UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: SUBOXONE (BUPRENORPHINE/ NALOXONE) FILM PRODUCTS LIABILITY LITIGATION	Case No. 1:24-md-03092-JPC Judge J. Philip Calabrese
DOUGLAS REBHOLZ, *Plaintiff*, v. **INDIVIOR INC.,** **INDIVIOR SOLUTIONS, INC., AND** **AQUESTIVE THERAPEUTICS, INC., F/K/A MONOSOL RX, LLC,** *Defendants*.	**Complaint with Jury Demand** Case No. _____

Plaintiff files this Complaint per CMO No. 3 and is to be bound by the rights, protections, privileges, and obligations of that CMO and other Orders of the Court. Per CMO No. 3, Plaintiff designates the United States District Court for the United States District Court for the Eastern District of Kentucky as Plaintiff's designated venue ("Original Venue"). Plaintiff makes this selection based on one or more of the following factors (for the first three options, complete each blank):

Plaintiff currently resides in Fort Thomas, Kentucky

Plaintiff was prescribed Suboxone film in Florence, Kentucky

Plaintiff used Suboxone film in Alexandria, Kentucky

For the following options, check only the box(es) that apply, and complete the corresponding blank(s):

☐ The Original Venue is a judicial district in which Defendant _____ resides, and all Defendants are residents of the State in which the district is located (28 U.S.C. § 1391(b)(1));

☒ The Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred (28 U.S.C. § 1391(b)(2)), Provide the factual basis for this assertion: Plaintiff currently resides in, was prescribed, and used Suboxone film in Kentucky; and/or

☐ There is no district in which an action may otherwise be brought under 28 U.S.C. § 1391, and the Original Venue is a judicial district in which Defendant _____ is subject to the Court's personal jurisdiction regarding this action (28 U.S.C. § 1391(b)(3).

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Plaintiff alleges the following upon information and belief and the investigation of counsel.

PRELIMINARY STATEMENT

1. American drug companies created the opioid crisis that has ravaged this nation for decades. Through the introduction of drugs to treat opioid dependence, that same industry has since profited from the devastation it wrought on the victims of this epidemic.

2. Plaintiff brings this action for damages caused by Defendants' wrongful conduct in connection with the development, design, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of the prescription drug Suboxone® and delay in releasing the alternative buprenorphine-containing product Sublocade® extended-release injection.

3. Defendants manufacture, promote, and sell Suboxone film as a prescription drug that treats opioid use disorder. Suboxone is intended to reduce withdrawal symptoms and the desire to use opioids without causing the cycle of highs and lows

associated with opioid misuse. Suboxone is a combination of buprenorphine and naloxone (Narcan) designed to be ingested through oral absorption. The active ingredient in Suboxone film is buprenorphine. The formulation of Suboxone film is designed to be acidic to maximize absorption of the buprenorphine while minimizing absorption of the naloxone, which has no clinically significant effect or detectable pharmacological activity when administered orally. This acidic formulation leads to dental erosion and decay.

4. Defendants knew or should have known that Suboxone film, when used as prescribed and intended, causes harmful damage to the teeth due to the drug's acidity.

5. Suboxone film injured Plaintiff by causing permanent damage to Plaintiff's teeth.

6. In early 2022, the FDA issued a Drug Safety Communication "warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues." *See* FDA Drug Safety Communication (Jan. 12, 2022) (available at https://www.fda.gov/media/155352/download?attachment) (last accessed September 10, 2024).

7. The FDA required a new warning about the risk of dental problems to be added to the prescribing information and patient medication guide for all buprenorphine

medicines dissolved in the mouth. No such warning was required for other forms of buprenorphine, including injectables or patches. *Id*.

8. In June 2022, Defendants changed the Suboxone film prescribing information to warn of the risk of dental problems. *See* Suboxone Prescribing Information (available at https://www.indivior.com/admin/resources/dam/id/1073/Suboxone_PI.pdf) (last accessed September 10, 2024).

9. Despite the foregoing change, the medication guide for Suboxone film still does not warn of these risks as possible side effects of this drug. *See* Suboxone Medication Guide (available at https://www.indivior.com/admin/resources/dam/id/1071/Suboxone_MedGuide.pdf) (last accessed September 10, 2024).

10. As a proximate result of Defendants' wrongful actions and inactions, Plaintiff was injured and suffered damages from Plaintiff's use of Suboxone film.

11. Plaintiff accordingly demands judgment against Defendants and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

PARTIES

Plaintiff

12. Plaintiff, Douglas Rebholz, is a resident and a citizen of the State of Kentucky, Campbell County. Plaintiff suffered damage to Plaintiff's teeth as a direct result of using Defendants' prescription Suboxone film.

13. Plaintiff was prescribed Suboxone film by a physician to treat opioid use disorder.

14. During the relevant time periods, Plaintiff and Plaintiff's treating physicians were given no warning and had no knowledge of the serious risk of dental erosion and decay Suboxone film posed. Specifically, and as discussed more fully below, there was no warning or indication that Suboxone film causes dental injuries, including, but not limited to, permanent damage to the teeth.

15. Subsequently, and as a result of Plaintiff's prescribed use of Suboxone film, Plaintiff now suffers from permanent tooth damage and/or had substantial dental work performed to repair the damage caused by Suboxone film.

