Court File No. VLC-S-S-243378
ACTION NO. _____
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN

GORDON JAMES BULL

PLAINTIFF

AND

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

DEFENDANTS

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

NOTICE OF CIVIL CLAIM

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

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

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

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

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

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

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

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

Time for response to civil claim

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

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

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

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

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

CLAIM OF THE PLAINTIFF

PART 1: STATEMENT OF FACTS

A. Overview

1. This action is about corporate greed and misconduct, and the deadly opioids crisis that has wrought havoc in British Columbia, the rest of Canada, and North America.

2. Just as other corporations brought about the opioids crisis, the defendants purported to offer a solution to assist individuals with opioids addictions: a product that relieves cravings to use and withdrawal symptoms, treats opioid use disorder, and reduces the mortality of opioid use disorder by 50%.

3. The defendants' product was Suboxone or SUBOXONE® (buprenorphine and naloxone), a prescription drug that treats opioid use disorder and is designed to be ingested through sublingual and oral absorption either as a tablet or film ("**Suboxone**"). Suboxone is also prescribed off label for the treatment of chronic pain, such as pain caused by arthritis. Suboxone is instructed to be dissolved under the tongue or placed against the inside of the cheek.

4. It has now come to light that the presence of Suboxone in the mouth increases the acidity of the mouth, causing severe dental damage such as oral infections, tooth decay, cavities, and tooth loss.

5. Although the defendants have marketed Suboxone in Canada since 2007, they neither warned about nor disclosed this increased risk inherent to the design of Suboxone.

6. The defendants knew about this risk but chose increased profits over the health, pain and suffering of the increasing number of British Columbians and other Canadians who resorted to Suboxone to confront the opioids crisis brought about by another group of pharmaceutical and other companies.

7. It was only recently that, compelled by United Stated regulators, the defendants disclosed Suboxone's risks to patients' teeth and warned of the need to have continued dental monitoring. This disclosure and warning came too late for many.

B. The Plaintiff

8. The plaintiff, Gordon James Bull, resides in Squamish, British Columbia. He is 61 years old.

9. Prior to starting Suboxone, Mr. Bull had no serious dental issues. He has historically, and continues to this day, to brush his teeth twice a day and floss once a day, as recommended by his dentist. As a result of Mr. Bull's good oral hygiene, he went over a decade without needing any dental visits other than routine cleaning, and before using Suboxone, only had minor dental issues.

10. Mr. Bull was prescribed Suboxone in or around 2014 or 2015 as a treatment for chronic arthritis pain. He was prescribed Suboxone following a referral by his family doctor to a pain specialist.

11. When Mr. Bull began Suboxone, he was not warned of its potential to cause serious dental issues and tooth decay by either his family doctor or the pain specialist that prescribed him Suboxone. Mr. Bull also reviewed the Suboxone product monograph upon receiving his prescription. The product monograph did not contain any warnings about dental issues or tooth decay.

12. Mr. Bull would have discontinued the use of Suboxone once he began to experience dental issues or taken other precautions if he had been warned about this side effect. When Mr. Bull's dental issues began, he specifically asked both his family doctor and his dentist in or around 2017 if any of his medications, including Suboxone, could be causing his tooth decay. They told him that none of his medications caused these side effects. As a result, Mr. Bull continued using Suboxone.

13. As a result of using Suboxone as prescribed, Mr. Bull suffers from permanent damage to his teeth and requires substantial dental work to repair this damage.

14. One to two years after starting Suboxone, in or around 2017, Mr. Bull began to experience serious dental issues. Several fillings fell out and when they were replaced, the replacement fillings would fall out after less than a year. The last filling Mr. Bull had replaced fell out within two weeks. Mr. Bull found himself needing to attend at the dentist frequently as a

result of these dental problems and has had to pay thousands of dollars out of pocket for these dental visits.

15. Unfortunately, despite his numerous dental appointments, Mr. Bull's dental issues worsened. His dentist made a number of recommendations, including the use of high fluoride toothpaste, which Mr. Bull followed. Despite these efforts, Mr. Bull began to lose his teeth. He has lost half of the teeth (8 out of 16) in his lower jaw and a third of his teeth (4 out of 16) in his upper jaw. Mr. Bull's dentist has informed him that he would recommend four crowns in his upper jaw, but his remaining teeth are too decayed to be able to place crowns.

16. As a result, Mr. Bull is now in consultations to have permanent dentures installed. In Mr. Bull's case, this will involve the removal of all of his remaining teeth, placing a number of dental implants, and a full set of dentures for his upper and lower jaw. This procedure is not covered by insurance and will cost Mr. Bull thousands of dollars in out-of-pocket expenses to attend at a dental clinic in Vancouver for the procedure and for the costs of the procedure itself. Further, Mr. Bull requires regular attendances at the dentist for the rest of his life to maintain and adjust the appliances that will be placed in his mouth.

17. Mr. Bull has suffered significant mental distress because of his tooth decay. Mr. Bull cannot smile or enjoy social occasions. Before taking Suboxone, Mr. Bull had perfect teeth that he was proud of. Now, many of his teeth are missing and many of those that remain are jagged. Because of his jagged teeth, Mr. Bull frequently injures himself by biting his lips while eating, talking, or even just moving his mouth causing both physical and emotional distress. He can no longer eat foods he once enjoyed, like Vector cereal, because

anything crunchy injures his gums where his teeth once were. Eating is often a painful experience and a difficult reminder of his tooth decay.

18. Visiting the dentist's office causes Mr. Bull significant stress and anxiety. The anxiety has become so severe that he requires prescription anxiolytics, Lorazepam, to make it through his many dental appointments. The prospect of the financial strain caused by his dental procedures has been causing Mr. Bull to suffer additional anxiety, stress, and depression.

19. The stress and anxiety Mr. Bull suffers as a result of his dental issues are so bad that they interfere with Mr. Bull's sleep. He experiences deeply disturbing dreams where his teeth fall out or explode in his mouth. The interference with Mr. Bull's sleep further exacerbates his depression and anxiety.

20. The loss and damage to his teeth in his early to mid-fifties has not only caused him bodily injuries and health issues; it has also caused him significant pain, emotional distress, eating and other health issues, and societal barriers and stigma as he feels like he cannot smile and has to suffer people's daily adverse reaction to his severely damaged mouth and face.

C. The Class and the Class Period

21. The plaintiff brings this action on behalf of himself and all persons resident in Canada who were prescribed Suboxone between 2007 and the date of certification of this action, or such other date as the court may deem appropriate, and who developed dental issues, including but not limited to, tooth decay, cavities, oral infections, tooth caries, gum disease, and loss of teeth.

D. The Defendants

22. The defendant Indivior PLC (carrying on business as Indivior) is a British corporation organized under the laws of the United Kingdom, with its principal place of business at 234 Bath Road, Slough, Berkshire, United Kingdom, SL1 4EE. Indivior PLC was formerly known as Reckitt Benckiser Pharmaceuticals, Inc. As part of the market authorization process, Indivior PLC, as Reckitt Beckiser Pharmaceuticals, Inc., sought, and was granted, approval for the product monographs provided with Suboxone that failed to warn the class of the serious dental side effects associated with Suboxone. Indivior PLC demerged from Reckitt Benckiser ("**Reckitt**") in 2014.

23. The defendant Indivior UK Limited is a corporation organized under the laws of the United Kingdom, with its principal place of business at The Chapleo Building Henry Boot Way, Priory Park, Hull, United Kingdom, HU4 7DY. Indivior UK holds the market authorization for Suboxone in Canada. Indivior UK developed Suboxone and brought it to market globally, including in Canada. As part of the market authorization process, Indivior UK sought, and was granted, approval for the product monographs provided with Suboxone that failed to warn the class of the serious dental side effects associated with Suboxone. Indivior UK Limited is a wholly owned subsidiary of Indivior PLC.

