No._____
Vancouver Registry

In the Supreme Court of British Columbia

Between

BRANDON SCHOLTEN and DEBORAH ANNIS

Plaintiffs

and

MERCK & CO., INC., SCHERING-PLOUGH CANADA INC., INDIVIOR PLC, INDIVIOR UK LIMITED, INDIVIOR CANADA LIMITED, INDIVIOR INC., INDIVIOR SOLUTIONS INC., RECKITT BENCKISER GROUP PLC, RECKITT BENCKISER HEALTHCARE (UK) LIMITED, RECKITT BENCKISER LLC, PHARMA IMPORTING INC., AQUESTIVE THERAPEUTICS, INC., MONOSOL RX, INC., and MONOSOL, LLC

Defendants

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

NOTICE OF CIVIL CLAIM

This action has been started by the plaintiffs 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 plaintiffs.

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 plaintiffs 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 plaintiffs,

(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 PLAINTIFFS

PART 1: STATEMENT OF FACTS

A. Nature of the Action

1. This is a proposed class proceeding for damages arising from pharmaceutical drugs marketed under the brand name Suboxone (collectively "Suboxone Products"), prescription medications which contain the active ingredients buprenorphine and naloxone. This action arises from the Defendants' unlawful, negligent, improper, unfair, and deceptive practices and misrepresentations related to, *inter alia*, their design, development, testing, research, manufacturing, licensing, labelling, warning, marketing, distribution, and sale of Suboxone 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 Suboxone Products, the Defendants failed to warn consumers adequately, or at all, of significant risks of dangerous side effects linked to the use of Suboxone Products, including serious dental issues (such as cavities, tooth decay, dental abscesses/infection, rampant caries, tooth erosion, fillings falling out, periodontal disease, cracking teeth, burning mouth syndrome, dental nerve damage, and total tooth loss). Ultimately, patients, including the Plaintiffs, have been placed at risk and harmed as a result of the conduct of the Defendants.

3. The Defendants misrepresented that their Suboxone Products are safe, when in fact these medications cause serious Injuries, Conditions, and Complications (as defined herein). Patients who were prescribed and/or ingested Suboxone 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 Plaintiffs

4. The Plaintiff, Brandon Scholten ("Mr. Scholten"), resides in Langley, British Columbia and was born on October 15, 1992.

5. On or around 2017, Mr. Scholten was prescribed and began taking Suboxone Products for pain management and opioid addiction.

6. Mr. Scholten has continued to be prescribed and use Suboxone Products on a regular basis since his initial prescription.

7. Subsequent to starting his regular prescriptions for Suboxone Products, Mr. Scholten experienced concerning signs and symptoms regarding his oral and/or dental health, including tooth decay, tooth erosion, and dental nerve damage. Mr. Scholten's worsening oral and/or dental health has required him to seek treatment from dental health professionals for his dental and/or oral health issues, including the receipt of fillings.

8. Mr. Scholten continues to experience concerning signs and symptoms regarding worsening oral and/or dental health today. He has been told by dental health professionals that he will require additional treatment for these issues, including the receipt of additional fillings.

9. The Plaintiff, Deborah Annis ("Mrs. Annis"), resides in Prince George, British Columbia and was born on April 28, 1960.

10. On or around 2010, Mrs. Annis was prescribed and began taking Suboxone Products for pain management and opioid addiction.

11. Mrs. Annis continued to be prescribed and use Suboxone Products on a regular basis until on or around 2013.

12. Subsequent to starting her regular prescriptions for Suboxone Products, Mrs. Annis experienced concerning signs and symptoms regarding her oral and/or dental health, including tooth decay, cavities, cracking teeth, and burning mouth syndrome. Mrs. Annis's worsening oral and/or dental health has required her to

seek treatment from dental health professionals for her dental and/or oral health issues, including the receipt of fillings and root canals.

13. Mrs. Annis continues to experience concerning signs and symptoms regarding her worsening oral and/or dental health today. She has been told by dental health professionals that she will require additional treatment for these issues, including the pulling of teeth.

14. The Plaintiffs bring this action on their 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

15. The Defendant, Schering-Plough Canada Inc. (“Schering-Plough Canada”), is a corporation incorporated pursuant to the laws of Canada and having a principal place of business at Kirkland, Quebec. Schering-Plough Canada is the original sponsor or market authorization holder for Suboxone Products in Canada, meaning that it was the entity formerly authorized by Health Canada to sell Suboxone Products in Canada. Schering-Plough Canada has authored, published, and distributed marketing materials, including product monographs, which were promoted as sources of information regarding the safety and efficacy of Suboxone Products and were readily available to and relied on by consumers, including in Canada. At times relevant to this action, Schering-Plough Canada designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil

Claim to Schering-Plough Canada include all of its divisions and predecessor companies.

16. Schering-Plough Canada is a wholly owned subsidiary of Merck & Co., Inc. At times relevant to this action, Merck & Co., Inc. (and its predecessor Schering-Plough Corporation) had responsibility for the operations of Schering-Plough Canada.

17. The Defendant, Merck & Co., Inc. (which does business as “Merck”), is a public company organized under the laws of New Jersey, in the United States of America (the “U.S.” or “USA”), and having a principal place of business at Rahway, New Jersey. At times relevant to this action, Merck (and its predecessor Schering-Plough Corporation) and its subsidiaries had responsibility for marketing Suboxone Products globally, including in Canada. Merck (and its predecessor Schering-Plough Corporation) has authored, published, and distributed marketing materials, which were promoted as sources of information regarding the safety and efficacy of Suboxone Products and were readily available to and relied on by consumers, including in Canada. At times relevant to this action, Merck designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to Merck include all of its divisions and predecessor companies, including Schering-Plough Corporation.

18. Hereinafter, Schering-Plough Canada and Merck shall be collectively referred to as the “Merck Defendants”.

19. The business of each of the Merck 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, Suboxone Products in Canada. In view of the close relationship between the Merck Defendants and the foregoing, each of the Merck Defendants is jointly and severally liable for the acts and omissions of each other and their predecessors.

