, the Plaintiff did not know the nature and extent of the injuries that could result from the intended and reasonably foreseeable use of Depo-Provera, including the risk of developing a meningioma.

106. Had the Defendants informed the Plaintiff and her health care providers of the risk of developing meningiomas arising from the use of Depo-Provera, she would not have taken Depo-Provera. She would have chosen an alternative option that does not have the propensity to cause or substantially contribute to the development of meningiomas.

107. As a direct and proximate result of the Plaintiff's use of Depo-Provera and the Defendants' negligent and wrongful conduct alleged herein, the Plaintiff developed meningiomas and has sustained losses and damages, as described at paragraph 99, some or all of which are or may be permanent.

108. In particular, as a result of her injuries, the Plaintiff has suffered damage to her central nervous system and will continue to be susceptible to future degeneration as a result. Additionally, the Plaintiff has suffered a loss and impairment of her general health, strength, and vitality. She has also suffered prolonged and serious mental distress, trauma and emotional dysfunction as a result of her injuries.

109. The Plaintiff's injuries have and will continue to cause her suffering, loss of enjoyment of life, permanent disabilities, loss of earning capacity and housekeeping capacity. She has and will continue to undergo medical care and treatment related to her injuries.

PART 2: RELIEF SOUGHT

110. The Plaintiff claims on her own behalf and on behalf of the Class Members:

(a) an order certifying this action as a class proceeding and appointing Robyn Klimek as the representative plaintiff under the *Class Proceedings Act,* R.S.B.C. 1996 c. 50 ("***CPA***");

(b) a declaration that the Defendants were negligent in the development, design, testing, labelling, warning, marketing, distribution and sale of Depo-Provera;

(c) a declaration that the Defendants engaged in conduct contrary to the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2 (the "***BPCPA***") and comparable legislation in the other provinces and territories (collectively, the "**Consumer Protection Legislation**"), including:

- *Consumer Protection Act*, 2002, SO 2002, c. 30 ("***ON CPA***");
- *Consumer Protection Act*, RSA 2000, c. C-26.3 ("***AB CPA***")
- *Consumer Protection and Business Practices Act*; SS 2014, c. C-30.2 ("***SK CPBPA***");
- *Business Practices Act*, CCSM, c.B120 ("***MB BPA***");
- *Consumer Protection Act*, CQLR c. P-40.1, ("***QC CPA***");
- *Business Practices Act*, RSPEI 1988, c. B-7 ("***PEI BPA***");
- *Consumer Product Warranty and Liability Act*, S.N.B. 1978, c. C-18.1 ("***NB CPWLA***");
- *Consumer Protection and Business Practices Act*, SNL 2009, c. C-31.1 ("***NL CPA***"),

(d) a declaration that the Defendants engaged in conduct contrary to s. 5(1) of the *Food and Drugs Act*, RSC 1985, c. F-27 ("***FDA***") and related legislation;

(e) a declaration that the Defendants are vicariously liable for the acts and omissions of their officers, directors, agents, employees, and representatives;

(f) general and special damages;

(g) non-pecuniary damages;

(h) damages pursuant to the *Family Compensation Act*, RSBC 1996, c. 126, and comparable legislation and common law in other provinces and territories, where applicable ("**Family Compensation Legislation**");

(i) relief pursuant to the Consumer Protection Legislation, where applicable;

(j) punitive, aggravated, and exemplary damages in an amount to be determined at trial;

(k) in alternative to the claim for damages, an accounting or other such restitutionary remedy disgorging the revenues realized by the Defendants from the sale of Depo-Provera;

(l) recovery of health care costs incurred by provincial and territorial governments on behalf of Class Members pursuant to the *Health Care Cost Recovery Act*, SBC 2008, c 27 and comparable health and hospital insurance legislation in other provinces and territories, where applicable ("**Health Care Cost Recovery Legislation**");

(m) costs;

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

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

PART 3: LEGAL BASIS

111. The Plaintiff realleges and reaffirms herein all factual pleadings set forth in paragraphs 1 through 110.

112. The Plaintiff pleads and relies on the *CPA*, the *Court Jurisdiction and Proceedings Transfer Act*, S.B.C. 2003, c. 28, the *Court Order Interest Act*, RSBC 1996, c 79; the Consumer Protection Legislation, the *Negligence Act*, RSBC 1996, c 333, the Family Compensation Legislation, the Health Care Cost Recovery Legislation, the *Limitation Act*, SBC 2012, c 13, the *Limitation Act*, RSBC 1996, c 266, the *Supreme Court Civil Rules*, BC Reg 168/2009, all as amended and any regulations

thereunder and any equivalent provincial and territorial legislation as may be enacted, and such further and other statutes as counsel may advise.