24. The defendant Indivior Inc. is a corporation organized under the laws of Delaware with its principal place of business in North Chesterfield, Virginia. Indivior Inc. was responsible for the research, testing, and regulatory approval to bring the sublingual film version of Suboxone to market globally. Indivior Inc also writes, publishes, and distributes marketing materials for Suboxone including but not limited to its webpages, press releases, and

marketing materials that represented to the class and healthcare professionals that Suboxone was safe and that failed to disclose the risk of serious dental issues associated with the use of Suboxone. Indivior Inc. is a wholly owned subsidiary of Indivior PLC.

25. The defendant Indivior Solutions, Inc. is a corporation organized under the laws of Delaware with its principal place of business in Wilmington, Delaware. Indivior Solutions is a wholly owned subsidiary of Indivior PLC and Indivior, Inc.

26. The defendant Indivior Canada Ltd. is a corporation organized under the laws of Ontario with its principal place of business located at Toronto, Ontario. Indivior Canada Ltd., as the Canadian operations of Indivior PLC was responsible for the promotion, marketing, research, development, and sale of Suboxone in Canada. Indivior Canada Ltd. is a wholly owned subsidiary of Reckitt Benckiser Pharmaceuticals Inc., now known as Indivior Inc., a subsidiary of Indivior PLC (together with Indivior PLC, Reckitt, Indivior UK Limited, Indivior Inc., Indivior Solutions, Inc., and Indivior Canada Ltd., "**Indivior**", unless otherwise specified).

27. The defendant Pharma Importing Inc. is a corporation organized under the laws of Ontario with a principal place of business at Toronto, Ontario. Pharma Importing Inc. is the importer and distributor of Suboxone, as identified on the Suboxone product monographs.

28. The defendant Aquestive Therapeutics, Inc. ("**Aquestive**") is a corporation organized under the laws of Delaware with its principal place of business in Warren, New Jersey. Aquestive is the global manufacturer of sublingual film for the sublingual film formulations of Suboxone. Aquestive was responsible for the research, development, and

introduction of the sublingual film formulation of Suboxone to the stream of commerce. Aquestive was responsible for the research, design, development, testing, manufacture, promotion, sale, and distribution of the sublingual film formulations of Suboxone in Canada. Aquestive was formerly known as, until in or around November 30, 2017, MonoSol Rx, LLC.

29. The defendant MonoSol Rx, Inc. is a corporation organized under the laws of Delaware with its principal place of business in Warren, New Jersey. MonoSol Rx, Inc. is a wholly owned subsidiary of Aquestive.

30. The defendant MonoSol LLC is a limited liability company organized under the laws of Delaware with its principal place of business at Merrillville, Indiana. Monosol LLC developed the soluble film used for the soluble film formulation of Suboxone. Monosol LLC was responsible for the research, development, and design of the soluble firm technology and its manufacture, marketing, supply, and distribution within Canada as part of the soluble film formulation of Suboxone.

31. The defendant Reckitt Benckiser LLC is a limited liability company organized under the laws of Delaware with its principal place of business at Wilmington, Delaware. Reckitt Benckiser LLC had responsibility for the design, development, research, testing, manufacture, marketing, supply, distribution, marketing, and sales of Suboxone in Canada. Reckitt Benckiser LLC is a wholly owned subsidiary of Reckitt Benckiser Group PLC.

32. The defendant Reckitt Benckiser Healthcare (UK) Ltd. is a corporation organized under the laws of the United Kingdom with its principal place of business at 103-105 Bath Road,

Slough, Berkshire, United Kingdom, SL1 3UH. Reckitt Bencksire Healthcare (UK) Ltd. was responsible for the development and marketing of Suboxone globally. It was responsible for the research, development, testing, post-marketing safety studies, manufacture, supply, and distribution of Suboxone in Canada.

33. The defendant Reckitt Benckiser Group PLC is a publicly traded company organized under the laws of the United Kingdom with its principal place of business at 103-105 Bath Road, Slough, Berkshire, United Kingdom, SL1 3UH. Reckitt Benckiser Group PLC was responsible for the development and marketing of Suboxone globally. It was responsible for the research, development, testing, post-marketing safety studies, manufacture, supply, and distribution of Suboxone in Canada.

34. The defendant Merck & Co., Inc. ("**Merck**") is a publicly traded corporation organized under the laws of New Jersey in the United States with its principal place of business at Rahway, New Jersey. Merck and its subsidiaries were responsible for the marketing, development, research, testing, distribution, and sales of Suboxone globally and in Canada specifically. References to Merck are inclusive of its subsidiaries and predecessor companies, including Schering-Plough Corporation.

35. The defendant Schering-Plough Canada Inc. is a wholly owned subsidiary of Merck. Merck acquired Schering-Plough Canada Inc. in or around August 7, 2009 following a merger with Schering-Plough Corporation. Schering-Plough Canada Inc. was responsible for the marketing, development, research, testing, distribution, and sales of Suboxone in Canada. On May 18, 2007 Schering Plough Canada Inc. received the first Notice of Compliance from Health Canada permitting the marketing and sales of Suboxone in Canada. At the

time of this approval, Schering-Plough Canada Inc. licensed the exclusive marketing rights to Suboxone in Canada from Reckitt Benckiser Group PLC until in or around 2011.

36. Each defendant was involved in the development, design, research, testing, licensing, manufacture, marketing, distribution, and/or sale of Suboxone in British Columbia and the rest of Canada, and derived revenue from Suboxone.

E. The Opioids Epidemic and the Advent of Suboxone

i. Overview and Purpose of Suboxone

37. Opioids are a class of drugs defined by a chemical compound that is naturally found in the opium poppy plant or which are synthetically made to have similar chemical structures. Opioids are powerful narcotics that work by binding to receptors on the spinal cord and in the brain, reducing the perception of pain. In addition to pain-controlling effects, opioids can also induce an addictive, euphoric high.

38. With continued use, users grow tolerant to opioids, meaning that they need to take progressively higher doses in order to get the same level of pain relief. The existence of a tolerance effect significantly increases the risks of withdrawal, addiction, and overdose.

39. In the late 1990s, the consumption of prescription opioids skyrocketed in British Columbia, and throughout Canada and the United States. This was due to the aggressive and concentrated marketing efforts made by pharmaceutical companies, to promote the long-term use of their opioid products for widespread chronic conditions such as back pain,

sports injuries, and arthritis, in order to broaden the market for opioid prescriptions and expand their profits.

40. In Canada, prescription use of prescription opioids increased immensely between 2000 and 2010, even though the proportion of Canadians who reported experiencing chronic pain did not change substantially over this period. This has resulted in an opioid epidemic and widespread opioid use disorder.

41. Opioid use disorder is a medical condition characterized by the problematic use of opioids, including both prescription pain relievers and illicit substances. It is a chronic disorder that often leads to physical and psychological dependence on opioids.

42. Individuals suffering from opioid use disorder experience grave physical and emotional struggles. They face relentless cycles of cravings, withdrawal symptoms, and the overwhelming compulsion to seek and use opioids despite the adverse consequences. Not only does this disorder pose significant danger to an individual's physical health, but it also poses a significant risk of producing severe emotional distress, which often disrupts personal relationships and daily functioning.

43. The pervasive impact of opioid use disorder underscores the urgent need to alleviate suffering and promote recovery. However, responses to this disorder still mainly rely on "treatment" programming known as Opioid Agonist Treatment ("**OAT**").

44. OAT consists of a range of drug treatments like oral buprenorphine or methadone. These medications reduce cravings for opioids and aid in managing withdrawal symptoms.