20. The Defendant, Indivior Canada Limited ("Indivior Canada"), is a corporation incorporated pursuant to the laws of Ontario and having a principal place of business at Toronto, Ontario. Indivior Canada is the Canadian operation of Indivior PLC. At times relevant to this action, Indivior Canada had responsibility for marketing Suboxone Products in Canada. Indivior Canada . At times relevant to this action, Indivior Canada designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to Indivior Canada include all of its divisions and predecessor companies.

21. Indivior Canada is a wholly owned subsidiary of Indivior PLC. At times relevant to this action, Indivior PLC had responsibility for the operations of Indivior Canada.

22. The Defendant, Indivior PLC (which does business as "Indivior"), is a public company organized under the laws of the United Kingdom and having a principal place of business at Slough, England. Indivior authors, publishes, and distributes marketing materials, including webpages and press releases, which are promoted

as sources of information regarding the safety and efficacy of Suboxone Products and are readily available to and relied on by consumers, including in Canada. At times relevant to this action, Indivior designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to Indivior include all of its divisions and predecessor companies.

23. The Defendant, Indivior UK Limited ("Indivior UK"), is a company incorporated pursuant to the laws of the United Kingdom and having a principal place of business at Hull, England. Indivior UK is the sponsor or market authorization holder for Suboxone Products in Canada, meaning that it is the entity authorized by Health Canada to sell Suboxone Products in Canada. Indivior UK had responsibility for developing Suboxone and first bringing it to market globally in the 2000s. Since October 2013, Indivior UK has been the registrant of various Suboxone trademarks in Canada. Currently, Indivior UK is the current registrant of the trademark to the word Suboxone (TMA712376) and multiple design trademarks for Suboxone (TMA773952 and TMA842600). Indivior UK authors, publishes, and distributes marketing materials, including product monographs, which are promoted as sources of information regarding the safety and efficacy of Suboxone Products and are readily available to and relied on by consumers, including in Canada. At times relevant to this action, Indivior UK designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil

Claim to Indivior UK include all of its divisions and predecessor companies, including RB Pharmaceuticals Limited.

24. Indivior UK is a wholly owned subsidiary of Indivior. At times relevant to this action, Indivior had responsibility for the operations of Indivior UK.

25. The Defendant, Indivior Inc. ("Indivior Inc"), is a corporation incorporated pursuant to the laws of Delaware, USA and having a principal place of business at Wilmington, Delaware. Indivior Inc is the American operation of Indivior. Indivior Inc had responsibility for developing the sublingual film version of Suboxone and first bringing it to market globally in the 2010s. Indivior Inc authors, publishes, and distributes marketing materials, including websites, which are promoted as sources of information regarding the safety and efficacy of Suboxone Products and are readily available to and relied on by consumers, including in Canada. At times relevant to this action, Indivior Inc designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to Indivior Inc include all of its divisions and predecessor companies, including Reckitt Benckiser Pharmaceuticals Inc.

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

27. The Defendant, Indivior Solutions Inc. ("Indivior Solutions"), is a corporation incorporated pursuant to the laws of Delaware, USA and having a principal place of business at Wilmington, Delaware. At times relevant to this action, Indivior Solutions designed, developed, tested, researched, manufactured, marketed,

supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to Indivior Solutions include all of its divisions and predecessor companies.

28. Indivior Solutions is a wholly owned subsidiary of Indivior. At times relevant to this action, Indivior had responsibility for the operations of Indivior Solutions.

29. Hereinafter, Indivior, Indivior Canada, Indivior UK, Indivior Inc, and Indivior Solutions shall be collectively referred to as the “Indivior Defendants”.

30. The business of each of the Indivior 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, Suboxone Products in Canada. In view of the close relationship between the Indivior Defendants and the foregoing, each of the Indivior Defendants is jointly and severally liable for the acts and omissions of each other and their predecessors.

31. The Defendant, Reckitt Benckiser Group PLC (which does business as “Reckitt”), is a public company organized under the laws of the United Kingdom and having a principal place of business at Slough, England. Reckitt and its then subsidiaries had responsibility for developing Suboxone and first bringing it to market globally in the 2000s. Reckitt and its then subsidiaries had responsibility for developing the film form of Suboxone and first bringing it to market globally in the 2010s. Reckitt authored, published, and distributed marketing materials, including webpages and press releases, which were promoted as sources of information regarding the

safety and efficacy of Suboxone Products and were readily available to and relied on by consumers, including in Canada. At times relevant to this action, Reckitt designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to Reckitt include all of its divisions and predecessor companies.

32. The Indivior Defendants were formerly wholly owned subsidiaries of Reckitt until December 2014 when the Indivior Defendants were spun off into a separate business, organized under Indivior as the new parent company. At times relevant to this action, Reckitt had responsibility for the operations of Indivior Defendants.

33. The Defendant, Reckitt Benckiser Healthcare (UK) Limited ("RB Healthcare"), is a company incorporated pursuant to the laws of the United Kingdom and having a principal place of business at Slough, England. RB Healthcare had responsibility for developing Suboxone and first bringing it to market globally in the 2000s. RB Healthcare was the original registrant of various Suboxone trademarks in Canada, including the trademark to the word Suboxone (TMA712376) and multiple design trademarks (TMA773952 and TMA842600), which it held from the time of their registrations until October 2013. At times relevant to this action, RB Healthcare designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to RB Healthcare include all of its divisions and predecessor companies.

34. RB Healthcare is a wholly owned subsidiary of Reckitt. At times relevant to this action, Reckitt had responsibility for the operations of RB Healthcare.

35. The Defendant, Reckitt Benckiser LLC ("RB LLC"), is a company incorporated pursuant to the laws of the Delaware, USA and having a principal place of business at Wilmington, Delaware. At times relevant to this action, RB LLC designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to RB LLC include all of its divisions and predecessor companies, including Reckitt Benckiser Inc.