16. As a proximate result of Defendants' acts and omissions, Plaintiff suffered the injuries described above due to Plaintiff's prescribed use of Suboxone film. Plaintiff accordingly seeks damages associated with these injuries.

Defendants

17. Defendant Indivior Inc. is a corporation organized under the laws of Delaware with its principal place of business at 10710 Midlothian Turnpike, Suite 430, North Chesterfield, Virginia 23235. On information and belief, Indivior Inc. is a wholly owned subsidiary of Indivior PLC. Indivior Inc. is formerly known as Reckitt Benckiser Pharmaceuticals, and before that was known as Reckitt & Colman Pharmaceuticals. Indivior demerged from Reckitt Benckiser and came under the umbrella of Indivior PLC in 2014 to better position itself in what it termed "the opioid dependence marketplace." *See* Press Release, Reckitt Benckiser Pharmaceuticals Inc. Announces Plans to Rebrand Under Indivior PLC Following Demerger (Oct. 21, 2014)

(available at https://www.prnewswire.com/news-releases/reckitt-benckiser-pharmaceuticals-inc-announces-plans-to-rebrand-under-indivior-plc-following-demerger-245324987.html) (last accessed September 10, 2024).

18. Defendant Indivior Solutions, Inc. is a corporation organized under the laws of Delaware with its principal place of business at 10710 Midlothian Turnpike, Suite 430, North Chesterfield, Virginia 23235. On information and belief, Indivior Solutions is a wholly owned subsidiary of Indivior PLC and Indivior Inc.

19. Defendant Aquestive Therapeutics, Inc., f/k/a MonoSol Rx, LLC, is a corporation organized under the laws of Delaware with its principal place of business at 30 Technology Drive, Warren, New Jersey 07059. Aquestive is the exclusive global manufacturer of Suboxone sublingual film.

20. Each Defendant was involved in the development, design, research, testing, licensing, manufacture, marketing, distribution, and/or sale of Suboxone film.

21. Each Defendant derives substantial revenue from interstate and international commerce, including significant revenue derived from products sold in the District where Plaintiff resides.

22. Defendants were responsible for the sales and marketing in the United States of Suboxone film.

23. Defendants transacted and conducted business within the State(s) where Plaintiff resides and/or used Suboxone film and have derived substantial revenue from goods and products disseminated and used throughout the United States.

24. At all relevant times, Defendants were pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Suboxone film, throughout the United States and in the State(s) where Plaintiff resides and/or used Suboxone film.

25. Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Suboxone film.

26. The term "Defendant" as used in the complaint shall include any and all named or unnamed parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

JURISDICTION AND VENUE

27. The Court has jurisdiction under 28 U.S.C. § 1332(a)(1) because the amount in controversy exceeds $75,000, exclusive of interest and costs, and is between citizens of different states.

28. Venue is proper either in this Court under 28 U.S.C. § 1391(a) or in the District Courts of the cities and States listed in Schedule A because Plaintiff were injured in and reside in these districts. Venue is also proper in these States under 28 U.S.C. § 1391(b), because Defendants conduct business in these districts and a substantial part of the acts and omissions giving rise to this complaint occurred in these districts.

NATURE OF THE CASE

29. Plaintiff brings this case against Defendants for damages associated with Plaintiff's prescribed use of Suboxone film, which was designed, manufactured, sold, and/or distributed by Defendants. Plaintiff suffered various injuries, serious physical pain, emotional distress, and medical expenses as a direct result of Plaintiff's prescribed use of Suboxone film.

30. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Suboxone film for the treatment of opioid use disorder.

31. Defendants' fraudulent and illegal conduct with respect to Suboxone film caused thousands of individuals—including Plaintiff—to develop severe and permanent damage to their teeth.

RELEVANT FACTUAL BACKGROUND

Opioid use disorder and treatment options

32. The opioid crisis was created by the American pharmaceutical industry. In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become dependent on opioid painkillers and healthcare providers began to prescribe them at greater rates.[1]

[1] United States Department of Health & Human Services, Opioid Facts and Statistics (available at https://www.hhs.gov/opioids/statistics/index.html) (last accessed June 10, 2024).

33. Increased prescription of opioid medication led to widespread misuse of both prescription and non-prescription opioids before it became clear that the medication could be highly addictive.[2]

34. Opioid use disorder is a chronic disease that changes the brain. Thanks to the American pharmaceutical industry, opioid dependence became and remains rampant in the United States. This epidemic has led to untold suffering by those who became dependent on these dangerous prescription drugs. Their families and communities have suffered with them as this powerful addiction shattered lives from coast to coast.

35. In 2017, the United States Department of Health and Human Services declared the opioid crisis a public health emergency.[3] HHS most recently renewed that determination effective September 29, 2023.[4]

36. More than 760,000 people have died since 1999 from a drug overdose. Nearly 75% of drug-overdose deaths in 2020 involved an opioid.[5]

37. Recovering from an opioid dependence often involves medication-assisted therapy. Such medications include methadone, naltrexone, or buprenorphine, each of which reduce cravings and the risk of relapse.

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[2] *Id*.