45. Buprenorphine is a synthetic opioid, and it is addictive. It treats opioid use disorder by reducing cravings and withdrawal symptoms.

46. Buprenorphine may be administered in various ways including:

(a) Orally through buccal film or sublingual tablets;

(b) Subdermal or subcutaneous implants; and

(c) Intravenous or intramuscular injections.

47. Suboxone is a combination of buprenorphine and naloxone. It is administered through a film or tablet that is placed buccally/sublingually or sublingually respectively. The swallowing/ingestion of Suboxone does not result in its absorption into the patient's body.

48. Indivior developed two products with buprenorphine aimed at addressing opioid addiction:

(a) Subutex – A single entity buprenorphine product designed for a brief induction stage; and

(b) Suboxone – A buprenorphine-naloxone combination for post-induction maintenance treatment.

49. In or around January 2004, MonoSol LLC began research, development, and testing of soluble film technologies for the sublingual administration of drugs. This technology was ultimately incorporated into the sublingual film formulation of Suboxone.

50. In or around 2004, MonoSol Rx, LLC (Aquestive's predecessor) was incorporated to further research, develop, and test soluble film technologies for the sublingual administration of drugs. MonoSol Rx, LLC continued the activities commenced at Monosol LLC.

51. On July 7, 2010, MonoSol Rx, LLC announced the first FDA approval of its soluble film technology for delivery of pharmaceuticals. The technology ultimately brought to market was called PharmFilm.

52. MonoSol Rx, LLC and Reckitt entered into an agreement for Monosol Rx, LLC to become the global exclusive manufacturer of and primary packager of a formulation of Suboxone using MonoSol Rx, LLC's PharmFilm technology, including in Canada. This agreement was continued after Monosol Rx, LLC became Aquestive and Reckitt became Indivior.

53. On or around August 31, 2010, MonoSol RX, LLC announced FDA approval of the sublingual film formulation of Suboxone using its PharmFilm technology.

54. Subutex and Suboxone tablets were distinctive in the pharmaceutical market since they were the sole medications that provided maintenance treatment for patients suffering from opioid use disorder and chronic pain. Importantly, they could be prescribed for home use by patients, unlike the alternative, methadone, which was required to be dispensed only at clinics.

55. Suboxone is not a one-time-use medication. Many patients are on Suboxone permanently or for long terms, increasing the damage to their teeth.

ii. United States Food and Drug Administration Approval of Suboxone and United States Criminal, Regulatory, and Civil Proceedings

56. Suboxone first made its way to the United States, approximately five years before Canada.

57. Suboxone tablets received approval from the U.S. Food and Drug Administration ("**FDA**") – the American regulator of pharmaceuticals, similar to Health Canada – in 2002 as an orphan drug for treating opioid dependence. The "orphan drug" designation is extremely exceptional and only granted when a product is intended to treat a disease or condition affecting fewer than 200,000 patients. Alternatively, it may be granted if the sponsor demonstrates that there is no reasonable expectation that the costs of developing and making the drug will be recovered from U.S. sales even though the product treats a disease or condition with a U.S. prevalence of more than 200,000 patients.

58. Suboxone's orphan drug designation expired on October 8, 2009.

59. In a bid to obstruct generic competition, the defendants designed, and pursued FDA approval for, Suboxone in the form of a dissolvable film instead of a tablet. This strategic move aimed to maintain their market dominance and profit margins by making it more challenging for generic alternatives to enter the market in the face of a looming opioids crisis in North America.

60. The defendants sought FDA approval for the Suboxone film in October 2008. This process included safety and efficacy studies for the tablets and assertions that the Suboxone film's packaging diminished the likelihood of inadvertent exposure to the drug by children.

61. The FDA rejected the assertion of diminished pediatric exposure but approved the application nonetheless on August 30, 2010, providing a continued market monopoly up to August 2013.

62. Upon approval of the film version of Suboxone, the defendants created financial disincentives for the select group of authorized doctors who prescribed the drug who were reluctant to shift their patients from the tablet to the film version.

63. The defendants discouraged physicians from continuing to prescribe the tablet version by exploiting alleged "safety" concerns as a pretext. In 2012, Indivior's predecessor, Reckitt, publicly announced it was withdrawing the tablet from the American market due to safety concerns. These purported safety concerns centered around Reckitt's specially commissioned data showing "consistently and significantly higher rates of accidental unsupervised pediatric exposure" with Suboxone tablets when compared to Suboxone film.

64. The same day, the defendant filed a Citizen's Petition with the FDA, asking the agency not to approve any generic versions of Suboxone tablets unless the manufacturers implemented "national public health safeguards involving pediatric exposure educational campaigns and child-resistant, unit-dosed packaging to reduce the risk of pediatric exposure."

65. Indivior has paid over US$2 billion in settlements related to various criminal, regulatory, and civil proceedings in the United States.

66. In 2016, the defendants were sued by 41 American states and the District of Columbia for antitrust violations related to deliberately preventing the entry and success of competitors

from the opioid-addiction treatment market. The litigation resulted in a US$102.5 million settlement in 2023.

67. On April 9, 2019, a federal grand jury in Virginia issued an indictment against Indivior, alleging the company used its "here to help" web and phone hotline, which was promoted as a resource for addiction patients, to connect patients with doctors that would prescribe Suboxone.

68. The indictment also charged Indivior with discontinuing the tablet form of Suboxone as a tactic to delay FDA approval for generic tablet forms. The indictment further alleged that Indivior engaged in a scheme to increase Suboxone film prescriptions throughout the United States by misrepresenting Suboxone film as being safer and less susceptible to abuse than similar pharmaceutical products. The indictment alleges that these misrepresentations were made in the absence of scientific studies sufficient to support those claims.

69. On July 11, 2019, approximately three months after the indictment was made public, Reckitt entered into an agreement with the United States Department of Justice related to the criminal conduct alleged in the indictment. In total, Indivior paid approximately US$1.4 billion, at that time the largest recovery in a case concerning an opioid drug. Indivior forfeited US$647 million in proceeds, paid US$700 million in civil settlements to the federal government and contributed US$50 million to the Federal Trade Commission. Additionally, Indivior's CEO, Shaun Thaxter and Indivior's medical director, Timothy Baxter, pleaded guilty to criminal misbranding of Suboxone under the *Food, Drug and*

Cosmetic Act, relating to false statements about accidental pediatric exposure in relation to the transition of Suboxone from tablet to film.

70. On June 30, 2020 the former CEO of Indivior PLC, Shaun Thaxter, pleaded guilty in the US federal court in Abingdon, Virginia to a violation of the Federal *Food, Drug, and Cosmetic Act*. Mr. Thaxter was sentenced to six months in prison and fined US$600,000.

71. On July 24, 2020, Indivior entered into a US$600 million settlement with the United States Attorney's Office regarding civil and criminal allegations related to the sale and promotion of Suboxone, including allegations that Indivior misrepresented to healthcare professionals that Suboxone was safe and effective for various uses that it was not, in fact, medically necessary or safe and effective for. Specifically, it was alleged that Indivior made false and misleading claims that Suboxone was less likely to be abused than other similar products and that it was less prone to accidental exposure to children. The settlement agreement required Indivior to implement heightened compliance measures including additional monitoring, auditing, training, education, reporting, and disclosure for five years.