Causes of Action

Negligence (including Negligent Design, Negligent Testing, and Failure to Warn)

113. The Plaintiff pleads and relies upon the provisions of the *Negligence Act*.

114. As the designers, developers, testers, researchers, manufacturers, labellers, packagers, marketers, importers and distributors of Depo-Provera, the Defendants were in such a close and proximate relationship to the Plaintiff and Class Members as to owe them a duty of care.

115. The Defendants designed MPA to be used as the active ingredient in Depo-Provera, conducted testing of MPA, DMPA and Depo-Provera products, procured regulatory approvals for the marketing and sale of Depo-Provera for contraceptive and other uses, and caused Depo-Provera to be introduced into the stream of commerce in Canada. This was done despite the Defendants' knowledge that any dangers or defects in Depo-Provera would cause foreseeable injury to the Plaintiff and the Class.

116. At all material times, the Defendants, and each of them, owed a duty of care to the Plaintiff and the Class to:

(a) ensure that Depo-Provera was fit for its intended and/or reasonably foreseeable use and of merchantable quality;

(b) design Depo-Provera so as to avoid safety risks and to make it reasonably safe for its intended purposes;

(c) conduct adequate pre- and post-market investigation to determine whether and to what extent use of Depo-Provera posed serious health risks, including the magnitude of the risk of developing meningiomas;

(d) monitor, investigate, evaluate and follow-up on scientific literature and adverse reaction data related to Depo-Provera;

(e) warn consumers of dangers inherent in the use of Depo-Provera which they knew or ought to have known;

(f) ensure that all healthcare professionals and patients were kept fully and adequately informed and warned regarding all risks associated with Depo-Provera;

(g) properly inform regulatory agencies of all risks associated with Depo-Provera.

117. The Defendants negligently breached their duty of care.

118. The damages suffered by the Plaintiff and the Class were caused by negligence of the Defendants in breach of their duty of care, including:

(a) failing to ensure that Depo-Provera was not dangerous to recipients during the course of its intended and/or reasonably foreseeable use and that it was of merchantable quality;

(b) designing and developing Depo-Provera in a way which created a substantial likelihood of harm when there existed safer alternative designs, active ingredients and/or products which were technically and economically feasible to manufacture and as effective;

(c) failing to conduct adequate pre- and post-market investigation of Depo-Provera in a manner that would disclose the risk of meningiomas arising from its use, including long-term studies and studies that would disclose the magnitude of the risk;

(d) failing to adequately monitor, investigate, evaluate, consider and act on available scientific literature and adverse reaction data relevant to Depo-Provera;

(e) failing to provide the Plaintiff, Class Members and their healthcare professionals with proper, adequate, full and/or fair warnings of the risk of meningiomas arising from the use of Depo-Provera;

(f) failing to adequately alert the public, patients and healthcare professionals of the risk of meningiomas arising from the use of Depo-Provera in a timely manner;

(g) failure to provide regulatory agencies, including Health Canada, with complete and accurate information respecting the risks of Depo-Provera as it became available;

(h) failing to provide adequate instructions, guidance and safety measures with respect to mitigating and monitoring meningioma risk for patients and healthcare professionals;

(i) failure to timely cease marketing of Depo-Provera that was misleading and/or deceptive with respect to the risk of meningiomas;

(j) misrepresenting the available research and evidence pertaining to the purported benefits of Depo-Provera and its associated risks, including the risk of meningiomas;

(k) failure to conform with applicable disclosure and reporting requirements pursuant to the *FDA* and its associated regulations;

(l) failing to establish any adequate procedures to educate and/or train their employees, sales representatives and physicians with respect to all of the above;

(m) failure to properly supervise their employees, subsidiaries and affiliated corporations with respect to all of the above;

(n) promoting a culture of silence whereby the harmful effects of its products were never investigated or communicated to the public;

(o) breach of other duties of care to the Plaintiff and Class Members, details of which breaches are known only to the Defendants; and

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

119. In all of the circumstances of this case, the Defendants applied callous and reckless disregard for the health and safety of the Plaintiff and Class.