[3] United States Department of Health & Human Services, Determination that a Public Health Emergency Exists (Oct. 26, 2017) (available at https://aspr.hhs.gov/legal/PHE/Pages/opioids.aspx) (last accessed June 10, 2024).

[4] United States Department of Health & Human Services, Renewal of Determination that a Public Health Emergency Exists (Sept. 26, 2023) (available at https://aspr.hhs.gov/legal/PHE/Pages/Opioid-26Sept2023.aspx#:~:text=%C2%A7%20247d%2C%20do%20hereby%20renew,public%20health%20emergency%20exists%20nationwide) (last accessed June 10, 2024).

[5] United States Department of Health & Human Services, Opioid Facts and Statistics (available at https://www.hhs.gov/opioids/statistics/index.html) (last accessed June 10, 2024).

38. The victims of the opioid epidemic needed safe and reliable support to manage their disease. And again, the American pharmaceutical industry let them down.

39. Buprenorphine is a synthetic opioid that treats acute pain, chronic pain, and opioid use disorder. It was discovered in the mid-1960s by Reckitt & Colman.

40. Buprenorphine is a schedule III narcotic analgesic. It was first marketed in the United States in 1985 as a schedule V narcotic analgesic. Initially, the only available buprenorphine product in the United States was a low-dose (0.3 mg/ml) injectable formulation under the brand name Buprenex®.

41. Buprenex was manufactured by Reckitt Benckiser Healthcare (UK) Ltd and distributed by Reckitt Benckiser Pharmaceuticals, now known as Defendant Indivior Inc.[6]

42. Buprenorphine is an addictive drug.

43. Opioids are full agonists at the mu receptor in the brain. Buprenorphine is a partial agonist at the mu receptor, meaning it only partially activates opiate receptors. It treats opioid dependence by partially activating those receptors, reducing cravings and the severe withdrawal symptoms that result from ceasing use of opioids.

44. Buprenorphine administration is possible via various means: subdermal or subcutaneous implant, intravenous or intramuscular injection, transdermal patch, and oral forms including tablets and films dissolved in the mouth.

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[6] *See* FDA-approved label for Buprenex (Feb. 11, 2002) (available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/018401_S014_BUPRENEX_PRNTLBL.pdf) (last accessed September 10, 2024).

45. Defendants' prescription drug Suboxone film is a combination of buprenorphine and naloxone that is placed sublingually or buccally. Naloxone has no clinically significant effect when administered orally. Naloxone is not a therapeutic aspect of Suboxone film and is included in the product only to deter diversion and abuse. Naloxone is a strong μ opioid antagonist and, when injected, counteracts the partial μ agonist effect of buprenorphine.

46. Depending on the patient, Suboxone film takes anywhere from 10–30 minutes to dissolve and leaves a filmy residue in the mouth for 60–120 minutes thereafter.

47. Defendants knew in 2011 that the time it takes the film to dissolve is dependent on saliva quantity and subject to individual variation, and dose and strength taken and was longer than the three minutes listed in its patent for Suboxone film.

48. For years, Defendants have known that Suboxone films can take longer to dissolve compared with the same dose tablet when administered buccally.

49. Suboxone film is typically prescribed in at least two (sometimes three) daily doses, usually one in the morning and one later in the day. A single dose can involve one, two, or three separate films.

Defendants design and seek FDA approval for Suboxone as a dissolvable tablet to treat opioid use disorder.

50. In 2002, Indivior Inc. (then Reckitt Benckiser Pharmaceuticals) received FDA approval for two buprenorphine tablet products for the treatment of opioid use disorder: Subutex—a monotherapy buprenorphine product—and Suboxone—a buprenorphine-naloxone combination product.

51. At the time of their introduction, Subutex and Suboxone tablets were the only pharmaceuticals on the market for patients suffering from chronic pain or opioid use disorder that could be prescribed in an office setting for the patient's home use. All other opioid-dependence maintenance treatments, such as methadone, could be dispensed only at a clinic.

52. Indivior secured FDA approval for the Subutex and Suboxone tablets relying on three government-sponsored studies. The three pivotal studies that secured FDA approval for Subutex and Suboxone tablets were completed through the National Institute for Drug Abuse (NIDA) and the Department of Veterans Affairs Cooperative Studies Program (VACSP). NIDA also subsidized the clinical development program through grants.

53. Pivotal trial one was a NIDA study using sublingual buprenorphine solution to assess the efficacy of buprenorphine for short-term maintenance/detoxification from opioids. Johnson RE, Jaffe JH, Fudala PJ, *A controlled trial of buprenorphine treatment for opioid dependence*, JAMA, 1992 May 27;267(20):2750–55 (available at https://pubmed.ncbi.nlm.nih.gov/1578593/) (last accessed September 10, 2024).

54. Pivotal trial two was a NIDA-grantee safety and efficacy study of sublingual buprenorphine solution for a 16-week period that informed the likely effective dosage range of buprenorphine for opioid dependence. Ling W, Charuvastra C, Collins, JF, et al., *Buprenorphine maintenance treatment of opiate dependence: a multicenter, randomized trial*, Addiction. 1998 Apr;93(4):475–86 (available at https://pubmed.ncbi.nlm.nih.gov/9684386/) (last accessed September 10, , 2024).

