Court File No. VLC-S-S-236840
No._____
Vancouver Registry

In the Supreme Court of British Columbia

Between

SUZANNE TALBOT

Plaintiff

and

NOVO NORDISK CANADA INC., NOVO NORDISK A/S, NOVO NORDISK INC., NOVO NORDISK US COMMERCIAL HOLDINGS INC., NOVO NORDISK US HOLDINGS INC., NOVO NORDISK NORTH AMERICA OPERATIONS A/S, NOVO NORDISK RESEARCH CENTER SEATTLE INC., NOVO NORDISK PHARMACEUTICAL INDUSTRIES LP

Defendants

Brought under the *Class Proceedings Act*, RSBC 1996, c 50

NOTICE OF CIVIL CLAIM

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

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

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

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

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

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

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

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

Time for response to civil claim

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

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

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

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

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

CLAIM OF THE PLAINTIFF

PART 1: STATEMENT OF FACTS

A. Nature of the Action

1. This is a proposed class proceeding for damages arising from the drugs Ozempic, Rybelsus, and Wegovy (collectively "Semaglutide Products"), prescription medications which contain the active ingredient semaglutide. This action arises from the Defendants' unlawful, negligent, improper, unfair, and deceptive practices and misrepresentations related to, *inter alia*, their design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of Semaglutide Products while they knew, or ought to have known, the drugs were defective and/or there were significant risks that should have been disclosed to regulators, healthcare professionals, and the general public.

2. During the relevant times that the Defendants labelled, marketed, distributed, and sold Semaglutide Products, the Defendants failed to warn consumers adequately, or at all, of significant risks of dangerous side effects linked to the use of Semaglutide Products, including serious hepatobiliary issues (such as cholelithiasis, or gallstones, hepatobiliary illnesses, and cholecystitis), serious gastrointestinal issues (such as gastroparesis, or stomach paralysis, gastroenteritis and intestinal blockages), and malnutrition. Ultimately, patients, including the Plaintiff, have been placed at risk and harmed as a result of the conduct of the Defendants.

3. The Defendants misrepresented that their Semaglutide Products are safe, when in fact these medications cause serious Injuries, Conditions, and Complications (as defined herein). Patients who were prescribed and/or ingested Semaglutide Products were misled as to the drugs' safety and efficacy, and as a result have suffered serious Injuries, Conditions, and Complications.

B. The Parties

i. The Plaintiff

4. The Plaintiff, Suzanne Talbot, resides in Jaffray, British Columbia and was born on April 1, 1966.

5. In or around 2021, the Plaintiff was prescribed and began taking Ozempic. The Plaintiff continued to be prescribed and ingest Ozempic on a regular basis until in or around 2023.

6. Subsequent to starting her regular prescriptions for Ozempic, the Plaintiff experienced concerning signs and symptoms, including, initially, chronic diarrhea, and, later, heartburn, shortness of breath, and pain, that have resulted in hospital admissions and have worsened over time.

7. In August 2023, the Plaintiff was admitted to hospital and was diagnosed with blockage in her biliary system. Healthcare professionals indicated to the Plaintiff that the blockage was linked to her Ozempic use. Shortly following that hospital admission, the Plaintiff ceased her use of Ozempic.

8. Subsequent to stopping Ozempic, the Plaintiff continued to experience concerning signs and symptoms, including pain, heartburn, and shortness of breath, and the Plaintiff continues to experience concerning signs and symptoms today.

9. 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”).

ii. The Defendants

10. The Defendant, Novo Nordisk A/S (which does business as “Novo Nordisk”), is a public limited liability company organized under the laws of Denmark and having a principal place of business at Bagsværd, Denmark. Novo Nordisk authors, publishes, and distributes marketing materials, including websites, which are promoted as sources of information regarding the safety and efficacy of Semaglutide Products and are used by consumers, including in Canada. At times relevant to this action, Novo Nordisk has held the Canadian trademarks to

"Ozempic," "Rybelsus," and "Wegovy". Novo Nordisk Inc. is a sponsor or market authorization holder for Semaglutide Products in the United States, meaning that it is an entity authorized by the FDA to sell Semaglutide Products in the United States. All references in this Notice of Civil Claim to Novo Nordisk include all of its predecessor corporations and all of their divisions.

11. The Defendant, Novo Nordisk Canada Inc. (which does business as "Novo Nordisk Canada"), is a corporation incorporated pursuant to the laws of Ontario and having a principal place of business at Mississauga, Ontario. Novo Nordisk Canada is the Canadian operation of Novo Nordisk A/S. At times relevant to this action, Novo Nordisk Canada designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Semaglutide Products in Canada. Novo Nordisk Canada is the sponsor or market authorization holder for Semaglutide Products in Canada, meaning that it is the entity authorized by Health Canada to sell Semaglutide Products in Canada. All references in this Notice of Civil Claim to Novo Nordisk Canada include all of its predecessor corporations and all of their divisions.

12. Novo Nordisk Canada is a wholly owned subsidiary of Novo Nordisk and is classified as engaging in "Sales and marketing" activities in Novo Nordisk's financial reporting documents. At times relevant to this action, Novo Nordisk had responsibility for the operations of Novo Nordisk Canada.

13. The Defendant, Novo Nordisk Inc., is a corporation incorporated pursuant to the laws of Delaware, USA and having a principal place of business at Plainsboro, NJ, USA. Novo Nordisk Inc. is a sponsor or market authorization holder for

Semaglutide Products in the United States, meaning that it is an entity authorized by the FDA to sell Semaglutide Products in the United States. All references in this Notice of Civil Claim to Novo Nordisk Inc. include all of its predecessor corporations.

14. Novo Nordisk Inc. is a wholly owned indirect subsidiary of Novo Nordisk and is classified as engaging in “Sales and marketing” activities in Novo Nordisk’s financial reporting documents. At times relevant to this action, Novo Nordisk had responsibility for the operations of Novo Nordisk Canada.

15. Novo Nordisk Inc. is also a wholly owned subsidiary of Novo Nordisk US Commercial Holdings, Inc. At times relevant to this action, Novo Nordisk US Commercial Holdings, Inc. also had responsibility for the operations of Novo Nordisk Inc.

16. The Defendant, Novo Nordisk US Commercial Holdings Inc., is a corporation incorporated pursuant to the laws of Delaware, USA and having a principal place of business at Wilmington, Delaware, USA. All references in this Notice of Civil Claim to Novo Nordisk US Commercial Holdings Inc. include all of its predecessor corporations and all of their divisions.

17. Novo Nordisk US Commercial Holdings, Inc. is a wholly owned indirect subsidiary of Novo Nordisk. and is classified as engaging in “Services/Investments” activities in Novo Nordisk’s financial reporting documents. At times relevant to this action, Novo Nordisk had responsibility for the operations of Novo Nordisk US Commercial Holdings, Inc.

18. Novo Nordisk US Commercial Holdings Inc. is also a wholly owned subsidiary of Novo Nordisk US Holdings, Inc. At times relevant to this action, Novo Nordisk US Holdings Inc. also had responsibility for the operations of Novo Nordisk US Commercial Holdings Inc.

19. The Defendant, Novo Nordisk US Holdings Inc., is a corporation incorporated pursuant to the laws of Delaware, USA and having a principal place of business at Wilmington, Delaware, USA. All references in this Notice of Civil Claim to Novo Nordisk US Holdings Inc. include all of its predecessor corporations and all of their divisions.