36. RB LLC is a wholly owned subsidiary of Reckitt. At times relevant to this action, Reckitt had responsibility for the operations of RB LLC.

37. Hereinafter, Reckitt, RB Healthcare, and RB LLC shall be collectively referred to as the "Reckitt Defendants".

38. The business of each of the Reckitt 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, Suboxone Products in Canada. In view of the close relationship between the Reckitt Defendants and the foregoing, each of the Reckitt Defendants is jointly and severally liable for the acts and omissions of each other and their predecessors.

39. The Defendant, Pharma Importing Inc. ("Pharma Importing"), is a corporation incorporated pursuant to the laws of Ontario and having a principal place of business at Toronto, Ontario. Pharma Importing is listed as an importer and distributor on the Product Monographs (as defined herein) for Suboxone Products

in Canada. At times relevant to this action, Pharma Importing designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to Pharma Importing. include all of its divisions and predecessor corporations.

40. The Defendant, Aquestive Therapeutics, Inc. ("Aquestive"), is a corporation organized under the laws of Delaware, USA and having a principal place of business at Warren, New Jersey. Aquestive is the exclusive global manufacturer of Suboxone sublingual film. Aquestive had responsibility for developing the sublingual film version of Suboxone and first bringing it to market globally in the 2010s. At times relevant to this action, Aquestive designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to Aquestive include all of its divisions and predecessor corporations, including MonoSol Rx, LLC.

41. The Defendant, MonoSol Rx, Inc. ("MonoSol Inc"), is a corporation organized under the laws of Delaware, USA and having a principal place of business at Warren, New Jersey. At times relevant to this action, MonoSol Inc designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to MonoSol Inc include all of its divisions and predecessor corporations.

42. MonoSol Inc. is a wholly owned subsidiary of Aquestive. At times relevant to this action, Aquestive had responsibility for the operations of MonoSol Inc.

43. Hereinafter, Aquestive and MonoSol Inc shall be collectively referred to as the "Aquestive Defendants".

44. The business of each of the Aquestive 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, Suboxone Products in Canada. In view of the close relationship between the Aquestive Defendants and the foregoing, each of the Aquestive Defendants is jointly and severally liable for the acts and omissions of each other and their predecessors.

45. The Defendant, MonoSol, LLC, is a company organized under the laws of Delaware, USA and having a principal place of business at Merrillville, Indiana. MonoSol, LLC had responsibility for developing the technology used in the soluble film form of Suboxone. At times relevant to this action, MonoSol, LLC designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Suboxone Products in Canada. All references in this Notice of Civil Claim to MonoSol, LLC include all of its divisions and predecessor corporations.

46. Aquestive was formed from a corporate reorganization of MonoSol, LLC in 2004. Aquestive continued activities that were previously carried out as part of the research and development efforts of MonoSol, LLC.

47. At all material times, all the Defendants were engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling, and/or selling Suboxone Products in Canada. The development of Suboxone 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 Suboxone Products, and other actions central to the allegations of this lawsuit, were undertaken by the Defendants in British Columbia and elsewhere.

C. The Defendants' Suboxone Products

48. "Suboxone Products" are drug products having the anatomical therapeutic chemicals buprenorphine and naloxone as their active pharmaceutical ingredients which were marketed, sold, and/or otherwise distributed to Canadians by the Defendants under the brand name "Suboxone".

49. The initial form of Suboxone Products was developed in the 2000s by the pharmaceutical arm of the Reckitt group of companies, including Reckitt and its then subsidiaries RB Pharmaceuticals Limited (now Indivior UK) and RB Healthcare.

50. Suboxone Products were initially developed and marketed in the form of a tablet for sublingual administration. Later, a soluble film form of Suboxone Products was developed and marketed, for sublingual use and buccal use.

51. Suboxone Products have been approved for use, marketed, distributed, and sold in Canada in various forms and dosages including in sublingual tablet form, including versions containing buprenorphine (as buprenorphine hydrochloride) and naloxone (as naloxone hydrochloride) in combination dosages of 2 mg / 0.5 mg, 8 mg / 2 mg, 12 mg / 3 mg and 16 mg / 4 mg, and in soluble film form, including versions containing buprenorphine (as buprenorphine hydrochloride) and

naloxone (as naloxone hydrochloride) in combination dosages of 2 mg / 0.5 mg, 4 mg / 1 mg, 8 mg / 2 mg and 12 mg / 3 mg.

52. Suboxone Products fall within a class of medicines called opioid agonists or partial opioid agonists, which are medications used to treat opioid addiction.

53. Suboxone Products are indicated for substitution treatment in adults with problematic opioid drug dependence. Suboxone Products work to reduce withdrawal symptoms when stopping opioids and for an extended period of time afterward. Suboxone Products can be placed under the tongue (sublingual) or between the gums and cheek (buccal), where they dissolve in the mouth. The drugs are fixed-dose combination medications that include the active ingredients buprenorphine (which is an opioid itself) and naloxone (which is an opioid antagonist). When absorbed by way of Suboxone Products, buprenorphine results in the usual opioid effects and is believed to result in a lower risk of overdose than some other opioids. Theoretically, buprenorphine's inclusion in Suboxone Products increases the ability of users to wean off of other opioids. Naloxone competes with and blocks the effect of other opioids (including buprenorphine), and theoretically, naloxone's inclusion in Suboxone Products also decreases the risk that people will misuse Suboxone Products.

54. The different formulations of Suboxone Products, including the soluble film form, are designed to be acidic to maximize absorption of buprenorphine while minimizing absorption of naloxone.

55. During the period of time that the Defendants' Suboxone 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 opioid dependence, which can be used in lieu of Suboxone Products, including, but not limited to, other pharmaceutical options, such as methadone, slow-release oral morphine, injectable opioid agonist treatment medications, and other forms of buprenorphine which are not administered sublingually or buccally (including injections), as well as non-pharmaceutical options, such as various non-medicinal forms of therapy.

i. Suboxone sublingual tablets

56. Suboxone Products were first approved for use in Canada in 2007 in their sublingual tablet form.

57. At the time of Suboxone Products's entry into the Canadian market, Schering-Plough Corporation, a predecessor of Merck and the parent company of Schering-Plough Canada, held exclusive marketing rights to Suboxone tablets in various global markets (including Canada) on a license from Reckitt.