55. Pivotal trial three was the *only* trial to use a tablet form of buprenorphine or buprenorphine/naloxone rather than buprenorphine-only solution. It was a NIDA/VACSP collaboration with a total of 326 study participants. Fudala PJ, Bridge TP, Herbert S, et al. *Office-based treatment for opiate addiction with a sublingual-tablet formulation of buprenorphine and naloxone*, 349 New Eng. J. Med. 949 (2003) (available at https://www.nejm.org/doi/10.1056/NEJMoa022164?url_ver=Z39.882003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200www.ncbi.nlm.nih.gov) (last accessed September 10, 2024).

56. Reckitt & Colman Pharmaceuticals, Inc., another predecessor to Indivior Inc., secured orphan-drug designation for buprenorphine in 1994.

57. Orphan-drug designation is granted where a product is intended to treat a disease or condition that has a U.S. prevalence <200,000 patients or where the sponsor can show that there is no reasonable expectation that the costs of developing and making the drug will be recovered from U.S. sales despite the fact that the product treats a disease or condition with a U.S. prevalence of >200,000 patients. FDCA, § 526(a)(2)(A)–(B). These alternatives to orphan-drug status are referred to as the "rare disease" and "cost recovery" pathways.

58. Reckitt & Colman initially sought orphan-drug designation for its buprenorphine-containing products under the "rare disease" pathway. But the FDA denied that request given the prevalence of opioid dependence (even before the opioid

epidemic). Reckitt & Colman amended its request to seek orphan-drug designation under the cost-recovery definition, which the FDA approved.

59. Orphan-drug designation provides an extended exclusivity period, significant tax incentives, and superior patent protection for a manufacturer.

60. The FDA approved Subutex and Suboxone tablets in 2002 as orphan drugs to manage opioid dependence. This meant that Reckitt had a seven-year exclusivity period from 2002–2009 where no generic versions of buprenorphine-containing products could enter the market.

61. Buprenorphine's orphan-drug designation was revoked in 2019. The FDA has acknowledged that orphan-drug status was "erroneously granted" because "it was unreasonable to conclude that there would be no cost recovery from sales of buprenorphine in the U.S." *See* letter from Lowell Schiller to Scott Lassman (Nov. 7, 2019) (available at https://www.regulations.gov/document/FDA-2019-P-1679-0079) (last accessed September 10, 2024).

In an effort to stymie generic tablet competition, Defendants design and seek FDA approval for Suboxone as a dissolvable film rather than a tablet.

62. In early 2006, in an effort to avoid generic competition with its Suboxone tablet product, Defendants began developing a Suboxone sublingual film. This product was bioequivalent to Suboxone tablets (meaning that the products release the same amount of active ingredients in a patient's bloodstream), but not A-B rated to tablets—and therefore not automatically substitutable by pharmacists due to the difference in dosage form.

63. Defendants sought FDA approval for the Suboxone film on October 20, 2008. In support of the application for the film, Defendants submitted safety and efficacy studies for the tablets.

64. Defendants should have properly analyzed (and/or reanalyzed based on subsequent developments) the data from these studies for FDA as to dental injuries.

65. In seeking approval for the film, Defendants also asserted that the film's individual packaging reduced the risk for accidental pediatric exposure to the drug.

66. The FDA rejected Defendants' assertion that the film provided reduced risk of pediatric exposure (and, indeed, expressed concerns that the film may increase the risk for pediatric exposure) but approved the application on August 30, 2010. This gave Defendants a three-year exclusivity period through August 2013.

67. Reckitt Benckiser Pharmaceuticals filed a patent application (US12/537,571) for sublingual and buccal film compositions on August 7, 2009. The patent application was granted on July 2, 2013 (US 8,475,832 B2) ("'832 patent"). The '832 patent provides that "[t]he present invention relates to compositions, methods of manufacture, products and methods of use relating to films containing therapeutic actives. The invention more particularly relates to self-supporting film dosage forms which provide therapeutically effective dosage, ***essentially matching that of currently marketed tablets containing the same active***." (emphasis supplied) (cleaned up).[7]

[7] Plaintiffs do not allege the truth of any statements in the referenced patent other than as specifically alleged in this Complaint.

68. Between 2009 and the present, the following entities have been assigned and/or reassigned the '832 patent: MonoSol Rx, LLC (now known as Defendant Aquestive Therapeutics) (2009, 2014, 2016–2021); Reckitt Benckiser Healthcare (UK) Ltd (2009, 2012); Reckitt Benckiser Pharmaceuticals (2009, 2012); and Indivior UK Ltd (2015, 2021–present).

69. Defendants executed a monopolistic strategy known as a product hop from sublingual Suboxone tablets to a sublingual Suboxone film for the purpose of foreclosing generic competition. A product hop involves modest reformulations of a brand-name drug before expiration of its market exclusivity for the purpose of stymieing generic competition and preserving monopoly profits.

70. Defendants intentionally designed the film as a bioequivalent to the tablet that could not be substituted for generic tablet versions of the same active ingredients. This design was specifically intended to secure Defendants' monopoly on the brand-name drug to the detriment of the generic equivalents that were entering the market. The film was not designed to be better than the tablets, and Defendants could have continued marketing the FDA-approved tablets. Suboxone tablets remain available today in several international markets, and generic competitors of the Suboxone tablet remain on the market in the U.S. today.