20. Novo Nordisk US Holdings Inc. is a wholly owned subsidiary of Novo Nordisk and is classified as engaging in “Services/Investments” activities in Novo Nordisk’s financial reporting documents. At times relevant to this action, Novo Nordisk had responsibility for the operations of Novo Nordisk US Holdings Inc.

21. The Defendant, Novo Nordisk North America Operations A/S is a company organized under the laws of Denmark and having a principal place of business at Bagsværd, Denmark. All references in this Notice of Civil Claim to Novo Nordisk North America Operations A/S. include all of its predecessor corporations and all of their divisions.

22. Novo Nordisk North America Operations A/S is a wholly owned subsidiary of Novo Nordisk and is classified as engaging in “Services/Investments” activities in Novo Nordisk’s financial reporting documents. At times relevant to this action, Novo Nordisk had responsibility for the operations of Novo Nordisk North America Operations A/S.

23. The Defendant, Novo Nordisk Research Center Seattle, Inc. is a corporation incorporated pursuant to the laws of Delaware, USA and having a principal place of business at Seattle, Washington, USA. All references in this Notice of Civil Claim to Novo Nordisk Research Center Seattle, Inc. include all of its predecessor corporations and all of their divisions.

24. Novo Nordisk Research Center Seattle, Inc. is a wholly owned subsidiary of Novo Nordisk and is classified as engaging in “Research and development” activities in Novo Nordisk’s financial reporting documents. At times relevant to this action, Novo Nordisk had responsibility for the operations of Novo Nordisk Research Center Seattle, Inc.

25. The Defendant, Novo Nordisk Pharmaceutical Industries LP is a corporation incorporated pursuant to the laws of Delaware, USA and having a principal place of business at Clayton, North Carolina, USA. Novo Nordisk Pharmaceutical Industries LP operates a manufacturing facility in Clayton, which serves as one of the primary facilities globally for the manufacturing of active pharmaceutical ingredients for all drugs distributed by Novo Nordisk and its subsidiaries. The vast majority of the Defendants’ diabetes and obesity products for North America are produced and packaged at the Clayton facility. All references in this Notice of Civil Claim to Novo Nordisk Pharmaceutical Industries LP include all of its predecessor corporations and all of their divisions.

26. Novo Nordisk Pharmaceutical Industries LP is a wholly owned subsidiary of Novo Nordisk and is classified as engaging in “Production” activities in Novo Nordisk’s

financial reporting documents. At times relevant to this action, Novo Nordisk had responsibility for the operations of Novo Nordisk Pharmaceutical Industries LP.

27. Hereinafter, each of the above Defendants shall be collectively referred to as the "Defendants".

28. The business of each of the Defendants is inextricably interwoven with that of the other and each is the agent of the other for the purposes of researching, designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, and/or selling for a profit, either directly or indirectly through an agent, affiliate or subsidiary, Semaglutide Products in Canada. In view of the close relationship between the Defendants and the foregoing, each of the Defendants is jointly and severally liable for the acts and omissions of each other and their predecessors.

29. At all material times, the Defendants were engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling, and/or selling Semaglutide Products in Canada. The development of Semaglutide Products for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Semaglutide Products, and other actions central to the allegations of this lawsuit, were undertaken by the Defendants in British Columbia and elsewhere.

C. The Defendants' Semaglutide Products

30. "Semaglutide Products" are drug products having the anatomical therapeutic chemical "semaglutide" as their active pharmaceutical ingredient which were marketed, sold and/or otherwise distributed to Canadians by the Defendants under the brand names "Ozempic" (as injections in various doses and forms including 2 mg/pen (0.68 mg/mL or 1.34 mg/mL), 4 mg/pen (1.34 mg/mL), 8 mg/pen (2.68 mg/mL) and pre-filled pen delivering doses of 0.25 mg, 0.5 mg, 1 mg and 2 mg), "Rybelsus" (as tablets in various doses and forms including 3 mg, 7 mg and 14 mg tablets), and "Wegovy" (as injections in various doses and forms including single-use pre-filled pen delivering doses of 0.25 mg, 0.5 mg, 1 mg, 1.7 mg or 2.4 mg and Multi-use pre-filled pen (FlexTouch®) delivering doses of 0.25 mg, 0.5 mg, 1 mg, 1.7 mg or 2.4 mg)

31. Semaglutide was developed by Novo Nordisk A/S.

32. Semaglutide falls within a class of medicines called glucagon-like peptide 1 ("GLP-1") agonists. GLP-1 agonists are intended to mimic the naturally occurring GLP-1 hormone. GLP-1 hormones stimulate a decrease in blood sugar levels, as they stimulate insulin production and reduce glucose production in the liver. Additionally, in the stomach, GLP-1 hormones inhibit gastric emptying, acid secretion and motility, which also decreases appetite.

33. GLP-1 agonist drugs work by attaching themselves to cell receptors and causing the same actions as the naturally occurring GLP-1 hormone. Meaning, GLP-1 agonists, like semaglutide, decrease blood sugar levels and suppress appetite.

34. Semaglutide was developed specifically to be a long-lasting GLP-1 agonist, to reduce the time needed to maintain the effect of the medication between doses and reduce the frequency at which patients received doses.

35. Semaglutide Products were first approved for sale in North America by the U.S. Food and Drug Administration.

36. Novo Nordisk and Novo Nordisk Inc. are the approved sponsors of Semaglutide Products marketed and sold in the United States.

37. In December 2017, semaglutide was first marketed and sold in the U.S. as an injection treatment for type 2 diabetes under the brand name Ozempic. In September 2019, semaglutide subsequently began to be marketed and sold in the U.S. in an oral tablet form for the treatment of type 2 diabetes under the brand name Rybelsus. In June 2021, semaglutide began to be marketed and sold in the U.S. for chronic weight management under the brand name Wegovy.

38. Semaglutide Products distributed and sold in the US have been readily accessible to Canadians for purchase and prescription through legal means. It was reasonably foreseeable that Canadians would obtain and use Semaglutide Products distributed and sold in the United States, including during periods prior to their approval or sale in Canada.

39. Subsequent to their approval in the US, Semaglutide Products received Health Canada approval.

40. Ozempic and Rybelsus drugs are approved by Health Canada to treat type 2 diabetes mellitus. Wegovy drugs are also approved by Health Canada for chronic

weight management. Ozempic and Rybelsus have been marketed and sold in Canada. Wegovy has yet to be marketed and sold in Canada.

41. Novo Nordisk Canada is the approved Health Canada sponsor of Semaglutide Products in Canada.

42. On January 4, 2018, Novo Nordisk Canada became the approved market authorization holder for Ozempic (i.e., held the Notice of Compliance for Ozempic). On February 22, 2018, following Health Canada approval, Novo Nordisk Canada first marketed and sold Ozempic (in the form of semaglutide injections) in Canada.

43. On March 30, 2020, Novo Nordisk Canada became the approved market authorization holder for Rybelsus (i.e., held the Notice of Compliance for Rybelsus). On April 19, 2020, following Health Canada approval, Novo Nordisk Canada first marketed and sold Ozempic (in the form of semaglutide injections) in Canada.