120. The Defendants' negligent and wrongful conduct, as alleged above, has resulted in foreseeable, real and substantial danger and harm of the Plaintiff and Class Members.

121. The Defendants knew, or ought to have known, that their Depo-Provera products were more dangerous than persons using such products, as reasonably prudent consumers, would expect when used in an intended or reasonably foreseeable manner.

122. The Defendants, at all material times, had the economic and technical means to provide a safer alternative design of Depo-Provera.

123. The Defendants knew, or ought to have known that the foreseeable risks of Depo-Provera exceeded the benefits associated with their use. Any benefit from using Depo-Provera was outweighed by the serious and undisclosed risk of its use when used as intended. There are no individuals for whom the benefits of Depo-Provera outweigh the risks, given that there are alternative products that are at least as effective as Depo-Provera and carry materially lower risks than Depo-Provera. In the alternative, if there are individuals for whom the benefits of Depo-Provera outweigh the risks, those individuals could have only made an informed decision as to whether to use Depo-Provera if they had been fully informed of the risks inherent in the use of Depo-Provera.

124. The Plaintiff and Class Members did not know the nature and extent of the injuries, including the risk of meningiomas, and the damages that could result from the foreseeable use of Depo-Provera. They would not have used Depo-Provera had they known.

125. The Plaintiff's and Class Members' injuries and losses would not have occurred but for the negligence of the Defendants in failing to ensure that Depo-Provera was safe for use and/or failing to provide an adequate warning of the risks associated with using Depo-Provera to the Plaintiff, Class Members and their healthcare providers.

126. Because of the way in which Depo-Provera is administered, particularly the long-term effectiveness of its use as a contraceptive or treatment for endometriosis, the standard of care expected in the circumstances is heightened and approaches the level of strict liability. The Defendants fell below this high standard of care in failing to ensure that Depo-Provera was safe for use and in failing to adequately warn the Plaintiff and Class Members of the unreasonable dangers inherent in the ordinary use of Depo-Provera.

127. The injuries, harms, losses and damages suffered by the Plaintiff and the Class Members were caused by the negligence of the Defendants, their servants and agents.

Negligent Misrepresentation and Marketing

128. The Defendants were negligent in representing that Depo-Provera was safe for its intended use. This representation was made either explicitly, or implicitly by failing to inform the Plaintiff and Class that the use of Depo-Provera exposes users to a heightened risk of developing meningiomas.

129. The Defendants' representation or omission was untrue, inaccurate, and/or misleading and was made negligently.

130. Collectively, the Defendants were in a proximate and special relationship with the Plaintiff and Class by virtue of, among other things:

(a) their research, design, development, and testing of Depo-Provera;

(b) their skill, experience and expertise in Depo-Provera, generally and specifically;

(c) their supply and sale of Depo-Provera to the Plaintiff and Class;

(d) their complete control of the promotion and marketing of Depo-Provera;

(e) their undertaking or responsibility to clearly, fully and accurately disclose information relating to the health risks associated with use of Depo-Provera; and

(f) the fact that the Class Members had no choice but to rely on the representation or omission of the Defendants in respect of Depo-Provera and its design, attributes and safety (including the absence of information regarding the risk of developing a meningioma arising from use of Depo-Provera).

131. It was intended by the Defendants, and reasonably foreseeable, that Class Members using Depo-Provera would rely upon the representation that Depo-Provera was safe for their intended or foreseeable uses, which representation was

made either explicitly, or implicitly by failing to state that the use of Depo-Provera exposes users to a heightened risk of developing meningiomas. It was also intended by the Defendants and reasonably foreseeable that Class Members would suffer the damages described herein.

132. The failure to state that the Depo-Provera exposes users to a heightened risk of developing meningiomas was material to each Class Members' use of Depo-Provera because it is inextricably linked to the Defendants' true intentions in marketing Depo-Provera, their non-disclosure of its inherent dangers and the availability of safer alternatives.