58. On May 18, 2007, Schering-Plough Canada became the initial approved market authorization holder for Suboxone Products in Canada (i.e., held the Notice of Compliance for Suboxone). Initially, the drugs were approved for marketing in their sublingual tablet form in combination doses (buprenorphine / naloxone) of 2 mg / 0.5 mg and 8 mg / 2 mg. On November 26, 2007, following Health Canada approval, Schering-Plough Canada first marketed and sold Suboxone Products (in the form of sublingual tablets) in Canada. Later, additional combination doses of the sublingual tablet form of Suboxone Products were approved and marketed in Canada, including combination doses (buprenorphine / naloxone) of 12 mg / 3 mg

(first marketed in February 2018) and 16 mg / 4 mg (first marketed in February 2018).

59. In or around 2009, Schering-Plough Corporation merged with Merck & Co, Inc. to become Merck.

60. In or around 2011, Merck's license to market Suboxone Products in Canada ended.

61. On April 26, 2011, RB Pharmaceuticals Limited, the predecessor company to Indivior UK, became the approved market authorization holder for Suboxone Products in Canada (i.e., held the Notice of Compliance for Suboxone).

62. In or around December 2014, Reckitt spun off much of its pharmaceutical business into a separate group of companies under the new parent company Indivior. The corporate change was achieved by way of a demerger agreement and saw Indivior, Indivior UK (then known as RB Pharmaceuticals Limited), and various other subsidiaries spun off as part of the newly formed Indivior group of companies. RB Healthcare was not spun off and remained a Reckitt subsidiary.

63. Following the December 2014 demerger, the Reckitt group of companies remained involved in the manufacturing of Suboxone Products. At the time of the demerger, a supply arrangement existed between RB Pharmaceuticals Limited and RB Healthcare. RB Healthcare manufactured active pharmaceutical ingredients ("API"), including buprenorphine, and finished pharmaceutical products, including Suboxone tablets, on behalf of RB Pharmaceuticals Limited, and RB Pharmaceuticals Limited purchased the API and finished products for onward

distribution. As part of the demerger agreement, Reckitt and Indivior were required to procure that RB Healthcare and Indivior UK (then known as RB Pharmaceuticals Limited) enter into a new agreement with respect to the supply arrangement for Suboxone Products, which commenced on April 1, 2015. Under the new agreement, RB Healthcare assumed responsibility for the formulation, compressing, and finished good packaging of Suboxone tablets and agreed to manufacture the finished products exclusively for Indivior UK. Indivior UK agreed to purchase those products exclusively from RB Healthcare for a period of at least seven years running through spring 2022.

64. In or around the summer of 2015, major operating companies within the new Indivior group of companies changed their names from their former Reckitt subsidiary names to Indivior branded names. RB Pharmaceuticals Limited changed its company name to Indivior UK Limited.

65. On August 25, 2015, Indivior UK was registered as the new approved market authorization holder for Suboxone Products in Canada (i.e., held the Notice of Compliance for Suboxone).

ii. Suboxone soluble film

66. On or before January 2004, MonoSol, LLC began developing water-soluble film technology for pharmaceutical applications.

67. In or around January 2004, MonoSol Rx, LLC (a predecessor of Aquestive) was formed as a separate entity from MonoSol, LLC, as a drug company specializing in proprietary dissolving thin film pharmaceutical products. MonoSol Rx, LLC

continued activities that were previously carried out as part of the research and development efforts of MonoSol, LLC.

68. By or before July 2010, Aquestive (then known as MonoSol Rx, LLC) announced the first FDA-approved commercial application of its pharmaceutical soluble film technology called PharmFilm. PharmFilm was designed for soluble film applications for pharmaceuticals to deliver quick-dissolving therapeutic doses of medication, including through sublingual and/or buccal administration.

69. In or around 2010, Aquestive (then known as MonoSol Rx, LLC) and Reckitt announced the development of a soluble film form of Suboxone. The film form of Suboxone was developed by Aquestive and Indivior Inc (then known as Reckitt Benckiser Pharmaceuticals Inc), leveraging Aquestive's PharmFilm technology. Pursuant to an agreement between Indivior Inc and Aquestive, Aquestive became the global exclusive manufacturer and primary packager of Suboxone film and Aquestive agreed to manufacture and supply Indivior Inc and its affiliates exclusively with finished products for onward distribution.

70. On July 14, 2016, Aquestive (then known as MonoSol Rx, LLC) and MonoSol, LLC entered into an agreement concerning the sharing of intellectual property, which included the sharing of Aquestive's intellectual property concerning PharmFilm.

71. In late 2017, Aquestive announced it would change its name from MonoSol Rx, LLC to Aquestive Therapeutics, Inc.

72. On July 17, 2020, Health Canada granted Indivior UK approval to market the soluble film form of Suboxone Products in Canada. Initially the soluble film form of

Suboxone Products was approved for marketing in combination doses (buprenorphine / naloxone) of 2 mg / 0.5 mg, 8 mg / 2 mg, and 12 mg / 3 mg. On January 20, 2021, following Health Canada approval, Indivior UK Canada first marketed and sold Suboxone Products in soluble film form in Canada. Later, an additional combination dose (buprenorphine / naloxone) of the soluble film form of Suboxone Products was approved and marketed in Canada as 4 mg / 1 mg (first marketed in June 2021).

iii. The Widespread Use of Suboxone Products

73. Suboxone Products are highly prescribed opioid agonists in Canada and worldwide.

74. In 2012 alone, Suboxone Products generated $1.55 billion USD in revenue in the U.S.

75. In Canada, Suboxone Products were the exclusive form of pharmaceutical drug containing buprenorphine and naloxone that were approved for use in the country from when Suboxone Products first hit the market in 2007 until at least July 2013. The soluble film form of Suboxone Products are the only soluble film drugs containing buprenorphine and naloxone that are approved for use in Canada and have had market exclusivity since they hit the market in early 2021.