71. Upon approval of the film version of Suboxone, Defendants exerted pressure on the limited number of doctors authorized to prescribe Suboxone to create economic disincentives for doctors that did not transition their patients to the film from the tablet. Defendants also discouraged physicians from continuing to prescribe the

tablets under the pretext of alleged "safety" concerns with the tablet and publicly announcing in 2012 it was pulling the tablet from the market due to "safety" issues (even though there were no safety issues and the product was not, in fact, pulled from the market until 2013 when Defendants implemented the conversion to film). This maneuvering was merely a ruse designed to delay generic entry into the marketplace of less-expensive treatment options. Defendants were committed to protecting the blockbuster profits from their "orphan" drug.

72. In 2016, 41 states and the District of Columbia sued Defendants for antitrust violations related to boxing out competitors from the opioid-dependence treatment market. *See In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, MDL No. 2445 (E.D. Pa.). That litigation resolved via settlement in the summer of 2023, with Indivior agreeing to pay $102.5 million to resolve the case.

73. On April 9, 2019, a federal grand jury in Virginia indicted Indivior accusing it of engaging in an illicit nationwide scheme to increase prescriptions of Suboxone film. The indictment alleged that Indivior's "Here to Help" web and phone program was marketed by the company as a resource for patients. But in reality, the program connected patients to doctors the company knew were prescribing Suboxone and other opioids to more patients than allowed by federal law. The indictment also charged Indivior with discontinuing its tablet form of Suboxone as a pretext to delay the FDA's approval of generic tablet forms. To get out from under the indictment, Reckitt agreed to forfeit $647 million of proceeds it received from Indivior, pay $700 million in civil settlements to the federal government and six states, and pay $50

million to the Federal Trade Commission. The settlement was more than twice the amount that Purdue Pharma—makers of OxyContin—paid to settle a case with the Justice Department over its marketing claims in 2007. In total, Reckitt paid $1.4 billion to the United States government to end criminal and civil probes into its marketing of Suboxone film.

74. On October 22, 2020, former Indivior CEO Shaun Thaxter was sentenced to six months in federal prison, ordered to pay a fine of $100,000 and forfeit $500,000. He pleaded guilty to misdemeanor misbranding of Suboxone film related to false statements about accidental pediatric exposure (akin to the pretextual "safety" statements made in relation to the transition from tablet to film). Indivior's former medical director, Timothy Baxter, pleaded guilty to the same crime. On December 17, 2020, he was sentenced to six months of home detention, 100 hours of community service, and a $100,000 criminal fine.

The dangers of dental erosion and decay from dissolvable buprenorphine in the published medical literature

75. The original label for Suboxone tablets contained no warning regarding the risk of damage to the teeth associated with their use as prescribed.

76. The original label for Suboxone film contained no warning regarding the risk of damage to the teeth associated with its use as prescribed.

77. Unlike the American labels, the combined Product Monograph for the tablets and the film in Canada reports that 7.8% of the patients in the pivotal tablet trials experienced "tooth disorder" and warns of dry mouth, gingivitis, gum hemorrhage, and tooth caries.

78. In 2012, Harvard Medical School professors affiliated with Brigham and Women's Hospital in Boston published a case report on a patient with a sudden decline in her oral health while using Suboxone tablets. Suzuki J and Park EM, *Buprenorphine/naloxone and dental caries: a case report.* Am J Addict. 2012 Sep–Oct;21(5):494–5. The patient was prescribed Suboxone tablets for opioid dependence resulting from prescription of oxycodone for back pain. After 18 months of stable treatment, the patient required endodontic treatment for extensive decay in multiple teeth. The authors concluded that the "patient's experience of a sudden decline in her oral health without any changes in her dental hygiene practices or sugary food/beverage consumption raises the possibility that chronic use of sublingual buprenorphine/naloxone may have played a role."

79. In 2013, the lead author of the 2012 case report along with two other Harvard colleagues published a case series of eleven patients at Brigham and Women's Hospital in Boston between May and November 2012. The case series included patients with opioid dependence with worsening dental health after initiation of buprenorphine. The study patients experienced dental caries, dental fillings, cracked teeth, crown replacements, root canals, and tooth extractions. The authors noted that cavities and tooth erosion "occur when teeth are exposed to an environment that has low pH." This observation was consistent with the generally accepted science involving the effects of acidic substances on teeth.

80. pH is a scale of the acidity or basicity of an aqueous solution. It inversely indicates the activity of hydrogen ions in the solution. The pH range runs from 0 to

14, with 7 being neutral. A pH of less than 7 indicates acidity and a pH of greater than 7 indicates a base.

81. Suboxone has a low pH. According to a letter the authors of the Suzuki article received from Timothy Baxter (then of Reckitt),[8] the Suboxone tablet is acidic with a pH of 3.4 when dissolved in water. Further, "due to the poor bioavailability of buprenorphine, patients are specifically instructed to keep the tablet and the accumulating saliva in their oral cavity to maximize absorption through the mucosal surfaces." Based on the average ingestion of Suboxone three times daily for an average span of nine minutes to dissolve, the authors concluded 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." Suzuki J, Mittal L, and Woo S. *Sublingual Buprenorphine and Dental Problems: A Case Series.* Prim Care Companion CNS Disord. 2013; 15(5) (Oct. 2, 2013).