133. The Plaintiff and Class Members reasonably relied on the Defendants' representation or omission in making decisions about beginning to use, and continuing to use, Depo-Provera. Their reliance can be inferred from the voluntary use of Depo-Provera. If the representation or omission had not been made, explicitly or implicitly, the Class Members would not have used Depo-Provera given that there are alternative treatments that are at least as efficacious.

134. The Plaintiff and Class Members suffered loss and damage as a result of relying on the Defendants' representation or omission regarding Depo-Provera.

Breaches of Consumer Protection Legislation

135. The Plaintiff pleads and relies on the Consumer Protection Legislation.

136. The Defendants' conduct particularized herein, including their failure to disclose material facts regarding the safety of Depo-Provera, constituted unfair, unconscionable and/or otherwise prohibited practices under the Consumer Protection Legislation, given that, among other things:

(a) the Plaintiff and Class Members purchased or used Depo-Provera for purposes that were for personal use. As such, they obtained Depo-Provera in the context of "consumer transactions" and contracts within the meaning of the Consumer Protection Legislation;

(b) the Defendants' engaged in deceptive, unconscionable and/or unfair acts and practices, including in their failure to properly or adequately disclose all material facts, including the risk of meningioma arising from use of Depo-Provera;

(c) the Defendants' conduct in their supply, promotion, marketing, advertising, solicitations, offers, and sales of Depo-Provera had the capability, tendency or capacity of deceiving or misleading consumers, such as the Plaintiff and Class Members, regarding the safety of the Depo-Provera;

(d) the Plaintiff and Class Members were not reasonably able to protect their interests because of disability, ignorance and the inherent informational asymmetry between the Defendants and the public;

(e) each consumer transaction and contract whereby the Plaintiff and Class Members obtained the Depo-Provera was excessively one-sided in favour of the Defendants;

(f) the terms of the consumer transactions were uniformly inequitable and adverse to the Plaintiff and Class Members;

(g) the Plaintiff and Class Members were not able to protect their interests.

137. In the circumstances of this case, the Court should dispense with any notice requirements under any of the Consumer Protection Legislation, where required, in the interest of justice.

i. British Columbia

138. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of Depo-Provera for personal use by the Plaintiff and by Class Members were "consumer transactions" within the meaning of s. 2 of the *BPCPA*. With respect to those transactions, the Plaintiff and Class Members who used Depo-Provera are "consumers" and the Defendants were "suppliers" within the meaning of the *BPCPA.*

139. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Depo-Provera had the capability, tendency or effect of

deceiving or misleading consumers regarding the safety and efficacy of the Depo-Provera, including the associated risk of meningiomas.

140. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of Depo-Provera, as particularized herein, was deceptive or unconscionable acts and practices contrary to ss. 4 and/or 8 of the *BPCPA*. The Defendants' deceptive acts and practices included the failure to properly disclose all material facts regarding the risks of using Depo-Provera.

141. As a result of the Defendants' deceptive or unconscionable acts and practices, the Plaintiff and Class Members have suffered losses and damages. The Plaintiff seeks injunctive and declaratory relief, damages and statutory compensation pursuant to ss. 171 and 172 of the *BPCPA* on her own behalf and on behalf of Class Members. Such relief includes the restoration of the profits or revenues received by the Defendants from the supply and/or sale of Depo-Provera in Canada.

142. The declaratory and injunctive relief sought by the Plaintiff in this case includes an order under s. 172 of the *BPCPA* that the Defendants advertise any judgment against them and that they properly inform consumers and healthcare professionals in Canada of the risk of meningiomas arising from the use of Depo-Provera, which includes sending a "Dear Doctor Letter" to alert physicians to this problem.

ii. Ontario

143. The supply of Depo-Provera to the Class, whether by the Defendants, their agents or third parties, were consumer transactions within the meaning of s. 1 of the *ON CPA*.

144. The Defendants' conduct, as particularized herein, constituted unfair practices contrary to ss. 14, 15 and/or 17 of the *ON CPA*.

145. As a result of the Defendants' unfair practices, the Plaintiff and Class Members suffered losses and are entitled to damages pursuant to s. 18 of the *ON CPA*.