76. Suboxone is identified by Health Canada as a first line treatment for opioid abuse, which is an issue impacting +100,000s of Canadians with +36,000 opioid deaths in Canada from 2016 to 2022.

77. Between 2010 to 2019, the total milligrams of Suboxone Products that were accepted and paid for by public drug plans in just three provinces – British Columbia, Manitoba, and Saskatchewan – was estimated at over 74.6 million milligrams.

78. Suboxone's popularity in Canada has continued even years after generics entered the Canadian market. Public drug programs in Canada spent over $45 million on Suboxone Products in 2017 and over $46 million in 2018.

79. In 2019, Nova Scotia alone had over 700,000 suboxone and methadone prescriptions.

D. Defendants' Marketing of Suboxone Products to Canadians

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

81. At all material times, the Defendants commissioned promotional materials for Suboxone Products that were received by Canadians online and through other forms of media.

82. The Defendants marketed Suboxone Products online at dedicated websites accessible to Canadians, including Suboxone.com.

83. The Defendants promoted Suboxone Products in Canada with marketing materials, including press releases, which promoted Suboxone Products to Canadians and represented Suboxone Products as safe and effective.

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

85. The Defendants' marketing and promotional activities were specifically directed at attracting consumers, including Canadians, to seek out the initiation and continuation of treatment with Suboxone Products, while simultaneously failing to sufficiently warn of the risks of development of Injuries, Conditions, and Complications. The Defendants' marketing and promotional materials, including webpages, press releases, and other forms of advertisements, were readily accessible by Canadians. 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 Suboxone Products.

86. The Defendants' aggressive tactics to gain and control the market for pharmaceutical treatments for opioid dependence, in order to increase prescriptions, sales, and use of Suboxone Products, have resulted in litigation and significant financial consequences.

87. In 2016, forty-one U.S. states and the District of Columbia sued Defendants for antitrust violations related to boxing out competitors from the opioid addiction treatment market. That litigation resolved via settlement in the summer of 2023, with Indivior agreeing to pay $102.5 million USD to resolve the case.

88. On April 9, 2019, a federal grand jury in Virginia indicted Indivior Inc and Indivior PLC for engaging in an illicit nationwide scheme to increase prescriptions of Suboxone film. The indictment ("Indictment") alleged that Indivior and Indivior Inc deceived health care providers and health care benefit programs into believing that Suboxone film is safer and less susceptible to diversion and abuse than other, similar drugs, even though there were no scientific studies to establish that claim. The Indictment further alleged that Indivior's "Here to Help" web and phone program was marketed by the company as a resource for addiction patients. But in reality, the program connected patients to doctors the company knew were prescribing Suboxone and other opioids to more patients than was lawful.

89. On July 11, 2019, the U.S. Department of Justice ("DOJ") announced that Reckitt had come to an agreement with the DOJ to resolve its potential criminal liability stemming from the conduct alleged in the Indictment as the former parent of the Indivior Defendants. Reckitt had agreed to forfeit $647 million USD of proceeds it received from Indivior Inc, pay $700 million USD in a civil settlement to the U.S. federal government and six U.S. states, and pay $50 million USD to the Federal Trade Commission ("FTC"). Both Reckitt and RB LLC were parties to the civil settlement. In total, Reckitt paid $1.4 billion USD, which was the largest recovery in a case concerning an opioid drug in U.S. history.

90. In 2020, two former Indivior executives, former CEO Shaun Thaxter and former global medical director Timothy Baxter, both pleaded guilty to misdemeanor misbranding of Suboxone film related to false statements about the drugs' safety relative to competitor drugs regarding the potential risk of accidental pediatric

exposure. Both individuals were sentenced to six figure USD fines and six months of jail time and home detention, respectively.

91. Shaun Thaxter had asked Indivior employees under his direction to devise a strategy to counteract a non-opioid competitor that was being considered for opioid-addiction treatment by a large U.S. state Medicaid agency. Timothy Baxter then met with the agency and concealed data on unintended pediatric exposure that was arguably unfavorable to Suboxone film. Then, during another meeting, Timothy Baxter concealed data showing that other buprenorphine drugs had lower rates of unintended pediatric exposure.

92. On July 24, 2020, the U.S. Department of Justice announced that several Indivior Defendants had come to an agreement with the DOJ to resolve the potential criminal and civil investigations against them associated with the marketing of Suboxone. Indivior, Indivior Inc, and Indivior Solutions had agreed to pay a total of $600 million USD, which consisted of a civil settlement with different levels of governments in the U.S., a payment to the FTC, and criminal penalties.

93. Under the civil settlement, Indivior and Indivior Inc, agreed to pay $209.3 million USD to the U.S. federal government and $90.7 million USD to certain states to resolve claims concerning the marketing of Suboxone, including allegations that they promoted the sale and use of Suboxone to physicians for uses that were unsafe, ineffective, and medically unnecessary and that they promoted the sale or use of Suboxone film to physicians and U.S. state Medicaid agencies using false and misleading claims that Suboxone film was less susceptible to abuse than other buprenorphine products and less susceptible to accidental pediatric exposure.

Under a separate agreement with the FTC, Indivior agreed to pay $10 million USD to resolve claims that it engaged in unfair methods of competition. Finally, Indivior Solutions was sentenced to pay $289 million USD in criminal penalties after pleading guilty to making false statements to a state Medicaid agency regarding the relative safety of Suboxone film for the risk of accidental pediatric exposure, in connection with the conduct of Shaun Thaxter and Timothy Baxter.

94. In total, U.S. government entities recovered over $2 billion USD from Reckitt Defendants, Indivior Defendants, and former Indivior executives relating to the U.S. government's criminal and civil investigations concerning improper marketing of Suboxone Products.