72. In August 2020, Timothy Baxter, the former medical director of Indivior PLC, pleaded guilty to making false and misleading representations to the Massachusetts Medicaid program regarding Suboxone. Specifically, that he failed to prevent Indivior from sending false and misleading information to the Massachusetts Medicaid Program related to the safety of the film version of Suboxone around children.

iii. *Canadian Regulation of Suboxone*

73. The defendants applied to Health Canada for approval of Suboxone tablets, which they received on May 18, 2007. Health Canada has issued the following Notices of Compliance for Suboxone:

Manufacturer	Notice of Compliance Date	DIN
Schering-Plough Canada Inc.	May 18, 2007	02295695, 02295709
RB Pharmaceuticals Ltd. (now Indivior PLC)	April 26, 2011	02295709, 02295695
Indivior UK Ltd.	August 25, 2015	02295709, 02295695
Indivior UK Ltd.	August 31, 2015	N/A
Indivior UK Ltd.	May 19, 2017	N/A
Indivior UK Ltd.	September 1, 2017	02468085, 02468093
Indivior UK Ltd.	January 22, 2019	N/A
Indivior UK Ltd.	July 17, 2020	02502313, 02502321, 02502348, 02502356
Indivior UK Ltd.	February 10, 2021	N/A
Indivior UK Ltd.	October 27, 2021	N/A
Indivior UK Ltd.	March 17, 2023	N/A

74. Suboxone tablets were listed on public formularies in each province in 2010.

75. Health Canada has authorized two dosage forms of Suboxone, both dissolvable in the mouth and similarly dangerous to patients' dental health: a sublingual tablet and a soluble film. Suboxone soluble film may be administered sublingually (for both induction and maintenance therapy) or buccally (for maintenance therapy). Suboxone sublingual tablet can only be administered sublingually.

76. Suboxone film was approved in Canada on July 17, 2020. However, the Canadian Agency for Drugs and Technologies in Health, a national health technology assessment agency, reviewed the film and identified no safety advantages compared to the tablet. The tablet and film both share a product monograph indicating identical dosing and safety information for the two formulations. Furthermore, Suboxone's sublingual film is therapeutically interchangeable with Suboxone's sublingual tablet, leading experts to question the innovation of the sublingual film method of administration.

77. The below table illustrates the Suboxone types that have been available in Canada during the Class Period:

Product	**Route of Administration**	**Strength**	**Health Canada Drug Identification Number**	**Medicinal Ingredients**
SUBOXONE Soluble Film	Sublingual/Buccal	2 mg / 0.5 mg	2502313	Buprenorphine/ Naloxone
SUBOXONE Soluble Film	Sublingual/Buccal	4 mg / 1 mg	2502321	Buprenorphine/ Naloxone
SUBOXONE Soluble Film	Sublingual/Buccal	8 mg / 2 mg	2502348	Buprenorphine/ Naloxone

SUBOXONE Soluble Film	Sublingual/Buccal	12 mg / 3 mg	2502356	Buprenorphine/ Naloxone
SUBOXONE Sublingual Tablet	Sublingual	2 mg / 0.5 mg	2295695	Buprenorphine/ Naloxone
SUBOXONE Sublingual Tablet	Sublingual	8 mg / 2 mg	2295709	Buprenorphine/ Naloxone
SUBOXONE Sublingual Tablet	Sublingual	12 mg / 3 mg	2468085	Buprenorphine/ Naloxone
SUBOXONE Sublingual Tablet	Sublingual	16 mg / 4 mg	2468093	Buprenorphine/ Naloxone

78. In recent years, the opioids epidemic has reached crisis levels in Canada, and very acutely in British Columbia where the overdose public health emergency is claiming four lives every day. The province continues to experience the highest number of overdose deaths among Canadian jurisdictions. As a result, treatments like Suboxone have found an ever-larger market.

F. Suboxone Causes Dental Erosion and Decay

79. For nearly two decades, the labelling for Suboxone did not contain any warning related to the risk of tooth damage associated with Suboxone's prescribed use.

80. Suboxone has a low pH. When dissolved in water, Suboxone is acidic with a pH of 3.4. It has long been understood that acidic compounds damage teeth and can lead to dental issues.

81. Because the active pharmaceutical ingredients in Suboxone have low bioavailability, Suboxone users were instructed to keep Suboxone in their mouth for as long as possible.

The product monographs for Suboxone instructed users to keep certain formulations of Suboxone in their mouth for over 12 minutes. As detailed below, because Suboxone is acidic, this prolonged exposure to Suboxone poses a significant risk of harm to a Suboxone user's teeth.

82. In 2012, a case report published by Harvard Medical School professors affiliated with Brigham and Women's Hospital in Boston, USA, highlighted a patient who, after 18 months of stable Suboxone tablet treatment for opioid dependence, experienced a sudden decline in oral health. The patient required extensive dental treatment, leading the authors to conclude that there may be a link between chronic use of sublingual buprenorphine/naloxone and the observed decline in dental health.

83. In 2013, a case series was published by the lead author of the 2012 case report. This series observed eleven patients being treated for opioid dependence at Brigham and Women's Hospital between May and November 2012. The patients experienced dental health deterioration after starting buprenorphine. This deterioration included cavities, dental fillings, cracked teeth, crown replacements, root canals and tooth extractions.

84. The authors of the series noted that tooth erosions "occur when teeth are exposed to an environment that has low pH". pH serves as a measure of the acidity or alkalinity of a solution in aqueous environments. The pH scale ranges from 0 to 14, where 7 represents neutrality. A pH below 7 signifies acidity, while a pH above 7 indicates a base.

85. The authors inferred from the average ingestion of Suboxone three times daily for approximately nine minutes for dissolution, that "prolonged contact between tooth surfaces

with buprenorphine/naloxone, therefore, may be a contributing factor in the alteration of the tooth microbial profile and/or the pH to promote dental caries, similar to what has been previously reported in patients who use methamphetamine."

86. These studies confirmed what was already suspected based on reported outcomes of patients using Suboxone: that dental erosion and decay follows from the use of this medication.

G. The Defendants Knew, or Should Have Known of, Dental Risks During Class Period

87. The defendants were aware of Suboxone's acidic nature and adverse impact on oral health.

88. Over the course of the years, adverse events continued to grow in relation to dental damage from Suboxone use. The following are examples of some of the cases that the defendants are known at this time to have been aware of:

(a) From 2007-2010, defendants were aware of at least 20 adverse events, that are publicly known, related to dental and oral health associated with Suboxone use.

(b) In 2011, defendants were aware of at least 36 adverse events, that are publicly known, related to oral and dental health associated with Suboxone use.

(c) At the end of 2013, defendants were aware of at least 46 adverse events, that are publicly known, related to oral and dental health associated with Suboxone use.

(d) Prior to Reckitt Benckiser becoming Indivior, it was aware of at least 61 adverse events, that are publicly known, related to oral and dental health associated with Suboxone use.

(e) At the end of 2015, defendants were aware of at least 67 adverse events related to oral and dental health associated with Suboxone use.

(f) At the end of 2016, defendants were aware of at least 76 adverse events, that are publicly known, related to oral and dental health associated with Suboxone use.

(g) At the end of 2017, defendants were aware of at least 100 adverse events, that are publicly known, related to oral health associated with Suboxone use.

(h) At the end of 2020, defendants were aware of at least 125 adverse events, that are publicly known, related to oral and dental health associated with Suboxone use.

(i) Prior to January 12, 2022, defendants were aware of at least 136 adverse events, that are publicly known, related to oral and dental health associated with Suboxone use.

89. Nonetheless, the defendants took no action in seeking a label change under the FDA's regulations or Health Canada.

90. The defendants similarly took no steps to alert patients or prescribers about the dangers that Suboxone posed.

91. On January 12, 2022, the FDA released a safety communication in the United States about Suboxone use warning of the serious dangers of tooth decay and erosion.

92. Adverse event reporting continued in 2022, after the FDA issued its safety communication. Only a small fraction of adverse events are reported to the FDA. Therefore, defendants were or ought to have been aware that there were significantly more adverse events.

H. The Defendants Failed to Disclose or Warn of Risks

93. The accumulation of evidence from peer-reviewed literature, alongside a rising number of adverse dental event reports, required the defendants to warn Health Canada, the FDA, healthcare providers, and consumers of the risk of dental erosion and decay posed by Suboxone.