146. Further, pursuant to s 18(12) of the *ON CPA*, each of the Defendants are jointly and severally liable to the Class Members together with any parties who directly entered into the consumer transactions for the supply of Depo-Provera to the Class.

iii. Alberta

147. The Defendants' supply of Depo-Provera to the Class were consumer transactions within the meaning of s. 1(1) of the *AB CPA*.

148. The Defendants' conduct, as particularized herein, constituted unfair practices contrary to ss. 6 and/or 7.3 of the *AB CPA*. The representations made by the Defendants constituted "material facts" that would reasonably be expected to affect the decision of a consumer to enter into a consumer transaction.

149. As a result of the Defendants' unfair practices, the Plaintiff and Class Members suffered losses and are entitled to damages pursuant to ss. 13 or 142.1 of the *AB CPA*.

iv. Saskatchewan

150. The Defendants' supply of Depo-Provera to the Class were consumer transactions within the meaning of ss. 2 and 5 of the *SK CPBPA*.

151. The Defendants' conduct, as particularized herein, constituted unfair practices contrary to ss. 6, 7, 8 and/or 19(d)-I of the *SK CPBPA*.

152. As a result of the Defendants' unfair practices, the Plaintiff and Class Members suffered losses and are entitled to damages pursuant to s. 93(1) of the *SK CPBPA*.

v. Manitoba

153. The Defendants' supply of Depo-Provera to the Class were consumer transactions within the meaning of s. 1 of the *MB BPA*.

154. The Defendants' conduct, as particularized herein, constituted unfair business practices contrary to s. 2, 3 and/or 5 of the *MB BPA*.

155. As a result of the Defendants' unfair business practices, the Plaintiff and Class Members suffered losses and are entitled to damages pursuant to s. 23 of the *MB BPA*.

vi. Québec

156. The Class Members in Québec were "consumers", the Defendants were "manufacturers", and the Depo-Provera products were "goods" within the meaning of s. 1 of the *QC CPA*.

157. The Defendants' conduct, as particularized herein, constituted prohibited practices contrary to ss. 37, 40, 41, 53, 215-221 and/or 228 of the *QC CPA*.

158. As a result of the Defendants' prohibited practices, the Plaintiff and Class Members suffered losses and are entitled to damages pursuant to s. 272 of the *QC CPA*.

vii. Prince Edward Island

159. The Defendants' supply of Depo-Provera to the Class were services within the meaning of s. 1 of the *PEI BPA*.

160. The Defendants' made unconscionable consumer representations, as particularized herein, contrary to s. 2 of the *PEI BPA.* The Defendants' conduct, as particularized herein, constituted unfair practices contrary to ss. 2 and 3 of the *PEI BPA.*

161. As a result of the Defendants' unfair practices and unconscionable consumer representations, the Plaintiff and Class Members suffered losses and are entitled to damages pursuant to s. 4 of the *PEI BPA*.

viii. New Brunswick

162. The Depo-Provera purchased or used by Class Members in New Brunswick were "consumer products" and the Defendants were "distributors" and "suppliers" within the meaning of s. 1 of the *NB CPWLA*.

163. The Defendants were in breach of the express and implied warranties that they made to Class Members in New Brunswick, as set out in ss. 4, 10 and 11 of the *NB CPWLA*. The Defendants made express and implied warranties to Class Members in New Brunswick, by way of packaging and marketing materials, that represented Depo-Provera to be safe and fit for its intended use. As particularized further herein, these warranties were false, deceptive or misleading.

164. Additionally, pursuant to s. 27 of the *NB CPWLA*, the Defendants are liable for the dangerous defects present in the design, materials and workmanship of Depo-Provera.

165. As a direct and proximate result of the Defendants' warranties and/or the defects in Depo-Provera, Class Members in New Brunswick suffered a "consumer loss" within the meaning of s. 1 of the *NB CPWLA* and are entitled to damages pursuant to s. 15 of the *NB CPWLA*.

ix. Newfoundland and Labrador

166. The Class Members in Newfoundland and Labrador were "consumers", the Defendants were "suppliers", and the supply of Depo-Provera to the Class were "consumer transactions" within the meaning of s. 2 of the *NL CPBPA*.