82. These publications confirmed what the adverse-event reporting for Suboxone tablets and film (alleged below) had already shown (and what the Product Monograph in Canada already cautioned): that dental erosion and decay were associated with ingesting oral forms of buprenorphine.

[8] As alleged above, Dr. Baxter was later convicted, along with Indivior's CEO, for criminal misbranding of Suboxone film under the Food, Drug, and Cosmetic Act. Those indictments and convictions stemmed from false statements made about the safety of Suboxone film around children.

83. Published medical literature dating back more than six decades confirms the negative effects of acidic substances like Suboxone film on the teeth.

Adverse events related to Suboxone put Defendants on notice of adverse dental events associated with the use of oral forms of buprenorphine.

84. Even a single adverse-event report can qualify as a potential signal that requires further research as part of standard pharmacovigilance. Ahmad SR, *Adverse Drug Event Monitoring at the Food and Drug Administration*. J Gen Intern Med 2003 Jan; 18(1): 57–60 (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1494803/) (last accessed September 10, 2024).

85. Defendants self-reported (or consumers, healthcare providers, or other pharmaceutical companies reported) adverse events related to dental health about Suboxone tablets and film to the FDA.

86. The FAERS database does not distinguish between the tablet and film forms of Suboxone in the reporting of adverse events. On information and belief, this is because it has the same active ingredient (buprenorphine).

87. Defendants also knew that Suboxone tablets were "acidic," stating the specific pH level in their letter to dental researchers in 2013 as noted above. Defendants also knew that Suboxone film was acidic. Myers, *et al.*, Sublingual and Buccal Film Compositions, US Patent 8,475,832 B2 (indicating that the target range of pH in the film is 2–4, with ideal pH being 3.5).[9]

[9] Plaintiffs do not allege the truth of any statements in the referenced patent other than as specifically alleged in this Complaint.

88. Despite knowing that Suboxone tablets and film are acidic, the mounting adverse events (listed below), the ongoing development of the published literature regarding dental damage from Suboxone use, and the fact that their Canadian label actually warned of potential dental harm, Defendants took no action to seek a label change under the FDA's Changes Being Effected ("CBE") regulation (21 C.F.R. § 314.70(c)(3)).

89. The following adverse events implicating dental health were reported to FDA regarding Suboxone tablets before the FDA approved Suboxone film on August 30, 2010:[10]

a. On February 20, 2007, FDA received a report from Reckitt Benckiser of a patient suffering mastication disorder, tooth loss, and pain while taking Suboxone;

b. On December 8, 2009, FDA received a report from Reckitt Benckiser of a patient suffering dental caries while taking Suboxone;

c. On January 19, 2010, FDA received a report from Reckitt Benckiser of a patient suffering jaw disorder while taking Suboxone;

d. On February 19, 2010, FDA received a report from Reckitt Benckiser of a patient suffering toothache while taking Suboxone;

e. On February 22, 2010, FDA received a report from Reckitt Benckiser of a patient suffering oral infection and dry mouth while taking Suboxone;

f. On May 6, 2010, FDA received a report from Reckitt Benckiser of a patient suffering dental caries while taking Suboxone;

g. On May 13, 2010, FDA received a report from Reckitt Benckiser of a patient suffering pain in jaw while taking Suboxone;

h. On May 27, 2010, FDA received a report from Reckitt Benckiser of a patient suffering dry mouth while taking Suboxone;

[10] *See* FDA Adverse Events Reporting System (FAERS) Public Dashboard, Suboxone (available at https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/6b5a135f-f451-45be-893d-20aaee34e28e/state/analysis) (last accessed Oct. 9, 2023).

i. On May 28, 2010, FDA received a report from Reckitt Benckiser of a patient suffering tooth disorder while taking Suboxone;

j. On June 24, 2010, FDA received a report from Reckitt Benckiser of a patient suffering toothache while taking Suboxone;

k. On July 14, 2010, FDA received a report from Reckitt Benckiser of a patient suffering tooth disorder and tooth discoloration while taking Suboxone;

l. On July 27, 2010, FDA received a report from Reckitt Benckiser of a patient suffering tongue discoloration while taking Suboxone;

m. On August 12, 2010, FDA received a report from Reckitt Benckiser of a patient suffering toothache while taking Suboxone;

90. Before Suboxone film was approved, Defendants were aware of at least 13 adverse events related to oral health associated with Suboxone tablet use.