44. On November 23, 2021, Novo Nordisk Canada became the approved market authorization holder for Wegovy (i.e., held the Notice of Compliance for Wegovy). As of October 5, 2023, Wegovy has yet to be marketed or sold in Canada.

45. Semaglutide Products are exceedingly popular in North America.

46. In Canada, Ozempic is the dominant GLP-1 agonist drug.

47. In Canada, more than 3.5 million prescriptions worth nearly $1.2 billion were dispensed for Ozempic by retail drugstores in 2022. The number of prescriptions filled for Semaglutide Products in Canada has been increasing over time from just over 81,000 scripts worth $26 million in 2018, Ozempic's first year on the market.

Today, Ozempic had garnered > 99% market share among public Provincial/Territorial drug plans.

48. In the US, Novo Nordisk reported that in the first six months of 2023 sales of Wegovy were nearly $1.7 billion, while sales of Ozempic were more than $3.7 billion. The number of Ozempic prescriptions filled in the US reached as high as 373,000 in one week in February of 2023.

49. During the period of time that the Defendants' Semaglutide Products have been marketed and sold to Canadians, there have existed safer and economically feasible alternative treatment options approved for use in Canada, for the treatment of type 2 diabetes and chronic weight management, which can be used in lieu of Semaglutide Products, including, but not limited to, other pharmaceutical options, such as insulin, metformin, sulfonylureas, sodium-glucose co-transporters type 2 (SGLT-2) inhibitors and other GLP-1 agonists, as well as non-pharmaceutical options, such as diet, exercise, and various non-medicinal forms of therapy.

D. Defendants' Marketing of Semaglutide Products to Canadians

50. The Defendants were engaged in a joint enterprise for the promotion, marketing, packaging, advertising, sale and distribution of Semaglutide Products in British Columbia and elsewhere in Canada. The Defendants jointly promoted Semaglutide Products through a variety of media sources in British Columbia and elsewhere in Canada.

51. At all material times, the Defendants commissioned promotional materials for Semaglutide Products that were received by Canadians online and on television stations broadcasting to Canadians.

52. With respect to television advertising, between 2018 and 2013, the Defendants spent over USD$ 884,000,000 on ads in North America to promote Ozempic, Wegovy and Rybelsus with the majority of the spending allocated specifically to advertising Ozempic.

53. The Defendants used several different multimedia commercials to promote Semaglutide Products to consumers, including the heavily publicised “Oh, Oh, Oh, Ozempic” campaign, viewable at https://www.ispot.tv/ad/d6Xz/ozempic-oh.

54. The “Oh, Oh, Oh, Ozempic” campaign was first aired on television in or around mid-2018. Nowhere within the “Oh, Oh, Oh, Ozempic” promotional content are viewers warned of the association between Ozempic and the development of Injuries, Conditions, and Complications.

55. With respect to online advertising, over 4,000 marketing advertisements for Ozempic and similar weight-loss medications have been placed on Facebook and Instagram.

56. Semaglutide Products have also been heavily promoted on social media. On TikTok, the hashtag #Ozempic currently has over 1.2 billion views.

57. Canadians were exposed to extensive commercial advertisements that were created, produced, designed, financed, uploaded, published, and monitored by the

Defendants. The marketing materials omitted any references to risks of any Injuries, Conditions, and Complications.

58. The Defendants also marketed Semaglutide Products online at dedicated websites accessible to Canadians, including Ozempic.ca and Ozempic.com. Visitors to the websites are urged to sign up to receive supportive resources to encourage treatment with Semaglutide Products. The Ozempic.com website features the "Text2Connect program", wherein users can sign up to receive daily medication reminders, prescription refill reminders, reminders to check their weight, and delivery of other motivational and support messages.

59. Further, the Defendants collectively solicited the initiation and continuation of treatment with Semaglutide Products by offering treatment support to patients through "patient assistance programs" for Semaglutide Products.

60. Through the patient assistance programs, enrolled patients are offered access to a "Diabetes Health Coach" to answer questions about and further encourage treatment with Ozempic through text, phone call, or email. The Diabetes Health Coach similarly offers support in selecting meal and exercise tips and in providing personalized motivational messaging. The Diabetes Health Coaches are employees and/or agents of the Defendants.

61. The "patient assistance programs" neglect to contemplate support upon the occurrence of Injuries, Conditions, and Complications.

62. Following Health Canada's initial approval of Ozempic, the Defendants promoted the launch of Semaglutide Products in Canada with marketing materials, including

press releases, which promoted Semaglutide Products to Canadians and represented semaglutide as safe and effective. The representations in these materials included that:

(a) Ozempic is safe and effective, proven to lower HbA1c (a test to measure blood glucose control in persons with diabetes) and may help with weight loss;

(b) Ozempic helps patients manage their weight, and patients receiving Ozempic experienced clinically significant weight loss;

(c) Ozempic reduces the risk of major cardiovascular events, including stroke, heart attack, and death;

(d) Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care and their experience and capabilities enable them to help people **defeat** obesity and their serious chronic conditions (emphasis added); and

(e) By implication, that the Defendants' Semaglutide Products were an acceptable option among other medication or lifestyle options with proven efficacy and acceptable safety profiles.

63. The Defendants' marketing materials for Semaglutide Products failed to warn of the risks of any Injuries, Conditions, and Complications.

64. The Defendants' marketing and promotional activities were specifically directed at attracting consumers, including Canadians, to seek out the initiation and continuation of treatment with Semaglutide Products, while simultaneously failing

to sufficiently warn of the risks of development of Injuries, Conditions, and Complications. It was reasonably foreseeable that Canadians would receive the messages from these marketing and promotional activities and would act in reliance upon them to purchase and use Semaglutide Products.

E. Risks of Serious Injuries, Conditions, and Complications

65. The ingestion of Semaglutide Products, which alter the human body's natural digestive processes and hormonal activity, can lead to serious adverse side effects with significant consequences, such as the development of gallbladder-related diseases and other hepatobiliary complications, gastrointestinal paralysis, gastrointestinal obstruction, malnutrition, and death, especially in certain special populations.

66. At all material times, the Defendants knew or ought to have known that Semaglutide Products could cause major gastrointestinal and hepatobiliary complications, including cholelithiasis (gallstones), cholecystitis (gallbladder inflammation), hepatobiliary illnesses, gastroparesis (paralyzed stomach), gastrointestinal obstruction, malnutrition, and death (i.e. all-cause mortality), as well as associated injuries, conditions, complications, and symptoms, including, but not limited to, for cholelithiasis and cholecystitis: pressure or gnawing pain between the shoulder blades, near the rib cage, back, breastbone, or upper abdomen, nausea, vomiting, fever, chills, jaundice, biliary obstruction, and diarrhea; for hepatobiliary illnesses: abdominal and/or back pain, loss of appetite, weight loss, jaundice, itching, fatigue, nausea, vomiting, biliary colic, biliary obstruction, blood clot, deep vein thrombosis, and pulmonary embolism; for

gastroparesis: nausea, vomiting, bloating, abdominal pain, indigestion, acid reflux, abdominal pain, loss of appetite, and blood glucose instability; for gastrointestinal obstruction: nausea, vomiting, abdominal pain, abdominal distension, diarrhea, incontinence, fever, chills, and loss of appetite; and for malnutrition: loss of appetite, fatigue, weight loss, and myalgias (collectively “Injuries, Conditions, and Complications”).