94. However, it was not until June 2022, when the FDA mandated a warning, that defendants eventually took steps to incorporate the advisory on the label in the United States.

95. In December 2022, a research letter in the *Journal of the American Medical Association* presented findings from a pharmacoepidemiologic study examining dental adverse events from the use of sublingual buprenorphine- containing medications, including Suboxone, and transdermal alternatives.

96. The study, spanning from 2006 to 2020, identified a heightened risk of adverse outcomes with sublingual buprenorphine compared to transdermal buprenorphine or oral naltrexone.

97. Even more delay in disclosure and warning followed in Canada, where the defendants failed to disclose, warn of risks, or notify patients of the need for dental monitoring while receiving Suboxone.

98. The defendants did not disclose the serious risks of dental decay in their product monograph directed at Health Canada until March 16, 2023, well over a year after the FDA warning in January 2022 relating to the United States.

99. The Health Canada product monograph for Suboxone (Buprenorphine and Naloxone Sublingual Tablet), revised in March 2023 for the first time contained some disclosure and warning of serious risks of cavities and tooth decay with reported cases requiring extensive dental treatments and that patients are advised to undergo regular dental check-ups, adopt oral hygiene practices and wait one hour after taking Suboxone before brushing teeth.

100. The defendants' prior Health Canada Suboxone monograph (October 2021 and earlier) contained no mention of dental decay and risks.

PART 2: RELIEF SOUGHT

101. The plaintiff, on his own behalf, and on behalf of all class members, seeks:

(a) an order certifying this action as a class proceeding and appointing the plaintiff as representative plaintiff;

(b) a declaration that the defendants, or any of them, were negligent and that they, or any of them, made fraudulent or negligent misrepresentations;

(c) a declaration that the defendants have each been unjustly enriched;

(d) an order that the defendants account for and make restitution to the plaintiffs and the other class members;

(e) relief for contraventions of consumer protection legislation, as follows:

(i) a declaration that the defendants' conduct amounted to unconscionable acts, prohibited practices, or unfair acts or practices pursuant to ss. 8, 9, 10, 171 and 172 of the British Columbia *Business Practices and Consumer Protection Act*, SBC 2004, c 2 ("**BPCPA BC**"); ss. 6 and 13 of the Alberta *Consumer Protection Act*, RSA 2000, c. C-26.3 ("**Alberta CPA**"); ss. 6, 7 and 93 of the Saskatchewan *Consumer Protection and Business Practices Act*, SS 2013, c C-30.2 ("**CPBPA SK**") ss. 2, 3, and 23 of the Manitoba *Business Practices Act*, CCSM, c B120 ("**Manitoba BPA**") ss. 15, 17 and 18 of the Ontario *Consumer Protection Act*, 2002, SO 2002, c 30, Sch A ("**CPA ON**"); ss. 8 and 272 of the Quebec *Consumer Protection Act*, CQLR c P-40.1 ("**CPA QC**"); ss. 2 and 4 of the P.E.I. *Business Practices Act*, RSPEI 1988, c B-7 ("**PEI BPA**"); and ss. 8 and 10 of the Newfoundland and Labrador *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1 ("**NL CPBPA**") (collectively "**Consumer Protection Legislation**");

(ii) damages under the Consumer Protection Legislation;

(iii)disgorgement of the defendants' gains and profits;

(iv)restitution;

(v) rescission;

(f) general and special damages;

(g) aggregate damages;

(h) punitive, exemplary and aggravated damages;

(i) disgorgement of the defendants' gains and profits;

(j) loss and damage and investigation costs under s. 36 of the *Competition Act*;

(k) the costs of administering and distributing an aggregate damage award;

(l) interest pursuant to the *Court Order Interest Act*, RSBC 1996, c 79, and similar provisions under the *Judgment Interest Act*, RSA 2000, c J-1, *Pre-judgment Interest Act*, SS 1984-85-86, c P-22.2, *The Court of Queen's Bench Act*, CCSM c C280, the *Courts of Justice Act*, R.S.O. 1990, c. C.43, the *Civil Code of Quebec*, CQLR c CCQ-1991, *Judicature Act*, RSNB 1973, c J-2, *Judicature Act*, RSNS 1989, c 240, *Judicature Act*, R.S.P.E.I. 1988 c. J-2.1, the *Judgment Interest Act*, RSNL 1990, c. J-2, the

Judicature Act, R.S.Y. 2002, c. 128, the *Judicature Act*, R.S.N.W.T., 1988 c. J-1, the *Rules of the Supreme Court of the Northwest Territories*, NWT Reg (Nu) 010-96;

(m) recovery of the past and future cost of health care services incurred for the benefit of class members to the extent not already provided for in other certified class actions; and

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

PART 3: LEGAL BASIS

A. The Defendants Were Negligent

102. The defendants were negligent:

(a) in their design, development, and manufacturing of Suboxone;

(b) in their research and testing of Suboxone, including post-marketing surveillance and pharmacovigilance;

(c) in their marketing of Suboxone; and

(d) in their failure to warn the plaintiff and the class of the dangers particularized in this claim.

103. The defendants had a duty to design a safe drug and maintain an adequate label. They were obligated to ensure continual sufficiency of warnings in the label, conduct post-marketing surveillance and promptly revise the label in case of emerging evidence of risks such as dental erosion and decay.

104. At all material times, the defendants were in a proximate relationship with the plaintiff and the class, and owed a duty of care to the plaintiff and the class members:

(a) to properly develop, manufacture, test, licence, distribute, sell and market Suboxone in a manner that did not pose a material adverse risk to the plaintiff

and class members' teeth;

(b) to label, market and sell Suboxone;

(c) to ensure that Suboxone was labelled, marketed and distributed and sold for their intended and reasonably foreseeable use;

(d) to properly supervise their employees;

(e) to monitor, investigate, evaluate and follow up on the improper or adverse effects of the use of Suboxone by patients;

(f) to warn the plaintiff and class that Suboxone carried a significant risk of dental injury;

(g) to ensure that physicians, dentists, surgeons and other health care practitioners were kept fully and completely informed of all risks associated with the use of Suboxone, including its risks to dental and oral health;

(h) to properly and promptly inform Health Canada and other regulatory agencies of the increasing risks associated with Suboxone; and

(i) to provide clear and proper instructions to physicians and patients about the need for continuous and recurrent dental monitoring and precautions to be taken, so as to avoid injury or damage from Suboxone.

105. The defendants' common law duties were informed, amongst others, by legislation and regulations including the *Food and Drugs Act*, R.S.C. 1985, c. F-27 and *Food and Drug Regulations*, C.R.C., c. 870. The regulations impose obligations on the defendants, beginning at licencing and continuing thereafter. They require the defendants to ensure the safety of Suboxone before selling it and to continuously monitor the safety of Suboxone thereafter. This includes reviewing complaints from doctors, hospitals, and patients, and keeping up with any new developments in the scientific literature, conducting more extensive testing as required, and taking prompt corrective actions including issuing warnings or recalls if new information becomes available that alters the medication's risk profile.

106. The defendants breached their duty of care by, amongst others:

(a) failing to disclose to regulators, patients, doctors, dentists and other health professionals or warn about the risks associated with Suboxone use;

(b) failing to conduct the necessary research and testing to determine the risks associated with Suboxone use, particularly its effect on dental and oral integrity in long term use; and

(c) failing to conduct follow up testing or to monitor Suboxone use once Suboxone began to be consistently prescribed for long-term use.

107. The defendants knew at all material times that Suboxone would cause harm or could potentially cause harm to the dental and oral integrity of the class. Despite knowledge of

Suboxone's causation of dental and oral injuries, the defendants withheld crucial information from consumers and prescribing physicians. This information was material to the risk of patients, like the plaintiff and the class, developing severe dental injuries due to Suboxone use.