91. The following adverse events implicating dental health were reported to FDA regarding Suboxone tablets or film:

a. On October 18, 2010, FDA received a report from Reckitt Benckiser of a patient suffering pain in jaw while taking Suboxone;

b. On November 9, 2010, FDA received a report from Reckitt Benckiser of a patient suffering pain in jaw while taking Suboxone;

c. On November 17, 2010, FDA received a report from Reckitt Benckiser of a patient suffering tongue discoloration while taking Suboxone;

d. On November 18, 2010, FDA received a report from Reckitt Benckiser of a patient suffering tooth disorder while taking Suboxone;

e. On December 6, 2010, FDA received a report from Reckitt Benckiser of a patient suffering tongue injury while taking Suboxone;

f. On December 22, 2010, FDA received a report from Reckitt Benckiser of a patient suffering oral mucosal discoloration, gingival pain, gingival erosion, and tongue disorder while taking Suboxone;

g. On December 27, 2010, FDA received a report from Reckitt Benckiser of a patient suffering oral hypoesthesia (reduced sensitivity or numbness in the mouth) while taking Suboxone;

92. By the end of 2010, Defendants were aware of at least 20 adverse events related to oral health associated with Suboxone film or tablet use. The adverse-event reports continued in 2011:

a. On January 17, 2011, FDA received a report from Reckitt Benckiser of a patient suffering tooth disorder while taking Suboxone;

b. On January 19, 2011, FDA received a report from Reckitt Benckiser of a patient suffering toothache and tooth disorder while taking Suboxone;

c. On February 9, 2011, FDA received a report from Reckitt Benckiser of a patient suffering dysgeusia (a foul, salty, rancid, or metallic taste sensation in the mouth) while taking Suboxone;

d. On February 17, 2011, FDA received a report from Reckitt Benckiser of a patient suffering pain in jaw while taking Suboxone;

e. On February 23, 2011, FDA received a report from Reckitt Benckiser of a patient suffering oropharyngeal pain (which can be caused by dental problems) while taking Suboxone;

f. On March 14, 2011, FDA received a report from Reckitt Benckiser of a patient suffering oral pain, dry mouth, and oropharyngeal pain while taking Suboxone;

g. On March 18, 2011, FDA received a report from Reckitt Benckiser of a patient suffering a coated tongue while taking Suboxone;

h. On May 25, 2011, FDA received a report from Reckitt Benckiser of a patient suffering tooth loss while taking Suboxone;

i. On June 21, 2011, FDA received a report from Reckitt Benckiser of a patient suffering toothache, tooth disorder, and oropharyngeal pain while taking Suboxone;

j. On August 5, 2011, FDA received a report from Reckitt Benckiser of a patient suffering dental discomfort while taking Suboxone;

k. On August 31, 2011, FDA received a report from Reckitt Benckiser of a patient suffering oral discomfort while taking Suboxone;

l. On September 26, 2011, FDA received a report from Reckitt Benckiser of a patient suffering a swollen tongue while taking Suboxone;

m. On September 27, 2011, FDA received a report from Reckitt Benckiser of a patient suffering tooth disorder while taking Suboxone;

n. On September 30, 2011, FDA received a report from Reckitt Benckiser of a patient suffering tooth disorder and toothache while taking Suboxone;

o. On October 13, 2011, FDA received a report from a healthcare professional of a patient suffering glossodynia (pain or a hot burning sensation in the mouth), mouth edema (swelling), oral discomfort, and a swollen tongue while taking Suboxone;

p. On November 28, 2011, FDA received a report from Reckitt Benckiser of a patient suffering a swollen tongue while taking Suboxone.

93. As of the end of 2011, Defendants were aware of at least 36 adverse events related to oral health associated with Suboxone tablet or film use. The adverse-event reports continued in 2012:

a. On February 23, 2012, FDA received a report from Reckitt Benckiser of a patient suffering a tooth fracture while taking Suboxone;

b. On July 16, 2012, FDA received a report from a patient who reported suffering tooth loss while taking Suboxone;

c. On July 25, 2012, FDA received a report from Reckitt Benckiser of a patient suffering tongue discoloration while taking Suboxone;

d. On December 31, 2012, FDA received a report from Reckitt Benckiser of a patient suffering toothache while taking Suboxone;

e. On March 6, 2013, FDA received a report from Reckitt Benckiser of a patient suffering toothache and tooth abscess while taking Suboxone;

f. On March 18, 2013, FDA received a report from Reckitt Benckiser of a patient suffering enamel anomaly while taking Suboxone;

g. On May 10, 2013, FDA received a report from a healthcare professional of a patient suffering tongue disorder while taking Suboxone;

h. On July 22, 2013, FDA received a report from Reckitt Benckiser of a patient suffering a swollen tongue while taking Suboxone;

i. On November 5, 2013, FDA received a report from Reckitt Benckiser of a patient suffering tooth fracture while taking Suboxone;

j. On December 16, 2013, FDA received a report from Reckitt Benckiser of a patient suffering dental caries while taking Suboxone.

94. On information and belief, the Suboxone film first was marketed in 2010, after the FDA approved it on August 30, 2010. The adverse-event reports available through the FAERS database do not distinguish between the tablet and film forms. Therefore, any of the AEs from that date forward could be related to either the film or the tablet.