67. At all material times, the Defendants knew or ought to have known that specific special populations who were users of Semaglutide Products, including, in particular, patients with type 2 diabetes, patients with obesity, patients with dyslipidemia, and patients already at risk for the development of hepatobiliary and gastrointestinal disorders, including patients who had previously undergone bariatric surgery, were at an increased or specific risk of Injuries, Conditions, and Complications, including, but not limited to, the risk of gallbladder events, hepatobiliary illnesses, gastroparesis, and gastrointestinal obstruction being higher for patients with type 2 diabetes and the risk of gallbladder events being higher for patients with obesity and/or dyslipidemia or who had previously undergone bariatric surgery.

F. Adverse Event Reports and Regulatory Action

68. The increased risk of Injuries, Conditions, and Complications which have been linked with the use of Semaglutide Products, including the elevated risks in certain cohorts of patients, have been the subject of thousands of adverse event reports filed to, safety reviews undertaken by, and warning communications issued from Health Canada and the U.S. Food and Drug Administration ("FDA”).

69. Health Canada's Canada Vigilance Adverse Reaction Online Database contains adverse reaction reports about suspected adverse reactions to health products, which are submitted by consumers and health professionals, as well as manufacturers and distributors (aka market authorization holders). The Canada Vigilance Adverse Reaction Online Database contains over 1,000 adverse reaction reports involving "Ozempic" as a suspected product, filed to Health Canada through to the end of September 2023. Similarly, in the U.S., there have been over 10,000 adverse events associated with "Ozempic" reported to the FDA's Adverse Event Reporting System.

70. Many of these adverse event reports involve gallbladder-related issues, other hepatobiliary complications, gastroparesis, or gastrointestinal obstruction.

71. Subsequent to the numerous adverse event reports filed, the FDA and Health Canada have taken action to warn consumers and healthcare professionals about the serious complications associated with the Defendants' Semaglutide Products.

72. In June 2022, the FDA posted a safety alert, advising that Ozempic and Wegovy were under evaluation by the FDA for reports of intestinal obstruction.

73. On April 6, 2023, Health Canada released a drug supply notice for Ozempic, which was last updated on August 18, 2023. In the notice, Health Canada stated that "Ozempic may also lead to serious side effects, such as… gallbladder problems".

G. Product Warnings

74. As the designers, developers, manufacturers, distributers, marketers, and sellers of Semaglutide Products in Canada and to Canadians, the Defendants, including

in particular those Defendants who are the sponsors of Semaglutide Products in Canada and the United States, have at all material times been responsible for ensuring that Canadian consumers and their health care professionals are fully and adequately warned of any foreseeable health risks and adverse side effects associated with Semaglutide Products' ingestion. One means by which the Defendants must communicate such risks is through the product monograph for Semaglutide Products (the "Product Monographs"). The Product Monographs are documents containing information on the uses, dosages and risks associated with Semaglutide Products. "Part I" of the Product Monograph is directed at health care professionals in Canada. "Part III" of the Product Monograph is directed at consumers in Canada.

75. The Product Monographs are distributed by the Defendants directly and indirectly to health care professionals and individual patients in Canada. The Product Monographs are made available on Novo Nordisk's Canadian website.

76. Despite all the available information regarding the Injuries, Conditions, and Complications linked to Semaglutide Products' use, the Defendants were negligent and failed to adequately or appropriately change the label or product monograph in a timely manner or take adequate or appropriate steps to warn the medical community and users of the drug regarding these effects on the gastrointestinal and hepatobiliary systems for patients taking Semaglutide Products.

77. At times relevant to this action, the product monographs, as well as the label and prescribing information that accompanied Semaglutide Products when prescribed to patients, have contained insufficient warnings related to risks of the Injuries,

Conditions, and Complications, including cholecystitis (i.e. gallbladder inflammation), cholelithiasis (i.e. gallstones), other hepatobiliary disease, gastroparesis (i.e. paralyzed stomach), gastrointestinal blockage, malnutrition, and death, including especially in certain special populations.

i. Hepatobiliary Warnings

78. Before February 2023, the Defendants did not provide any meaningful warning whatsoever about serious risks of hepatobiliary issues in the Canadian Product Monographs for any Semaglutide Products.

79. Currently, the Canadian Product Monograph for Ozempic, which was revised on August 4, 2023, still contains no meaningful warning whatsoever about serious risks of Hepatobiliary issues. And, to the extent that the current Canadian Product Monographs for Rybelsus and Wegovy contain information about the risk of hepatobiliary issues, those warnings are inadequate, deficient, and/or misleading.

80. In the current Canadian Product Monographs for all Semaglutide Products, the "Serious Warnings and Precautions" sections directed at both healthcare professionals and patients (aka the "Black Box Warnings" – the most stringent warnings for drugs and medical devices) contain no reference to gallbladder issues, including cholelithiasis or cholecystitis.

81. In the current Canadian Product Monograph for Ozempic, the "Warnings and Precautions" section directed at healthcare professionals, and the "Warnings" section directed at patients, again contain no reference to the gallbladder, cholelithiasis, or cholecystitis. In the patient information section, gallstones are

referenced in passing amongst a list of common potential side effects, while other potential hepatobiliary events are wholly overlooked.

82. Despite the Defendants neglecting to update the Canadian Product Monograph for Ozempic to reflect the association between Semaglutide Products and hepatobiliary disease, elsewhere, the Defendants have taken action to acknowledge the severity of the risk, demonstrating their knowledge of the risk of harm.

83. In March 2022, the Defendants updated the U.S. Approved Drug Label for Ozempic, adding a provision to the “Warnings and Precautions” section to advise of an association between Ozempic and acute gallbladder disease.

84. On February 2, 2023, the Canadian Product Monograph for Rybelsus received a similar addition to the “Warnings and Precautions” section of the Healthcare Professional Information portion of the Monograph. The Rybelsus Product Monograph was also revised to reflect that patients should speak with their physician about their history of “liver and gallbladder problems” prior to beginning Ozempic.

85. Although Wegovy is yet to be marketed in Canada, the Canadian Product Monograph contains a substantially similar “Acute Gallbladder Disease” subsection within the “Warnings and Precautions” section for Healthcare Professionals.

86. None of the Canadian Product Monographs for any Semaglutide Products explain the seriousness or severity of hepatobiliary issues linked to the drug, including but

not limited to failing to explain that hepatobiliary issues may require medical treatment to correct and/or may result in hospitalization, and/or failing to explain that hepatobiliary issues may increase in severity over time and/or persist even after usage of the drug has stopped.

ii. Gastrointestinal Warnings

87. The Defendants have not and do not provide any meaningful warnings whatsoever about serious risks of gastrointestinal issues in the Canadian Product Monographs for any Semaglutide Products, or, in the alternative, to the extent that the current Canadian Product Monographs for Semaglutide Products contain information about the risk of gastrointestinal issues, those warnings are inadequate, deficient, and/or misleading.

88. In the current Canadian Product Monographs for all Semaglutide Products, the "Serious Warnings and Precautions" sections directed at both healthcare professionals and patients (aka the "Black Box Warnings" – the most stringent warnings for drugs and medical devices) contain no reference to gastrointestinal issues, including no references to gastroparesis, stomach paralysis, delayed stomach or gastric emptying, or stomach or gastric blockages.