108. The defendants breached the standard of care expected in the circumstances and the harm they caused to the plaintiff and class members was foreseeable. The patient populations targeted by the defendants face a heightened risk of losing continuity in follow-up care compared to individuals without opioid use disorder. These patient populations experience additional barriers related to stigma, health insurance and finances generally. In this context, the defendants' behaviour was not only detrimental but also aggravating, further exacerbating the challenges faced by the plaintiff and class members, all individuals with opioid use disorder.

109. Notably, despite being aware of the connection between long-term Suboxone use and dental deterioration, the defendants chose to continue promoting the drug as safe and effective for addiction treatment, rather than adequately disclosing warnings of Suboxone or entirely removing its oral absorption form from the market. The defendants knowingly withheld and/or misrepresented information from consumers and physicians concerning the safety and efficacy of Suboxone, including but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Suboxone.

110. The defendants conduct caused damages to the plaintiff and the class.

B. The Defendants Breached s. 52 of the *Competition Act*

111. The defendants breached s. 52 of the *Competition Act*, and thereby committed an unlawful act because the defendants' representations surrounding Suboxone and their stated reasons for preferring the sublingual film format over the tablet format:

(a) were made for the purpose of promoting the continued profitable supply or use of Suboxone by the defendants for the business interests of the defendants;

(b) were made to the public; and

(c) were false and misleading in a material respect.

112. Furthermore, the defendants' failure to disclose the dangers inherent in Suboxone particularized herein to the class similarly breached s. 52 of the *Competition Act*.

113. The plaintiff and class suffered the damages as a result of the defendants' unlawful breach of s. 52 of the *Competition Act* and seek compensation for their damages, as well as their costs of investigation, pursuant to s. 36 of the *Competition Act*.

C. The Defendants Breached Consumer Protection Legislation

114. The plaintiffs and members of the class plead and rely on the BPCPA BC, the CPA ON, the Alberta CPA, the CPBPA SK, the Manitoba BPA, the CPA QC, the PEI BPA and the NL CPBPA (collectively, the "**Consumer Protection Legislation**").

115. The defendants' conduct particularized herein and the defendants' failure to disclose a material fact constituted unfair, unconscionable and/or otherwise prohibited practices under the Consumer Protection Legislation, given that, among other things, the defendants knew, or ought to have known, that:

(a) the members of the class purchased Suboxone for purposes that were primarily personal. As such, the plaintiffs obtained Suboxone in the context of consumer transactions and contracts within the meaning of Consumer Protection Legislation.

(b) the plaintiff and the class were not reasonably able to protect their interests because of disability, ignorance, and the inherent informational asymmetry between the class and the defendants;

(c) each consumer transaction and contract whereby the plaintiff and the class obtained Suboxone was excessively one-sided in favour of the defendants;

(d) the terms of the consumer transactions and contracts were uniformly inequitable and adverse to the plaintiff and the class; and

(e) the members of the class were not able to protect their interests.

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

i. British Columbia

117. During the class period, the defendants supplied Suboxone to members of the class for purposes that were primarily personal, family or household. As such, the defendants are suppliers engaging in consumer transactions within the meaning of s. 1 of the BPCPA BC.

118. The defendants' impugned conduct breached the BPCPA BC. Amongst others, it constituted unconscionable acts contrary to the BPCPA BC:

> 8 (1) An unconscionable act or practice by a supplier may occur before, during or after the consumer transaction.
>
> (2) In determining whether an act or practice is unconscionable, a court must consider all of the surrounding circumstances of which the supplier knew or ought to have known.
>
> (3) Without limiting subsection (2), the circumstances that the court must consider include the following:
>
> > (b) that the supplier took advantage of the consumer or guarantor's inability or incapacity to reasonably protect his or her own interest because of the consumer or guarantor's physical or mental infirmity, ignorance, illiteracy, age or inability to understand the character, nature or language of the consumer transaction, or any other matter related to the transaction;
> >
> > (c) that, at the time the consumer transaction was entered into, the total price grossly exceeded the total price at which similar subjects of similar consumer transactions were readily obtainable by similar consumers;
> >
> > (e) that the terms or conditions on, or subject to, which the consumer entered into the consumer transaction were so harsh or adverse to the consumer as to be inequitable.

> 9(1) A supplier must not commit or engage in an unconscionable act or practice in respect of a consumer transaction.
>
> (2) If it is alleged that a supplier committed or engaged in an unconscionable act or practice, the burden of proof that the unconscionable act or practice was not committed or engaged in is on the supplier.

119. The plaintiff and the class suffered injury and damages due to the defendants' unfair practices and are entitled to damages pursuant to s. 171 of the BPCPA BC.

ii. Ontario

120. The supply of Suboxone to the class, whether by the defendants, their agents, or third parties, were consumer transactions within the meaning of s. 1 of the CPA ON.

121. The defendants' conduct particularized herein constituted unfair practices contrary to the CPA ON:

> 14 (1) It is an unfair practice for a person to make a false, misleading or deceptive representation.
>
> (2) Without limiting the generality of what constitutes a false, misleading or deceptive representation, the following are included as false, misleading or deceptive representations
>
> …
>
> 14. A representation using exaggeration, innuendo or ambiguity as to a material fact or failing to state a material fact if such use or failure deceives or tends to deceive.
>
> 15 (1) It is an unfair practice to make an unconscionable representation. 2002, c. 30, Sched. A, s. 15 (1).
>
> Same

> (2) Without limiting the generality of what may be taken into account in determining whether a representation is unconscionable, there may be taken into account that the person making the representation or the person's employer or principal knows or ought to know,
>
> > (a) that the consumer is not reasonably able to protect his or her interests because of disability, ignorance, illiteracy, inability to understand the language of an agreement or similar factors;
> >
> > (b) that the price grossly exceeds the price at which similar goods or services are readily available to like consumers;
> >
> > (c) that the consumer is unable to receive a substantial benefit from the subject-matter of the representation;
> >
> > (d) that there is no reasonable probability of payment of the obligation in full by the consumer;
> >
> > (e) that the consumer transaction is excessively one-sided in favour of someone other than the consumer;
> >
> > (f) that the terms of the consumer transaction are so adverse to the consumer as to be inequitable;
> >
> > (g) that a statement of opinion is misleading and the consumer is likely to rely on it to his or her detriment; or
> >
> > (h) that the consumer is being subjected to undue pressure to enter into a consumer transaction.

122. The class suffered losses due to the defendants' unfair practices and are entitled to damages pursuant to s. 18 of the CPA ON.

123. Furthermore, pursuant to s. 18(12) of the CPA ON the defendants are jointly and severally liable to the plaintiff and the class together with any other parties who directly entered into the consumer transactions for the supply of Suboxone to the class.

iii. *Alberta*

124. The defendants' supply of Suboxone to the class were consumer transactions within the meaning of s. 1 (1) of the Alberta CPA.

125. The defendants' conduct amounted to unfair practices contrary to the Alberta CPA:

> 6(1) In this section, "material fact" means any information that would reasonably be expected to affect the decision of a consumer to enter into a consumer transaction.
>
> (1.1) It is an offence for a supplier to engage in an unfair practice.
>
> (2) It is an unfair practice for a supplier, in a consumer transaction or a proposed consumer transaction,
>
> > (a) to exert undue pressure or influence on the consumer to enter into the consumer transaction;
> >
> > (b) to take advantage of the consumer as a result of the consumer's inability to understand the character, nature, language or effect of the consumer transaction or any matter related to the transaction;
> >
> > (c) to use exaggeration, innuendo or ambiguity as to a material fact with respect to the consumer transaction;

126. The class suffered losses due to the defendants' unfair practices and are entitled to damages pursuant to s. 13 or s. 142.1 of the Alberta CPA.

iv. *Saskatchewan*

127. The defendants' supply of Suboxone to the plaintiff and the class constituted consumer transactions within the meaning of s. 5 and s. 2 of the CPBPA SK.