167. The Defendants' conduct, as particularized herein, constituted unfair or unconscionable acts and practices contrary to ss. 7, 8 and/or 9 of the *NL CPBPA*.

168. As a result of the Defendants' unfair or unconscionable acts and practices, the Plaintiff and Class Members suffered losses and are entitled to damages and other remedies pursuant to the *NL CPBPA*

Causation and Damages

i. General damages

169. The injuries, harms, losses and damages suffered by the Plaintiff and the Class Members were caused by the negligent and wrongful acts and omissions of the Defendants, their servants and agents.

170. As a result of the Defendants' negligence, the Plaintiff and Class Members have suffered and continue to experience serious personal injuries and harm with resultant pain and suffering. The Plaintiff and other Class Members have suffered special damages for medical costs incurred in the screening, diagnosis, and treatment of meningiomas related to the use of Depo-Provera.

171. The Plaintiff and Class are entitled to damages, including those set out at paragraph 99, of a nature and amount to be particularized prior to trial.

172. The Class Members who are entitled to claim by virtue of a personal, familial or beneficiary relationship have experienced personal and financial losses resulting from the injuries sustained by related persons in the Class. They are entitled to damages pursuant to the Family Compensation Legislation where applicable.

ii. Punitive damages

173. The Defendants engaged in conduct that is appropriately characterized as a marked departure from ordinary standards of decent behaviour. The Defendants' conduct was intentional, deliberate, malicious, and shocks the conscience, warranting punitive and exemplary damages.

174. The Defendants exhibited an utter indifference to whether the product may cause or substantially contribute to the development of unnecessary brain tumours. In particular, punitive damages are justified because the Defendants' decades-long wilful blindness and deliberate disregard for indicators of Depo-Provera's meningioma risk. The Defendants egregiously, deceitfully and/or recklessly overlooked and withheld information regarding serious risks with Depo-Provera.

The Defendants failed to provide any warning or any adequate warning of the risk of meningioma arising from use of Depo-Provera, despite a preponderance of scientific evidence and other reports that linked Depo-Provera to this risk.

An award of punitive damages would help deter the Defendants and others from similar conduct in the future, and to express society's condemnation of conduct such as the Defendants.

iii. Disgorgement

175. Further, or in the alternative, given the extreme nature of the Defendants' conduct and the resulting harm to a Class entirely vulnerable to the Defendants, disgorgement of the Defendants' revenues is an appropriate remedy that should be granted to the Class on an aggregate basis.

176. The Class's interests cannot be fully vindicated by other forms of relief, and the Plaintiff and the Class have a legitimate interest in preventing the Defendants' profit-making activity.

iv. *Health Care Cost Recovery Legislation*

177. The Plaintiff pleads and relies on the Health Care Cost Recovery Legislation.

178. Some of the expenses related to the medical treatments and care that the Plaintiff and Class Members have undergone, and will continue to undergo, have been born by various provincial and/or territorial health insurers.

179. As a result of the negligent and wrongful conduct of the Defendants, the various provincial and/or territorial health insurers have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their right of subrogation in respect of all past and future insured services.

180. The Plaintiff claims health care costs incurred herself and by Class Members and paid by provincial and territorial governments as a result of the wrongdoing of the Defendants:

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

(b) On behalf of the government of British Columbia, the Plaintiff claim the past and future cost of providing "health care services" under *Health Care Costs Recovery Act*, SBC 2008, c 27, ss 1-3 and 7 and *Health Care Costs Recovery Regulation*, BC Reg 397/2008, s 3;

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

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

(e) On behalf of His Majesty in right of the Province of Nova Scotia, the Plaintiff claim the past and future cost of "insured hospital services", and other care, services, and benefits under *Health Services and Insurance Act*, RSNS 1989, c 197, ss 2 and 18;

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

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

Medical Care and Hospital Insurance Act, SNL 2016, c M-5.01, ss. 41-42 and 44, and *Hospital Insurance Regulations*, CNLR 742/96, s 2 and Schedule.

Joint and Several Liability

181. Each of the Defendants are jointly and severally liable for the actions, omissions and damages attributable to any of them.