89. In the current Canadian Product Monographs for all Semaglutide Products, the "Warnings and Precautions" sections directed at both healthcare professionals and patients also contain no references to gastroparesis, stomach paralysis, delayed stomach or gastric emptying, or stomach or gastric blockages.

90. Despite the Defendants neglecting to update the Canadian Product Monograph for Ozempic to reflect the association between Semaglutide Products and severe gastrointestinal issues, elsewhere, the Defendants have taken action to acknowledge the severity of the risk, demonstrating their knowledge of the risk of harm.

91. On September 22, 2023, the FDA updated the Approved Drug Label for Ozempic in recognition of the reported gastrointestinal adverse events noted to be occurring in persons ingesting Ozempic. The revised Approved Drug Label noted that, during post-approval use of semaglutide, some users had reported occurrences of gastrointestinal paralysis, also known as an ileus.

92. No such updates or modifications to the Defendants' Semaglutide Products Monographs to reflect the occurrence of adverse gastrointestinal events have been added in Canada.

93. In passing, the Product Monographs for the Defendants' Semaglutide Products describe the potential for delayed gastric motility to impact the absorption of other medications within the body or to reduce the rate by which glucose appears in the circulation following consumption of a meal.

94. Delayed gastric motility is described only within the "Drug Interactions" and "Pharmacodynamics" sections and does not appear within the "Warnings and Precautions" or "Serious Warnings and Precautions" sections.

95. The Product Monographs for the Defendants' Semaglutide Products fail to substantially warn of the severity of the risk or potential consequences of developing delayed gastric motility.

96. The potential for developing a gastrointestinal blockage as a result of consumption of the Defendants' Semaglutide Products, requiring subsequent medical treatment or surgeries to correct, does not appear within the Product Monographs.

97. Similarly, the increased risk of pulmonary aspiration associated with general anesthesia in persons experiencing delayed gastric emptying does not appear within the Product Monograph.

98. The Canadian Product Monographs for Semaglutide Products have failed to substantially warn patients or doctors of the risks of developing Injuries, Conditions, and Complications.

H. The Defendants Failed to Warn of the Risks Linked to Semaglutide Products

99. At all material times, the Defendants knew or should have known that the risks of using their Semaglutide Products included severe Injuries, Conditions, and Complications.

100. In 2018, the year following Ozempic's approval for diabetes, the Defendants began a clinical trial for patients who were overweight or experiencing obesity.

101. On June 23, 2018, Novo Nordisk issued a press release wherein they acknowledged an increased association between gastrointestinal adverse events and people consuming Ozempic for all body mass index subgroups when

compared to treatment with low dose dulaglutide, another GLP-1 with a different active ingredient.

102. On January 16, 2020, Novo Nordisk issued another press release wherein they noted gastrointestinal adverse events to occur more frequently in users taking Ozempic than in users of a placebo.

103. On June 26, 2021, Novo Nordisk presented data from a 40-week, phase 3b, efficacy and safety trial comparing once-weekly semaglutide 2 mg ingestion vs 1 mg ingestion in 961 adults with type 2 diabetes. Both groups found a significant incidence of gastrointestinal adverse events, regardless of the dosage taken.

104. Despite the Defendants repeatedly noting a heightened association between their Semaglutide Products and adverse gastrointestinal and hepatobiliary events, the Defendants failed to sufficiently warn or further investigate the noted potential harms to consumers.

105. In addition to the studies conducted by the Defendants, Semaglutide Products were also the subject of multiple research studies examining the link between semaglutide and adverse gastrointestinal and hepatobiliary events.

106. The Defendants knew or ought to have known of the numerous scientific articles and studies that identified the potential risks of semaglutide products to cause serious injuries. For example:

(a) A 2011 randomized, double-blinded, prospective clinical trial that examined the effects of a GLP-1 analogue on gut motility in 166 patients with pain associated with irritable bowel syndrome. The study concluded GLP-1

analogues exert a motility inhibiting and antispasmodic effect in the gut, slowing down gastric emptying. See Hellström PM. “GLP-1 playing the role of a gut regulatory compound.” *Acta Physiol (Oxf)*. 2011 Jan;201(1):151-6. doi: 10.1111/j.1748-1716.2010.02150.x;

(b) A 2016 population-based cohort study of 71,369 patients which found GLP-1 analogues to be associated with a significantly increased risk of bile duct and gallbladder disease in patients with type 2 diabetes mellitus when compared to use of other oral antidiabetic drugs. See Faillie, Jean-Luc et al. “Association of Bile Duct and Gallbladder Diseases With the Use of Incretin-Based Drugs in Patients With Type 2 Diabetes Mellitus.” *JAMA internal medicine* vol. 176, 10 (2016): 1474-1481. doi:10.1001/jamainternmed.2016.1531;

(c) A 2020 review article that specifically noted that Ozempic can exacerbate diabetic gastroparesis, recommending against the use of Ozempic in patients with symptoms of gastroparesis. See Young CF, Moussa M, Shubrook JH, “Diabetic Gastroparesis: A Review”. *Diabetes Spectr*. 2020 Aug; 33(3): 290–297, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/;

(d) A 2020 meta-analysis of randomized control trials which reviewed 43 studies, for a total of 38,953 patients consuming GLP-1 and 35,893 in the control group. 25 of the studies reported at least one case of cholelithiasis, finding a significant increase in the risk of cholelithiasis in patients treated with GLP-1. See Nreu, Besmir et al. “Cholelithiasis in patients treated with

Glucagon-Like Peptide-1 Receptor: An updated meta-analysis of randomized controlled trials." *Diabetes research and clinical practice* vol. 161 (2020): 108087. doi:10.1016/j.diabres.2020.108087;

(e) A 2021 meta-analysis funded by the Defendants and comprising almost 12,000 participants consuming semaglutide for at least 26 weeks, which noted a 28% increased risk of cholelithiasis with GLP-1RA treatment. See Smits MM, Van Raalte DH. "Safety of Semaglutide." *Front Endocrinol (Lausanne)*. 2021 Jul 7; 12:645563. doi: 10.3389/fendo.2021.645563;

(f) A 2022 research letter which reviewed the FDA Adverse Event Reporting System from April 28, 2005 to September 16, 2012 to identify cases of acute cholecystitis associated with GLP-1 products that did not have warnings and precautions regarding acute gallbladder disease. 36 cases were reviewed. Researchers found an increased risk of gallbladder issues when semaglutide was taken in higher doses or for longer durations. See Woronow D et al. "Acute cholecystitis associated with the use of glucagon-like peptide-1 receptor agonists reported to the US Food and Drug Administration". *JAMA Intern Med* 2022 Aug 29; [e-pub]. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/279547;

(g) A 2022 double-blind, parallel-group, randomized, placebo-controlled study involving 201 adolescents with obesity or with overweight and at least one weight-related coexisting condition. Participants were randomized to receive either once-weekly subcutaneous semaglutide or placebo for 68 weeks, plus lifestyle intervention. 4% of participants in the semaglutide

group developed cholelithiasis, compared to 0 participants in the placebo group. See Weghuber, Daniel et al. “Once-Weekly Semaglutide in Adolescents with Obesity.” *The New England Journal of Medicine* vol. 387,24 (2022): 2245-2257. doi:10.1056/NEJMoa2208601;