E. Risks of Serious Injuries, Conditions, and Complications

95. The use of Suboxone Products can lead to serious adverse side effects with significant consequences including the development of dental issues such as cavities, tooth decay, dental abscesses/infection, rampant caries, tooth erosion, fillings falling out, periodontal disease, cracking teeth, burning mouth syndrome, dental nerve damage, and total tooth loss.

96. The pH scale is a scale of the acidity or basicity of an aqueous solution. The scale has values ranging from zero (acidic) to fourteen (basic).

97. The pH of buprenorphine is acidic and has measured on or around 3.4 on the pH scale.

98. Acidic compounds are well known to adversely impact dental integrity, leading to dental erosion and decay.

99. Buprenorphine also has low oral bioavailability, so patients are instructed to keep the tablet in their mouth for as long as possible. The Product Monograph provides different recommendations for how long to let Suboxone Products dissolve, depending upon the form of the drug and route of administration, with 7.2 to 12.4 minutes for tablets administered sublingually, 4.2 to 11.8 minutes for film administered buccally, and 5.4 to 8.3 minutes for film administered sublingually.

100. When a substance as acidic as buprenorphine is kept in the mouth for such prolonged durations of time, it poses serious harms to oral and dental hygiene, akin to chronically drinking soda.

101. At all material times, the Defendants knew or ought to have known that Suboxone Products could cause major dental and oral complications, including but not limited to cavities, tooth decay, dental abscesses/infection, rampant caries, tooth erosion, fillings falling out, periodontal disease, cracking teeth, burning mouth syndrome, dental nerve damage, and total tooth loss (collectively “Injuries, Conditions, and Complications”).

F. Adverse Event Reports and Regulatory Action

102. The increased risk of Injuries, Conditions, and Complications which have been linked with the use of buprenorphine, and to Suboxone Products in particular, have been the subject of adverse event reports filed to Health Canada and FDA and warning communications issued from the FDA.

103. 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 400 adverse reaction reports involving “Suboxone” as a suspected product, filed to Health Canada through to the end of November 2023.

104. In the U.S., there have been over 20,700 cases of adverse events associated with “Suboxone” reported to the FDA’s Adverse Event Reporting System through to the end of December 2023, including over 14,200 serious cases and over 1,100 death cases.

105. Many of these adverse event reports involve dental or oral harms.

106. By or before January 2022, the Defendants were aware of over 300 reports of adverse dental events filed to the FDA in patients taking Suboxone, including over 130 serious reports.

107. Of the Adverse Reaction Reports filed to the Canada Vigilance Adverse Reaction Online Database, there are also over two dozen that specifically identify dental issues among the adverse reactions suffered by patients taking buprenorphine/naloxone products.

108. Subsequent to the numerous adverse event reports filed, regulators have taken action to warn consumers and healthcare professionals about the serious complications associated with the Defendants’ Suboxone Products.

109. In January 2022, the FDA made a series of public communications (including a January 12, 2022 Drug Safety Communication, a Medical Product Safety

Information bulletin, a drug safety podcast, and designated webpages) warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth, and that the dental problems, including tooth decay, cavities, oral infections, periodontal disease, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues.

G. Product Warnings

110. As the designers, developers, manufacturers, distributers, marketers, and sellers of Suboxone Products in Canada and to Canadians, the Defendants, including in particular those Defendants who are the sponsors of Suboxone Products in Canada, 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 Suboxone Products. One means by which the Defendants must communicate such risks is through the product monograph for Suboxone Products (the "Product Monograph" or "Product Monographs"). The Product Monographs are documents containing information on the uses, dosages, and risks associated with Suboxone 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.

111. 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 Indivior webpages.

112. Despite all the available information regarding the Injuries, Conditions, and Complications linked to Suboxone 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 patients regarding these effects on the teeth, mouth, gums, and tongue for patients taking Suboxone Products.

113. At times relevant to this action, the Product Monographs, as well as the label, packaging, and other prescribing information that accompanied Suboxone Products when prescribed to patients, have contained insufficient warnings related to risks of the Injuries, Conditions, and Complications, including cavities, tooth decay, dental abscesses/infection, rampant caries, tooth erosion, fillings falling out, periodontal disease, cracking teeth, burning mouth syndrome, dental nerve damage, and total tooth loss.

114. Before March 2023, the Defendants did not provide any meaningful warning whatsoever about serious risks of dental issues in the Canadian Product Monographs for any Suboxone Products.

115. On March 16, 2023, Indivior UK revised the Canadian product monograph for all Suboxone Products to add in warning information as it pertained to dental issues.

116. In “PART I: HEALTH PROFESSIONAL INFORMATION” under “WARNINGS AND PRECAUTIONS” the following subsection was added:

> **Dental Adverse Events**
>
> Cases of dental caries, some severe (i.e., tooth fracture, tooth loss), have been reported following the use of transmucosal buprenorphine-containing products. Reported events include cavities, tooth decay, dental abscesses/infection, rampant caries, tooth erosion, fillings falling out, and, in some cases, total tooth loss. Treatment for these events included tooth extraction, root canal, dental surgery, as well as other restorative procedures

> (i.e., fillings, crowns, implants, dentures). Multiple cases were reported in individuals without any prior history of dental problems. However, the causality has not been established in all the cases.
>
> Refer patients to dental care services and encourage them to have regular dental checkups while taking SUBOXONE. Educate patients to seek dental care and strategies to maintain or improve oral health while being treated with transmucosal buprenorphine-containing products. Strategies include, but are not limited to, gently rinsing the teeth and gums with water and then swallowing after SUBOXONE has been completely dissolved in the oral mucosa. Advise patients to wait for at least one hour after taking SUBOXONE before brushing teeth (see 4.4 Administration).