Discoverability

182. The Defendants concealed their wrongful conduct, as set forth above, from the public, the Plaintiff and the Class Members. The Defendants carried out their acts and omissions in a manner that precluded detection by the Plaintiff and Class. The Plaintiff relies on the doctrines of postponement and discoverability to postpone running the limitation period.

183. In addition, the Plaintiff and Class Members could not reasonably have known that loss or damage had occurred, that it was caused or contributed to by actions of inactions of the Defendants, or that a court proceeding would be the appropriate means to seek to remedy the injury until this action was commenced.

184. The Plaintiff and Class Members plead and rely on and the *Limitation Act*, SBC 2012, c 13, and in particular ss 8, 21(3). In the alternative, or in addition, the Plaintiff and Class Members rely on the *Limitation Act*, SBC 2012, c 13, s 30 and the Limitation Act, RSBC 1996, c 266.

Jurisdiction

185. The allegations of this lawsuit were undertaken by the Defendants in British Columbia and elsewhere, including throughout Canada.

186. Without limiting the foregoing, the Plaintiff relies on ss. 7, 10 and 13 of the *Court Jurisdiction and Proceedings Transfer Act*, S.B.C. 2003, c. 28 and pleads that there is a real and substantial connection between the facts on which this proceeding is based and the Province of British Columbia because this proceeding concerns:

(a) restitutionary obligations that, to a substantial extent, arose in British Columbia;

(b) a tort committed in British Columbia; and

(c) a business carried on in British Columbia.

Form 11 (Rule 4-5(2))

ENDORSEMENT ON ORIGINATING PLEADING OR PETITION

FOR SERVICE OUTSIDE BRITISH COLUMBIA

The Plaintiff claims the right to serve this pleading/petition on the Defendants outside British Columbia on the ground that:

The Plaintiff has at all material times been a resident of British Columbia and has suffered loss in British Columbia. The Supreme Court of British Columbia has jurisdiction with respect to this matter and the Plaintiff pleads the *Court Jurisdiction and Proceedings Transfer Act*, 2003, SBC Chapter 28 and amendments thereto.

Plaintiff's address for service:	**RICE HARBUT ELLIOTT LLP** 820 - 980 Howe Street Vancouver, BC V6Z 0C8
Fax number address for service (if any):	Nil
E-mail address for service (if any):	service@rhelaw.com
Place of trial:	Vancouver
The address of the registry is:	800 Smithe Street, Vancouver

Date: September 13, 2024

Signature of ☐ plaintiff ☒ lawyers for plaintiff
Anthony Leoni
Jesse R. Kendall
Katherine Shapiro

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

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

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

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

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

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

Appendix

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

This is a claim for injuries, loss and damages suffered as a result of the Defendants' negligence in design, development, testing, research, manufacture, licensing, warning, marketing, distribution, and sale of Depo-Provera.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

A personal injury arising out of:

- ☐ a motor vehicle accident
- ☐ medical malpractice
- ☒ another cause

A dispute concerning:

- ☐ contaminated sites
- ☐ construction defects
- ☐ real property (real estate)
- ☐ personal property
- ☐ the provision of goods or services or other general commercial matters
- ☐ investment losses
- ☐ the lending of money
- ☐ an employment relationship
- ☐ a will or other issues concerning the probate of an estate
- ☒ a matter not listed here

Part 3: THIS CLAIM INVOLVES:

- ☒ a class action
- ☐ maritime law
- ☐ aboriginal law
- ☐ constitutional law
- ☐ conflict of laws
- ☐ none of the above
- ☐ do not know

Part 4:

1. *Class Proceedings Act*, R.S.B.C. 1996, c. 50
2. *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2
3. *Food and Drugs Act*, RSC, 1985, c F-27
4. *Negligence Act*, RSBC 196 c 333
5. *Family Compensation Act,* RSBC 1996, c 126
6. *Health Care Costs Recovery Act*, SBC, 2008, c 27
7. *Court Jurisdiction and Proceedings Transfer Act*, SBC 2003, c 28
8. *Court Rules Act*, RSBC 1996, c 80
9. *Supreme Court Civil Rules*, BC Reg 168/2009
10. *Court Order Interest Act*, RSBC 1996, c 79
11. *Limitation Act*, SBC 2012, c 13
12. *Limitation Act*, SBC 2012, c 13, s 30