(h) A 2022 large, population-based study which used a new-user active comparator study design wherein initiators of incretin-based drugs (GLP-1 RAs and DPP-4 inhibitors) were compared with initiators of SGLT-2 inhibitors. The study found that the use of GLP-1 was associated with an increased risk of intestinal obstruction. See Faillie, J.-L., Yin, H., Yu, O.H.Y., Herrero, A., Altwegg, R., Renoux, C. and Azoulay, L. (2022), “Incretin-Based Drugs and Risk of Intestinal Obstruction Among Patients With Type 2 Diabetes.” *Clin. Pharmacol. Ther.*, 111: 272-282. https://doi.org/10.1002/cpt.2430;

(i) A two-year study published in 2022 that examined semaglutide use in patients with overweight or obesity. Researchers found 82.2% of patients taking semaglutide experienced mild to moderate gastrointestinal adverse events compared with 53.9% in the placebo group. See Garvey, W.T., Batterham, R.L., Bhatta, M. et al. “Two-year effects of semaglutide in adults with overweight or obesity: the STEP 5 trial.” *Nat Med* 28, 2083–2091 (2022). https://doi.org/10.1038/s41591-022-02026-4;

(j) A 2023 research letter which used a random sample of 16 million patients to examine gastrointestinal adverse events associated with GLP-1 agonists used for weight loss. The study concluded that use of GLP-1 agonists for

weight loss, when compared to treatment with bupropion-naltrexone (another weight-loss agent with a different active ingredient), were associated with a significantly increased risk of pancreatitis, bowel obstruction, and gastroparesis. See Sodhi M, Rezaeianzadeh R, Kezouh A, Etminan M. “Risk of Gastrointestinal Adverse Events Associated With Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss.” JAMA. Published online October 05, 2023. doi:10.1001/jama.2023.19574; and

(k) Multiple published case reports noting an association between semaglutide, delayed gastric emptying, and consequent intraoperative pulmonary aspiration. See Klein SR, Hobai IA. “Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report.” *Can J Anaesth.* 2023 Aug;70(8):1394-1396. English. doi: 10.1007/s12630-023-02440-3. Epub 2023 Mar 28. PMID: 36977934 and Kalas MA, Galura GM, McCallum RW. “Medication-Induced Gastroparesis: A Case Report.” *J Investig Med High Impact Case Rep*. 2021 Jan-Dec;9:23247096211051919. doi: 10.1177/23247096211051919. PMID: 34663102; PMCID: PMC8529310.

107. At all material times, the Defendants, through their servants and agents, failed to adequately warn physicians and consumers, including the Plaintiff and other putative class members, of the risk of Injuries, Conditions, and Complications caused by their Semaglutide Products.

108. At all material times, the Defendants did not provide adequate safety data to Health Canada with respect to their Semaglutide Products. The Defendants knew or

should have known that their Semaglutide Products posed a serious risk of harm to consumers and were not fit for their intended purposes.

109. At all material times, the Defendants, through its servants and agents, negligently, recklessly and/or carelessly marketed, distributed and/or sold their Semaglutide Products without adequate warnings of the products' serious side effects and unreasonably dangerous risks.

I. The Plaintiff and Class Suffered Harms from Use of Semaglutide Products

110. Class Members, including the Plaintiff, suffered harms and losses as a result of the Defendants' negligence and failure to warn.

111. Subsequent to ingesting Semaglutide Products, the Plaintiff and Class Members have suffered and continue to suffer physical and mental injury, loss and damage. In particular, the Plaintiff has suffered blockage in her biliary system, heartburn, chronic diarrhea, shortness of breath and pain.

112. Had the Plaintiff and Class Members been aware of the nature and severity of the risk of Injuries, Conditions, and Complications associated with ingesting Semaglutide Products, they would not have agreed to take Semaglutide Products and would have explored one or more of the many other viable treatment options available to them. In particular, had the Plaintiff been aware of the nature and severity of the risk of Injuries, Conditions, and Complications associated with ingesting Semaglutide Products, she would not have agreed to take Semaglutide Products and would have explored one or more other viable treatment options.

113. The Plaintiff's injuries have and will continue to cause her suffering, loss of enjoyment of life, permanent physical disability, loss of earning capacity, past and future, and loss of housekeeping capacity, past and future. Other Class Members have suffered similar injuries.

114. The Plaintiff has suffered injury to her hepatobiliary health and will be more susceptible to future degenerative changes to her hepatobiliary health as a result of taking Semaglutide Products. The Plaintiff's symptoms have continued even after ceasing her use of Semaglutide Products.

115. The Plaintiff has sustained damages for the cost of medical treatment, including past and future cost of health care services provided by the government of British Columbia. Other Class Members have suffered similar injuries, as have the governments of other provinces and territories in Canada. In particular, the Plaintiff has suffered injuries from Semaglutide Products that necessitated hospital admission in August 2023. The Plaintiff continues to undergo medical care and treatment and continues to sustain damages. Class Members in other provinces or territories have sustained similar damages.

116. As a result of her injuries, the Plaintiff has received, and in the future will continue to receive, care and services from family members. Other Class Members will require similar care.

117. The Plaintiff and Class Members paid some or all of the costs for Semaglutide Products out of their own pocket. Third Party payors have also indemnified some or all of the costs for Semaglutide Products used by the Plaintiff and Class Members.

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

PART 2: RELIEF SOUGHT

119. The Plaintiff claims, on her own behalf and on behalf of all members of the proposed class, as follows:

(a) an order certifying this action as a class proceeding and appointing her as representative Plaintiff for the Class, to be further defined on the application for certification;

(b) a declaration that the Defendants were negligent in the design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of their Semaglutide Products;

(c) a declaration that the Defendants made certain representations regarding Semaglutide Products that were false, and that these Representations were made negligently;

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

(e) pecuniary and special damages in the amount of $500,000 for each person prescribed one of the Defendants' Semaglutide Products or as aggregated following a trial on the common issues;

(f) non-pecuniary damages in an amount to be assessed for each person who was prescribed with one of the Defendants' Semaglutide Products;

(g) in the alternative to the claim for damages, an accounting or other such restitutionary remedy disgorging the revenues realized by the Defendants from the sale of their Semaglutide Products;

(h) damages for family members, pursuant to provincial legislation and common law in each province, where applicable, including the *Family Compensation Act,* R.S.B.C. 1996, c. 126

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

(j) costs for the administration of any court award or judgment obtained in this action;

(k) recovery of health care costs incurred by the Ministry of Health Services on their behalf pursuant to the *Health Care Costs Recovery Act*, SBC, 2008, c 27 and similar legislation in other provinces and/or territories, where applicable;

(l) interest pursuant to the *Court Order Interest Act*, RSBC 1996 c 79; and

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

PART 3: LEGAL BASIS

120. In bringing this action on behalf of a class which includes residents of Canada who used Semaglutide Products at any time on or before the date of the certification order, the Plaintiff pleads and relies upon the provisions of the *Class Proceedings*

Act, RSBC 1996, c 50, as amended and regulations thereunder, the *Food and Drugs Act*, RSC, 1985, c F-27, as amended and regulations thereunder, the *Negligence Act*, RSBC 196 c 333, as amended and regulations thereunder, the *Court Rules Act*, RSBC 1996, c 80, as amended and regulations thereunder, and the *Court Jurisdiction and Proceedings Transfer Act*, RSBC 2003, c 28, as amended and regulations thereunder. The Plaintiff also brings this action on behalf of a class which includes persons resident in Canada entitled to claim by virtue of a personal or familial relationship to any one or more of the persons described above and pleads and relies upon the applicable provincial and/or territorial legislation and common law, including the British Columbia *Family Compensation Act,* R.S.B.C. 1996, c. 126, as amended and regulations thereunder.