128. The defendants' conduct amounted to unfair practices contrary to the CPBPA SK, which states, amongst other things, that:

> 6 It is an unfair practice for a supplier, in a transaction or proposed transaction involving goods or services, to:
>
> (c) take advantage of a consumer if the person knows or should reasonably be expected to know that the consumer:
>
> (i) is not in a position to protect his or her own interests; or
>
> (ii) is not reasonably able to understand the nature of the transaction or proposed transaction; or
>
> 7 The following are unfair practices:
>
> (a) representing that goods or services have sponsorship, approval, performance characteristics, accessories, ingredients, components, qualities, uses or benefits that they do not have;
>
> (c) representing that goods or services are of a particular standard, quality, grade, style, model, origin or method of manufacture if they are not;
>
> (h) representing that a service, part, repair or replacement is needed if that is not so, or that a service has been provided, a part has been installed, a repair has been made or a replacement has been provided if that is not so;
>
> (i) representing that a price benefit or advantage exists respecting goods or services if a price benefit or advantage does not exist;
>
> (o) using exaggeration, innuendo or ambiguity in representing a material fact, or failing to disclose a material fact, if the representation or failure is deceptive or misleading;
>
> (p) representing that goods or services have been made available in accordance with a previous representation if they have not;
>
> (q) taking advantage of a consumer by including in a consumer agreement terms or conditions that are harsh, oppressive or excessively one-sided;

129. The class suffered losses due to the defendants' unfair practices and are entitled to damages pursuant to s. 93(1) of the CPBPA SK.

v. Manitoba

130. The defendants' supply of Suboxone to the plaintiff and the class were consumer transactions within the meaning of s. 1 of the Manitoba BPA.

131. The defendants' conduct amounted to unfair practices contrary to the Manitoba BPA:

> 2(1) It is an unfair business practice for a supplier
>
> > (a) to do or say anything or to fail to do or say anything if, as a result, a consumer might reasonably be deceived or misled; or
> >
> > (b) to make a false claim or representation.
>
> 2(3) Without limiting the generality of subsection (1), any of the following representations, acts or omissions, when made or engaged in by a supplier in relation to goods or to a consumer transaction, is deemed for the purposes of this Act to be an unfair business practice within the meaning of that subsection:
>
> > (a) a representation that the goods have sponsorship, approval, performance characteristics, accessories, ingredients, components, quantities, uses or benefits that they do not have;
> >
> > (c) a representation that the goods are of a particular standard, quality, grade, style or model when they are not;
> >
> > (g) a false representation as to the reason the goods are available;
> >
> > (p) the use of exaggeration, innuendo or ambiguity as to a material fact, or the failure to disclose a material fact, with respect to the goods or with respect to the consumer transaction;

132. The class suffered losses due to the defendants' unfair practices and are entitled to damages pursuant to s. 23 of the Manitoba BPA.

vi. Quebec

133. The class members in Quebec were "consumers"; the defendants were each a "manufacturer"; and Suboxone was "goods" within the meaning of s. 1 of the CPA QC.

134. The defendants' impugned conduct constituted a prohibited practice contrary to the CPA QC, which states, amongst other things, that:

> 216. For the purposes of this title, representation includes an affirmation, a behaviour or an omission.
>
> 217. The fact that a prohibited practice has been used is not subordinate to whether or not a contract has been made.
>
> 218. To determine whether or not a representation constitutes a prohibited practice, the general impression it gives, and, as the case may be, the literal meaning of the terms used therein must be taken into account.
>
> 219. No merchant, manufacturer or advertiser may, by any means whatever, make false or misleading representations to a consumer.
>
> 220. No merchant, manufacturer or advertiser may, falsely, by any means whatever,
>
> (a) ascribe certain special advantages to goods or services;
>
> (b) hold out that the acquisition or use of goods or services will result in pecuniary benefit;
>
> (c) hold out that the acquisition or use of goods or services confers or insures rights, recourses or obligations.

135. The defendants imposed obligations on the class that were excessive, harsh or unconscionable, contrary to s. 8 of the CPA QC.

136. As a result of the defendants' breaches of the CPA QC, the class members are entitled to damages.

vii. *Prince Edward Island*

137. The defendants' supply of Suboxone to the plaintiff and the class are services within the meaning of s. 1 of the PEI BPA.

138. The defendants made unconscionable consumer representations contrary to the PEI BPA:

> 2 For the purposes of this Act, the following shall be deemed to be unfair practices:
>
> (b) an unconscionable consumer representation made in respect of a particular transaction and in determining whether or not a consumer representation is unconscionable there may be taken into account that the person making the representation or his employer or principal knows or ought to know
>
> > (i) that the consumer is not reasonably able to protect his interests because of his physical infirmity, ignorance, illiteracy, inability to understand the language of an agreement or similar factors,
> >
> > (ii) that the price grossly exceeds the price at which similar goods or services are readily available to like consumers,
> >
> > (iii) a representation that the goods are of a particular standard, quality, grade, style or model, if they are not
> >
> > (v) that the proposed transaction is excessively one-sided in favour of someone other than the consumer,

> (vi) that the terms or conditions of the proposed transaction are so adverse to the consumer as to be inequitable,
>
> (xiii) a representation using exaggeration, innuendo or ambiguity as to a material fact or failing to state a material fact if such use or failure deceives or tends to deceive, …
>
> 3(1) No person shall engage in an unfair practice.
>
> (2) A person who performs one act referred to in section 2 shall be deemed to be engaging in an unfair practice.

139. The defendants' impugned conduct breached the PEI BPA. Members of the class are entitled to damages pursuant to s. 4(1) of the PEI BPA.

viii. *Newfoundland and Labrador*

140. Class members were "consumers"; the supply of Suboxone to the class were "consumer transactions"; Suboxone constituted "goods"; and the defendants were "suppliers" all within the meaning of s. 2 of the NL CPBPA.

141. The defendants' impugned conduct constituted unfair practices and unconscionable acts or practices contrary to the NL CPBPA:

> 7. (1) In this Part, an unfair business practice is a representation, conduct or failure to disclose material facts that has the effect, or might reasonably have the effect, of deceiving or misleading a consumer, and includes
>
> (c) a representation that the goods or services are of a particular standard, quality or grade where they are not;
>
> (d) a representation that the goods are of a particular style, model or origin where they are not;

> 8. (1) In determining whether an act or practice is unconscionable the court shall consider the circumstances that the supplier knew or ought to have known, including
>
> > (d) that the terms and conditions of the consumer transaction were so one-sided, harsh or adverse to the consumer as to be inequitable;
> >
> > (e) that the supplier used trickery or undue pressure in order to induce the consumer to enter into the consumer transaction; or
> >
> > (f) that the supplier took advantage of the extreme necessity or helplessness of the consumer or the inability of the consumer to protect his or her interests because of his or her physical or mental disability, his or her ignorance, illiteracy, age or emotional state, or his or her inability to understand the character, nature or language of the consumer transaction.
>
> (2) An unconscionable act or practice may occur before, during or after a consumer transaction.
>
> 9. (1) A person shall not engage in an unfair business practice or unconscionable act or practice.
>
> (2) Where it is alleged that a supplier is engaging in or has engaged in an unfair business practice or an unconscionable act or practice, the burden of proof that the supplier is not engaging in or has not engaged in an unfair business practice or an unconscionable act or practice rests with the supplier.