117. In "PART III: CONSUMER INFORMATION" under "Other warnings you should know about" the following subsection was added:

> **Dental Problems**: Some people taking SUBOXONE have experienced dental problems such as cavities, tooth decay, dental infection, fillings falling out and/or tooth loss. You should have regular dental check-ups. If you have any problems with your teeth tell your healthcare professional and schedule an appointment with a dentist right away. Tell your dentist that you are taking SUBOXONE.

118. The updates from March 16, 2023, did not include adding any information about dental issues to the "Serious Warnings and Precautions" sections of the Product Monograph. In the current Canadian Product Monographs for all Suboxone 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) still contain no references to dental harms.

119. Despite the fact that it took until March 16, 2023, for any of the Defendants to update the Canadian Product Monographs for Suboxone Products, the Defendants updated the labelling for Suboxone drugs in certain other markets at

least a year earlier to acknowledge the severity of the risk of serious dental and/or oral health harms, demonstrating their knowledge of the risk of those harms.

120. In June 2022, the American labelling and prescribing information for Suboxone Products was updated to add in a new warnings and precautions section on dental adverse events. Indivior Inc, Indivior UK, and Aquestive are identified on the June 2022 update to the American labelling for Suboxone Products.

121. The Canadian Product Monographs for Suboxone Products have failed, and continue to fail, 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 Suboxone Products

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

123. Suboxone Products were the subject of multiple research studies examining the link between Suboxone and adverse dental and/or oral health events.

124. The Defendants knew or ought to have known of the numerous scientific articles and studies that identified the potential risks of Suboxone Products to cause serious dental and/or oral health injuries, including but not limited to:

(a) A 2008 survey conducted among over 500 individuals receiving methadone and buprenorphine which documented that the most common problems patients sought help for were dental (29.9%) and the most commonly discussed health problems with a doctor were dental problems (50.2%);

(b) A 2012 case report documenting a case of significant dental caries during buprenorphine/naloxone maintenance, wherein after 18 months of stable treatment the subject required endodontic therapy on four molars due to extensive decay;

(c) A 2013 study of a cohort of women who reported worsening dental health after starting buprenorphine which documented a mean of 5.2 dental caries, 3.6 dental fillings, 2.4 cracked teeth, 0.9 crown placements, 0.8 root canal treatment, and 0.7 tooth extractions as having developed among the cohort after taking the drug;

(d) A 2014 study of the oral health and dental neglect of over 50 prenatally buprenorphine-exposed 3-year-old children which found that buprenorphine-exposed children exhibited significantly more early childhood caries (including decayed, missing, and filled teeth or tooth surfaces and decayed teeth) than a control group;

(e) A 2017 article examining data from the biggest pharmacovigilance safety database in which buprenorphine/naloxone was found to have a high disproportionality for dental caries with a reporting odds ratio of 26.1;

(f) A 2022 article describing an FDA review of 305 reported cases of dental problems in buprenorphine users in which the FDA classified 131 reports as serious and identified 26 cases wherein the patients had no prior history of dental problems;

(g) A 2022 study that followed 21,404 new users of sublingual buprenorphine/naloxone and two comparator groups – 5,383 users of transdermal buprenorphine and 6,616 users of oral naltrexone – and concluded that there was an increased risk of adverse dental outcomes with sublingual buprenorphine/naloxone, with dental caries and tooth loss being identified more than twice as often among the sublingual users than among the comparator groups; and

(h) A 2024 study which reviewed adverse event reports submitted to the FDA between 2015 and 2022 to measure disproportionality of dental disorder among buprenorphine drugs and identified significantly disproportionate reporting of dental disorders among patients treated with buprenorphine medications, including formulations administered by sublingual, buccal and oral routes, with sublingual buprenorphine-naloxone combination medications having a reporting odds ratio for dental disorders of 19.47 compared to all other medications in the database.

125. At all material times, the Defendants, through their servants and agents, failed to adequately warn physicians and consumers, including the Plaintiffs and other putative Class Members, of the risk of Injuries, Conditions, and Complications caused by their Suboxone Products.

126. At all material times, the Defendants did not provide adequate safety data to Health Canada with respect to their Suboxone Products. The Defendants knew or should have known that their Suboxone Products posed a serious risk of harm to consumers and were not fit for their intended purposes.

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

I. Plaintiffs and Class Members Suffered Harms from Suboxone Products

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

129. Subsequent to ingesting Suboxone Products, the Plaintiffs and Class Members have suffered and continue to suffer physical and mental injury, loss, and damage. In particular, the Plaintiffs have suffered serious dental and/or oral harms.

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

131. The Plaintiffs' injuries have and will continue to cause them 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.

132. The Plaintiffs have suffered injury to their health and will be more susceptible to future degenerative changes to their dental and oral health as a result of taking Suboxone Products. The Plaintiffs' symptoms have continued even after ceasing their use of Suboxone Products.

133. The Plaintiffs have 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 Plaintiffs have suffered injuries from Suboxone Products that necessitated dental treatment. Private Third-Party payors have also indemnified some or all of the costs of medical and/or dental treatment received by the Plaintiffs and Class Members for their injuries. The Plaintiffs continue to undergo medical care and treatment and continue to sustain damages. Class Members in other provinces or territories have sustained similar damages.

134. As a result of their injuries, the Plaintiffs have received, and in the future will continue to receive, care and services from family members. Other Class Members will require similar care.

135. The Plaintiffs and Class Members paid some or all of the costs for Suboxone Products out of their own pocket. Third-Party payors have also indemnified some or all of the costs for Suboxone Products used by the Plaintiffs and Class Members.

136. 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 Plaintiffs would not have incurred damages.