A. Causes of Action

i. Negligence (including Negligent Design or Testing, Negligent Manufacture and Failure to Warn)

121. As the designers, testers, researchers. manufacturers, marketers, distributors, importers, labellers, packagers, handlers, storers, or sellers of Semaglutide Products, the Defendants were in such a close and proximate relationship to the Plaintiff, and other Class Members, as to owe them a duty of care. The Defendants designed semaglutide to be used as the active ingredient in Semaglutide Products, conducted testing of semaglutide and Semaglutide Products, procured regulatory approvals for the use of semaglutide in Semaglutide Products, and caused Semaglutide Products to be introduced into the stream of commerce in Canada,

when they knew that any dangers or defects related to Semaglutide Products would cause foreseeable injury to the Plaintiff and Class Members.

122. The Defendants at all material times owed a duty of care to the Plaintiff and Class Members to:

(a) ensure that their Semaglutide Products were fit for their intended and/or reasonably foreseeable use;

(b) design their Semaglutide Products so as to avoid safety risks and to make them reasonably safe for their intended purposes;

(c) see that there were no defects in manufacture of their Semaglutide Products that were likely to give rise to injury in the ordinary course of use;

(d) conduct appropriate testing to determine whether and to what extent use of their Semaglutide Products posed serious health risks, including the magnitude of risk of developing Injuries, Conditions, and Complications;

(e) ensure that physicians were kept fully and completely warned and informed regarding all risks associated with their Semaglutide Products;

(f) warn consumers of dangers inherent in the use of their Semaglutide Products of which they knew or ought to have known;

(g) monitor, investigate, evaluate and follow up on adverse reactions to the use of their Semaglutide Products; and

(h) properly inform Health Canada and other regulatory agencies of all risks associated with their Semaglutide Products.

123. The Defendants negligently breached their duty of care.

124. The Plaintiff states that her damages, and the damages of prospective Class Members, were caused by the negligence of the Defendants. Such negligence includes, but is not limited to the Defendants:

(a) failure to ensure that their Semaglutide Products were not dangerous to recipients during the course of their use and that they were fit for their intended purpose and of merchantable quality;

(b) failure to ensure that their Semaglutide Products were free of any manufacturing defects that would expose recipients to Injuries, Conditions, and Complications;

(c) failure to adequately test their Semaglutide Products in a manner that would fully disclose the magnitude of the risks associated with their use, including but not limited to Injuries, Conditions, and Complications;

(d) adopting unreasonable and/or careless and/or defective product design with their Semaglutide Products, resulting in Injuries, Conditions, and Complications;

(e) designing their Semaglutide Products in a way which created a substantial likelihood of harm when there existed safer alternative designs and/or products which were economically feasible to manufacture;

(f) carelessly choosing to employ semaglutide as the active ingredient in Semaglutide Products when the Defendants knew, or ought to have known,

that it could have chosen a safer active ingredient that was at least as effective as semaglutide;

(g) failure to provide Health Canada complete and accurate information with respect to their Semaglutide Products as it became available;

(h) failure to conduct any or adequate follow-up studies on the efficacy and safety of their Semaglutide Products;

(i) failure to conduct any or adequate long-term studies of the risks of their Semaglutide Products;

(j) failure to adequately review, consider, and act up on available scientific literature relevant to semaglutide;

(k) failure to provide the Plaintiff, Class Members, her physicians and Health Canada with proper, adequate, and/or fair warning of the risks associated with use of their Semaglutide Products, including but not limited to risk of Injuries, Conditions, and Complications;

(l) failure to adequately monitor, evaluate and act upon reports of adverse reactions to their Semaglutide Products in Canada and elsewhere;

(m) failure to provide any or any adequate updated and/or current information to the Plaintiff, Class Members, physicians and/or Health Canada respecting the risks of their Semaglutide Products as such information became available from time to time;

(n) failure to provide adequate warnings of the risks associated with their Semaglutide Products, including the risk of Injuries, Conditions, and

Complications in all persons receiving their Semaglutide Products on the patient information pamphlets, product labels, and product monographs in Canada;

(o) failure, after noticing problems with their Semaglutide Products, to issue adequate warnings, timely recall their Semaglutide Products, publicize the problems and otherwise act properly and in a timely manner to alert the public, including adequately warning the Plaintiff, Class Members, and their physicians of their Semaglutide Products' inherent dangers, including but not limited to the danger of Injuries, Conditions, and Complications;

(p) failure to establish any adequate procedures to educate their sales representatives and physicians respecting the risks associated with their Semaglutide Products;

(q) representation, explicitly and/or implicitly, that their Semaglutide Products were safe and fit for their intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;

(r) misrepresentation of the state of research pertaining to the purported benefits of their Semaglutide Products and their associated risks, including the risk of Injuries, Conditions, and Complications;

(s) misrepresentations that were unreasonable in the face of the risks that were known or ought to have been known by the Defendants;

(t) failure to timely cease the manufacture, marketing and/or distribution of their Semaglutide Products when they knew or ought to have known that their Semaglutide Products caused Injuries, Conditions, and Complications;

(u) failure to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act*, RSC 1985, c F 27 and its associated regulations;

(v) failure to properly supervise their employees, subsidiaries and affiliated corporations;

(w) breach of other duties of care to the Plaintiff and putative class members, details of which breaches are known only to the Defendants; and

(x) in all of the circumstances of this case, the Defendants applied callous and reckless disregard for the health and safety of the Plaintiff and putative class members.

125. The Defendants' conduct in negligently designing, testing, manufacturing, marketing, distributing, importing, labeling, packaging, handling, storing, and/or selling Semaglutide Products has resulted in foreseeable, real and substantial danger to the health and safety of the Plaintiff and Class Members.

126. Any benefit from using Semaglutide Products was outweighed by the serious and undisclosed risks of its use when used as intended. There are no individuals for whom the benefits of Semaglutide Products outweigh the risks, given that there are alternative products that are at least as effective as Semaglutide Products and carry materially lower risks than Semaglutide Products, or, in the alternative, if

there are individuals for whom the benefits of Semaglutide Products outweigh the risks, those individuals could have only made an informed decision as to whether to purchase or use Semaglutide Products if they had been fully informed of the risks inherent in the use of Semaglutide Products.

127. The Defendants knew, or ought to have known, that the foreseeable risks of Semaglutide Products exceeded the benefits associated with their use.

128. The Defendants knew, or ought to have known, that Semaglutide Products were more dangerous than persons using such products and their physicians or other health care providers, as reasonably prudent consumers and health care providers, would expect when used in an intended or reasonably foreseeable manner.

129. The Defendants, at all material times, had the economic and technical means to provide a safer alternative design of Semaglutide Products.

130. The risks associated with use of the Defendants' Semaglutide Products, including Injuries, Conditions, and Complications in all persons receiving their Semaglutide Products, were in the exclusive knowledge and control of the Defendants. The extent of the risks was not known to, and could not have been known by, the Plaintiff or Class Members. The Plaintiff's injuries, and Class Members' injuries, would not have occurred but for the negligence of the Defendants in failing to ensure that their Semaglutide Products were safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with using their Semaglutide Products to the Plaintiff and putative class members, and to their physicians.