142. Class members suffered losses due to the defendants' conduct particularized herein contrary to the NL CPBPA and are entitled to damages and other remedies pursuant to the NL CPBPA.

D. Fraudulent and Negligent Misrepresentation

143. The defendants made misrepresentations about the safety of Suboxone despite knowing that those representations were false.

144. Alternatively, the defendants were reckless as to whether their representations about the safety of Suboxone were true or false, or without an honest belief in their truth.

145. The defendants made the representations and the material omissions particularized herein, intending to deceive the plaintiff and the class.

146. These representations include, but are not limited to, marketing materials authored, published, and distributed by Indivior PLC and the other Indivior defendants, including those contained in Indivior webpages, press releases, and trade announcements that were presented to the class and healthcare professionals as reliable sources of information about Suboxone, including its benefits, efficacy, and safety. These representations were readily available in Canada to the class and healthcare professionals and were meant to, and were, relied upon by them in making decisions about beginning to use, and continuing to use, Suboxone.

147. The representations were material to the plaintiff and class's decision to use Suboxone. This can be determined on a class-wide basis because the representations are inextricably linked to the defendants' true intentions in marketing Suboxone and their non-disclosure of the dangers of the latter. The plaintiff and class members would not have used Suboxone if informed of the risks of Suboxone particularized herein.

148. The plaintiff and class suffered damages as a result of the representations.

E. Unjust Enrichment

149. The plaintiff and the class are entitled to claim and recover based on equitable and restitutionary principles.

150. The defendants caused the plaintiff and class to pay money for a defective and dangerous product that they should not have been offered for sale or, in the alternative, for which they should have paid less than they did.

151. As a result, the defendants were enriched by the payment or overpayment.

152. The class suffered a deprivation corresponding to the defendants' enrichment.

153. There is no juristic reason for the defendants' enrichment and the plaintiff's and class's corresponding deprivation. The plaintiff and class are entitled to restitution for the defendants' unjust enrichment.

F. Fraudulent Concealment

154. The defendants intentionally and fraudulently concealed the existence of their unlawful conduct from the public, including the plaintiff and the class members. The defendants represented to the plaintiff, the class members, and the general public that Suboxone only resulted in the risk of the disclosed warnings with no mention of the risk of tooth erosion and decay although it had received a significant number of adverse event notifications.

155. Additionally, the defendants engaged in criminal misbranding of Suboxone through false

statements about accidental pediatric exposure in relation to the transition of Suboxone from tablet to film.

156. The affirmative acts of the defendants particularized herein were fraudulently concealed and carried out in a manner that precluded detection. Because the defendants' conduct was kept secret, the plaintiff and the class members were unaware of the defendants' unlawful conduct.

G. Health Care Costs Recovery

157. As a result of all of the above, the defendants are "wrongdoers" within the meaning of the *Crown's Right of Recovery Act*, SA 2009, c C-35 and the *Health Care Costs Recovery Act*, SBC 2008, c 27.

158. The wrongful actions of the defendants caused the Class to suffer personal injuries within the meaning of the *Health Care Costs Recovery Act*, SBC 2008, c 27 and the *Crown's Right of Recovery Act*, SA 2009, c C-35.

H. Damages

159. As a result of defendants' statutory breaches and common law tortious conduct particularized above, the class has suffered and will continue to suffer damages including, but not limited to, damages for personal injuries, mental anguish, pain and suffering, loss of employment income and benefits, loss of enjoyment of life, inconvenience damages, and special damages and expenses.

I. Disgorgement

160. Given the extreme nature of the defendants' conduct and the resulting harm to a class entirely vulnerable to the defendants, disgorgement of the defendants' profits is an appropriate remedy that should be granted to the class on an aggregate basis.

161. Other remedies are inadequate in the circumstances of this case because the class's interests cannot be fully vindicated by other forms of relief, and the plaintiff and the class have a legitimate interest in preventing the defendant's profit-making activity.

J. Punitive Damages

162. The defendants' conduct was high-handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, disgraceful, wilful, and in contumelious disregard of the plaintiff's rights and the rights of the class.

163. The defendants' conduct wantonly or recklessly targeted a particularly vulnerable class of individuals, causing the plaintiff and the class extreme mental and physical suffering and societal alienation and embarrassment, for no reason other than to maximize the defendants' profits.

164. The defendants are therefore liable to pay aggravated, exemplary, and punitive damages.

K. Jurisdiction

165. The plaintiff relies on sections 7(c), 8(b), 10(g)(h) and 11(c)(d) of the *Court Jurisdiction*

and Proceedings Transfer Act, SBC 2003, c 28 and pleads that there is a real and substantial connection between the subject matter of this action and the Province of British Columbia for the following reasons:

a) the representative plaintiff resides in British Columbia, was prescribed Suboxone while resident in British Columbia; and

b) a substantial number of class members reside in British Columbia, one of the provinces in Canada with the highest rates of opioid-related harm.

Plaintiffs' address for service:	**Sotos LLP** 820 – 980 Howe Street Vancouver BC V6Z 0C8 Telephone: (236) 301-4919 Mobile: (647) 996-8228 **Attention: Mohsen Seddigh** **Thomson Rogers** 390 Bay Street, Suite 3100 Toronto, ON M5H 1W2 Telephone: 416.868.3137 **Attention: Stephen Birman**
Fax number address for service (if any):	N/A
E-mail address for service (if any):	mseddigh@sotos.ca mtaylor@sotos.ca sbirman@trlaw.com clazaris@trlaw.com
Place of trial:	Vancouver, British Columbia

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

Dated: May 24, 2024

Signature of Mohsen Seddigh,
Lawyer for the Plaintiffs

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 claim relates to the negligent design, manufacture, marketing, and distribution of Suboxone. Suboxone is a prescription medication used, amongst others, to treat opioid use disorder and sometimes for treatment of chronic pain. Suboxone is administered sublingually. Suboxone causes serious dental issues including tooth decay and loss. While Suboxone was approved for use in Canada on May 18, 2007, its product monograph did not provide for any warnings related to dental issues until March 16, 2023. The Defendants did not include any warnings relating to dental issues until forced to do so by the United States Food and Drug Administration.

The Defendants knew, or ought to have known, that Suboxone caused serious dental side effects. Because of this, the Defendants ought to have warned the plaintiff and the class members of these serious risks. However, they failed to provide any, let alone adequate, warnings of these side effects. The Defendants were negligent, made fraudulent and/or negligent misrepresentations, violated consumer protection legislation, the Competition Act, and were unjustly enriched.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

A personal injury arising out of:

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

A dispute concerning:

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

Part 3: THIS CLAIM INVOLVES:

- ☒ a class action
- ☐ maritime law

- ☐ aboriginal law
- ☐ constitutional law
- ☐ conflict of laws
- ☐ none of the above
- ☐ do not know

Part 4:

1. *Business Practices Act, CCSM, c B120;*
2. *Business Practices Act, RSPEI 1988, c B-7;*
3. *Business Practices and Consumer Protection Act, SBC 2004, c 2;*
4. *Class Proceedings Act, RSBC 1996, c. 50;*
5. *Competition Act, RSC 1985, c C-34;*
6. *Consumer Protection Act, 2002, SO 2002, c 30, Sch A*
7. *Consumer Protection Act, CQLR c P-40.1;*
8. *Consumer Protection Act, RSA 2000, c. C-26.3;*
9. *Consumer Protection and Business Practices Act, SNL 2009, c C-31.1;*
10. *Consumer Protection and Business Practices Act, SS 2013, c C-30.2;*
11. *Court Order Interest Act, RSBC 1995, c 7;*
12. *Food and Drug Regulations, C.R.C., c. 870;*
13. *Food and Drugs Act, R.S.C. 1985, c. F-27; and*
14. *Negligence Act, RSBC 1996, c 333.*