PART 2: RELIEF SOUGHT

137. The Plaintiffs claim, on their 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 them as representative Plaintiffs 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 Suboxone Products;

(c) a declaration that the Defendants made certain representations regarding Suboxone 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 Class Member who was prescribed and ingested the Defendants' Suboxone Products or as aggregated following a trial on the common issues;

(f) non-pecuniary damages in an amount to be assessed for each Class Member who was prescribed and ingested the Defendants' Suboxone 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 Suboxone Products;

(h) damages for family members, pursuant to provincial legislation and common law in each province, where applicable, including the *Family Compensation Act,* RSBC 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

138. In bringing this action on behalf of a class which includes residents of Canada who used Suboxone Products at any time on or before the date of the certification order, the Plaintiffs plead and rely 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 Plaintiffs also bring 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 plead and rely upon the applicable provincial and/or territorial legislation and common law, including the British Columbia *Family Compensation Act,* RSBC 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)

139. As the designers, testers, researchers. manufacturers, marketers, distributors, importers, labellers, packagers, handlers, storers, or sellers of Suboxone Products, the Defendants were in such a close and proximate relationship to the Plaintiffs, and other Class Members, as to owe them a duty of care. The Defendants designed buprenorphine and naloxone to be used as the active ingredients in Suboxone Products, designed Suboxone Products to be administered sublingually or buccally, conducted testing of buprenorphine and naloxone and Suboxone Products, procured regulatory approvals for the use of buprenorphine and naloxone in Suboxone Products, and caused Suboxone Products to be introduced into the stream of commerce in Canada, when they

knew that any dangers or defects related to Suboxone Products would cause foreseeable injury to the Plaintiffs and Class Members.

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

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

(b) design their Suboxone 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 Suboxone 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 Suboxone 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 Suboxone Products;

(f) warn consumers of dangers inherent in the use of their Suboxone 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 Suboxone Products; and

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

141. The Defendants negligently breached their duty of care.

142. The Plaintiffs states that their 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 Suboxone 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 Suboxone Products were free of any manufacturing defects that would expose recipients to Injuries, Conditions, and Complications;

(c) failure to adequately test their Suboxone 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 Suboxone Products, resulting in Injuries, Conditions, and Complications;

(e) designing their Suboxone 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 buprenorphine and naloxone as the active ingredients in Suboxone Products when the Defendants knew, or ought to

have known, that they could have chosen safer active ingredients that were at least as effective as buprenorphine and naloxone;

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

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

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

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

(k) failure to provide the Plaintiffs, Class Members, their physicians, and Health Canada with proper, adequate, and/or fair warning of the risks associated with use of their Suboxone 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 Suboxone Products in Canada and elsewhere;

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

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

Complications in all persons receiving their Suboxone Products on the patient information pamphlets, product labels, and Product Monographs in Canada;

(o) failure, after noticing problems with their Suboxone Products, to issue adequate warnings, timely recall their Suboxone Products, publicize the problems and otherwise act properly and in a timely manner to alert the public, including adequately warning the Plaintiffs, Class Members, and their physicians of their Suboxone 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 Suboxone Products;

(q) representation, explicitly and/or implicitly, that their Suboxone 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 Suboxone 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 Suboxone Products when they knew or ought to have known that their Suboxone 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 Plaintiffs 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 Plaintiffs and putative Class Members.

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

144. Any benefit from using Suboxone 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 Suboxone Products outweigh the risks, given that there are alternative products that are at least as effective as Suboxone Products and carry materially lower risks than Suboxone Products, or, in the alternative, if there are

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

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

146. The Defendants knew, or ought to have known, that Suboxone 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.

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

148. The risks associated with use of the Defendants' Suboxone Products, including Injuries, Conditions, and Complications in all persons receiving their Suboxone 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 Plaintiffs or Class Members. The Plaintiffs’ injuries, and Class Members’ injuries, would not have occurred but for the negligence of the Defendants in failing to ensure that their Suboxone Products were safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with using their Suboxone Products to the Plaintiffs and putative Class Members, and to their physicians.

149. Because the Defendants were designing, manufacturing, marketing, distributing, importing, labelling, packing, handling, storing, and/or selling Suboxone Products for human consumption, 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 Plaintiffs and the Class Members of the dangers inherent in the ordinary use of Suboxone Products, either directly or through a learned intermediary.

ii. Negligent Misrepresentation and Marketing

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

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

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

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

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

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

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

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

152. The Defendants owed a duty of care to the Plaintiffs and to other Class Members. It was intended by the Defendants, and reasonably foreseeable, that Class Members, when they were purchasing and/or using Suboxone Products, would rely upon the representation that Suboxone Products were safe for their intended uses, which representation was made either explicitly or implicitly by failing to state that the ingestion of Suboxone 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.

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

154. The Plaintiffs and the Class Members reasonably relied on the representation that Suboxone Products were safe for their intended uses, which was made either explicitly or implicitly by failing to state that the ingestion of Suboxone 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 Suboxone Products. If the representation had not been made, or if the Defendants had disclosed that the ingestion of Suboxone 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 Suboxone Products given that there are alternative treatments that are at least as efficacious.

155. The representations were false and made negligently.

156. The Plaintiffs and Class Members suffered loss and damage as a result of relying on the Defendants' representations or omissions in treatment with Suboxone Products. The Defendants are liable to pay damage to the Class Members.

B. Damages

157. The Plaintiffs and other putative Class Members' injuries and damages were caused by the negligence of the Defendants, their servants, and agents.

158. As a result of the Defendants' negligence, the Plaintiffs and Class Members have suffered and continue to experience serious personal injuries and harm with resultant pain and suffering.

159. The Plaintiffs 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' Suboxone Products.

160. As a result of the conduct of the Defendants, the Plaintiffs 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.

161. Some of the expenses related to the medical treatment that the Plaintiffs 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 Plaintiffs 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.

162. The Plaintiffs claim punitive, aggravated, and exemplary damages for the reckless and unlawful conduct of the Defendants.

163. 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 Suboxone 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 Suboxone Products to these risks.

C. Jurisdiction

164. There is a real and substantial connection between British Columbia and the facts alleged in this proceeding. The Plaintiffs 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.

Plaintiffs' 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: 5 APR 2024

_____
Signature of lawyer for Plaintiffs
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 Suboxone 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 Plaintiffs, BRANDON SCHOLTEN and DEBORAH ANNIS, claim 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 Plaintiffs 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.