131. Because the Defendants were designing, manufacturing, marketing, distributing, importing, labelling, packing, handling, storing, and/or selling Semaglutide Products for human consumption and injection, the standard of care expected in the circumstances rises to the level of strict liability as to whether the Defendants fell below the standard of care in failing to warn the Plaintiff and the Class Members of the dangers inherent in the ordinary use of Semaglutide Products, either directly or through a learned intermediary.

ii. Negligent Misrepresentation and Marketing

132. The Defendants were negligent in representing that Semaglutide Products were safe for their intended use. The representation was made either explicitly or implicitly by failing to inform the Plaintiff and other Class Members that the ingestion of Semaglutide Products exposes users to a heightened risk of developing serious Injuries, Conditions, and Complications.

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

(a) their design, manufacture, and testing of Semaglutide Products;

(b) their skill, experience, and expertise in the design, manufacture, and testing of Semaglutide Products generally;

(c) their supply and/or sale of Semaglutide Products to the Plaintiff and the other Class Members;

(d) the Defendants' complete control of the promotion and marketing of Semaglutide Products;

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

(f) the fact that Class Members had no option but to rely on the representations of the Defendants in respect of Semaglutide Products and their features, attributes, and safety (including the absence of information regarding the risk of developing serious Injuries, Conditions, and Complications).

134. The Defendants owed a duty of care to the Plaintiff and to other Class Members. It was intended by the Defendants, and reasonably foreseeable, that Class Members, when they were purchasing and/or using Semaglutide Products, would rely upon the representation that Semaglutide Products were safe for their intended uses, which representation was made either explicitly or implicitly by failing to state that the ingestion of Semaglutide Products exposes users to a heightened risk of developing serious Injuries, Conditions, and Complications. It was also intended by the Defendants and reasonably foreseeable that Class Members would suffer the damages described herein.

135. The representation was untrue, inaccurate, and/or misleading and was made negligently.

136. The Plaintiff and the Class Members reasonably relied on the representation that Semaglutide Products were safe for their intended uses, which was made either explicitly or implicitly by failing to state that the ingestion of Semaglutide Products exposes users to a heightened risk of developing serious Injuries, Conditions, and Complications. Their reliance can be inferred on a class-wide base from the

voluntary ingestion of Semaglutide Products. If the representation had not been made, or if the Defendants had disclosed that the ingestion of Semaglutide Products exposes users to a heightened risk of developing serious Injuries, Conditions, and Complications, the Class Members would not have agreed to be treated with Semaglutide Products given that there are alternative treatments that are at least as efficacious.

137. The representations were false and made negligently.

138. The Plaintiff and Class Members suffered loss and damage as a result of relying on the Defendants' representation or omission in treatment with Semaglutide Products. The Defendants are liable to pay damage to the Class Members.

B. Damages

139. The Plaintiff and other putative class members' injuries and damages were caused by the negligence of the Defendants, their servants, and agents.

140. 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.

141. The Plaintiff and other putative class members have suffered special damages for medical costs incurred in the screening, diagnosis, and treatment of Injuries, Conditions, and Complications related to use of the Defendants' Semaglutide Products.

142. As a result of the conduct of the Defendants, the Plaintiff and other putative class members suffered and continue to suffer expenses and special damages, of a nature and amount to be particularized prior to trial.

143. Some of the expenses related to the medical treatment that the Plaintiff and class members have undergone, and will continue to undergo, have been borne by the various provincial health insurers and/or territorial health insurers. As a result of the negligence 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. These subrogated interests are asserted by the Plaintiff and the putative class members pleading and relying upon the *Health Care Costs Recovery Act*, SBC 2008, c 27 and similar legislation in other provinces and/or territories, where applicable.

144. The Plaintiff claims punitive, aggravated, and exemplary damages for the reckless and unlawful conduct of the Defendants.

145. The Defendants engaged in conduct that is appropriately characterized as a marked departure from ordinary standards of decent behaviour. The Defendants egregiously overlooked and/or deceitfully withheld information regarding serious risks with Semaglutide Products. The Defendants failed to provide any warning or any adequate warning of the risks of Injuries, Conditions, and Complications, despite a preponderance of scientific evidence and other reports that linked Semaglutide Products to these risks.

C. Jurisdiction

146. There is a real and substantial connection between British Columbia and the facts alleged in this proceeding. The Plaintiff and Class Members plead and rely upon the *Court Jurisdiction and Proceeding Transfer Act*, SBC 2003, c 28 ("*CJPTA*") in respect of the Defendants. Without limiting the foregoing, a real and substantial connection exists between British Columbia and the facts alleged in this proceeding pursuant to sections 10(f) to 10(h) of the *CJPTA* because this proceeding:

(a) concerns restitutionary obligations that arose in British Columbia;

(b) concerns a tort committed in British Columbia; and

(c) concerns a business carried on in British Columbia.

Plaintiff's address for service: **Siskinds LLP**
Barristers & Solicitors
555 Burrard Street, Suite 16-111
Vancouver, BC, V7X 1M8

Fax number address for service (if any): 1.519.660.7859

E-mail address for service (if any): jill.mccartney@siskinds.com

Place of trial: Vancouver, British Columbia

The address of the registry is: 800 Smithe Street, Vancouver, BC, V6Z 2E1

Date: 06 OCT 2023

Signature of lawyer for Plaintiff
Jill S. McCartney
James E. Boyd
Charles M. Wright

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 the design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of their Semaglutide Products.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

A personal injury arising out of:

[ ] a motor vehicle accident
[ ] medical malpractice
[x] another cause

A dispute concerning:

[ ] contaminated sites
[ ] construction defects
[ ] real property (real estate)
[ ] personal property
[x] 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:

[x] a class action
[ ] maritime law
[ ] aboriginal law
[ ] constitutional law
[ ] conflict of laws
[ ] none of the above
[ ] do not know

Part 4:

Class Proceedings Act, RSBC 1996, c 50
Food and Drugs Act, RSC, 1985, c F-27
Negligence Act, RSBC 196 c 333
Family Compensation Act, RSBC 1996, c 126
Health Care Costs Recovery Act, SBC, 2008, c 27
Court Jurisdiction and Proceedings Transfer Act, SBC 2003, c 28
Court Rules Act, RSBC 1996, c 80
Supreme Court Civil Rules, BC Reg 168/2009
Court Order Interest Act, RSBC 1996, c 79

ENDORSEMENT ON ORIGINATING PLEADING OR PETITION FOR SERVICE OUTSIDE BRITISH COLUMBIA

The Plaintiff, SUZANNE TALBOT, claims the right to serve this pleading on the Defendants outside British Columbia on the ground that there is a real and substantial connection between British Columbia and the facts alleged in this proceeding and the Plaintiff and other Class Members plead and rely upon the *CJPTA* in respect of these Defendants. Without limiting the foregoing, a real and substantial connection between British Columbia and the facts alleged in this proceeding exists pursuant to section 10(f) to 10(h) of the *CJPTA* because this proceeding:

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

(g) concerns a tort committed in British Columbia; and

(h) concerns a business carried on in British Columbia.