95. As of the end of 2013, Defendants were aware of at least 46 adverse events related to oral health associated with Suboxone film or tablet use. The adverse-event reports continued in 2014:

a. On April 18, 2014, FDA received a report from Reckitt Benckiser of a patient suffering tooth disorder while taking Suboxone;

b. On May 30, 2014, FDA received a report from a patient suffering gingivitis, pain in jaw, tooth fracture, dry mouth, tooth loss, dental caries, and toothache while taking Suboxone;

c. On August 18, 2014, FDA received a report from Reckitt Benckiser of a patient suffering toothache while taking Suboxone;

d. On October 1, 2014, FDA received a report from Reckitt Benckiser of a patient suffering tooth loss while taking Suboxone;

e. On October 22, 2014, FDA received five different reports from Reckitt Benckiser of adverse dental events in patients taking Suboxone:

   i. One patient had oral mucosal blistering, tongue blistering, oral disorder, and tongue discomfort;

   ii. One patient had tongue disorder;

   iii. One patient had pain in jaw;

   iv. One patient had tooth injury and pain in jaw; and

   v. One patient had oral pain, mouth swelling, and salivary duct obstruction;

f. On January 22, 2015, FDA received a report from Reckitt Benckiser of a patient suffering tooth loss while taking Suboxone;

g. On February 19, 2015, FDA received a report from Reckitt Benckiser of a patient suffering dental caries while taking Suboxone;

h. On March 11, 2015, FDA received a report from a patient suffering gingival atrophy, pain in jaw, and tooth loss while taking Suboxone;

i. On April 20, 2015, FDA received a report from Reckitt Benckiser of a patient suffering glossodynia and a swollen tongue while taking Suboxone;

j. On June 12, 2015, FDA received a report from Reckitt Benckiser of a patient suffering pain in jaw while taking Suboxone;

k. On August 24, 2015, FDA received a report from an unspecified source of a patient suffering mastication disorder, oral pain, stomatitis (inflammation of the oral mucosa), and oral disorder while taking Suboxone.

96. On information and belief, Defendants stopped marketing the Suboxone tablet in the United States in 2013. All adverse-event reports from that time forward would have stemmed from film usage.

97. Before Reckitt Benckiser Pharmaceuticals became Indivior PLC, it was aware of at least 61 adverse events related to oral health associated with Suboxone film or tablet use. The adverse-event reports continued following the demerger of Indivior (all of which most likely would have been linked to usage of the film form of Suboxone):

a. On October 13, 2015, FDA received a report from Indivior of a patient suffering dry mouth while taking Suboxone;

b. On October 14, 2015, FDA received a report from Indivior of a patient suffering toothache, dental caries, tooth erosion, dry mouth, tooth fracture, gingival recession, and tooth loss while taking Suboxone;

c. Also on October 14, 2015, FDA received a report from Indivior of a patient suffering pain in jaw, dental caries, and trismus (spasms of the jaw) while taking Suboxone;

d. On October 15, 2015, FDA received a report from Indivior of a patient suffering tooth infection and taste disorder while taking Suboxone;

e. Also on October 15, 2015, FDA received a report from Indivior of a patient suffering tooth loss while taking Suboxone;

f. FDA received a third report from Indivior on October 15, 2015, of a patient suffering pain in jaw while taking Suboxone.

98. As of the end of 2015, Defendants were aware of at least 67 adverse events related to oral health associated with Suboxone use. The adverse-event reports continued in 2016:

a. On March 4, 2016, FDA received a report from Indivior of a patient suffering pain in jaw and tooth disorder while taking Suboxone;

b. Also on March 4, 2016, FDA received a report from Indivior of a patient suffering a jaw cyst, toothache, tooth loss, and oral pain while taking Suboxone;

c. On June 2, 2016, FDA received a report from a patient suffering pain in jaw, oral pain, and a swollen tongue while taking Suboxone;

d. On June 20, 2016, FDA received a report from Indivior of a patient suffering tooth disorder and mouth ulceration while taking Suboxone;

e. On July 8, 2016, FDA received a report from Indivior of a patient suffering a swollen tongue while taking Suboxone;

f. On September 23, 2016, FDA received a report from Indivior of a patient suffering oral discomfort and stomatitis while taking Suboxone;

g. On September 28, 2016, FDA received a report from a patient suffering while glossitis taking Suboxone;

h. On October 7, 2016, FDA received a report from Indivior of a patient suffering tooth fracture while taking Suboxone;

i. On December 7, 2016, FDA received a report from Teva of a patient suffering tooth impacted and toothache while taking Suboxone and other prescription medication.

99. As of the end of 2016, Defendants were aware of at least 76 adverse events related to oral health associated with Suboxone use. The adverse-event reports continued in 2017:

a. On February 3, 2017, FDA received a report from Indivior of a patient suffering trismus while taking Suboxone;

b. On May 5, 2017, FDA received a report from a healthcare professional of a patient suffering stomatitis while taking Suboxone;

c. On May 11, 2017, FDA received a report from a healthcare professional of a patient suffering stomatitis while taking Suboxone;

d. On August 14, 2017, FDA received a report from Indivior of a patient suffering tooth loss while taking Suboxone;

e. On October 5, 2017, FDA received a report from Indivior of a patient suffering toothache, pain in jaw, and tooth fracture while taking Suboxone;

f. On January 2, 2018, FDA received a report from Indivior of a patient suffering tooth fracture while taking Suboxone;

g. On January 24, 2018, FDA received a report from Indivior of a patient suffering tooth loss while taking Suboxone;

h. On March 12, 2018, FDA received a report from a patient suffering a swollen tongue, tongue disorder, a coated tongue, oropharyngeal pain, and glossodynia while taking Suboxone;

i. On June 15, 2018, FDA received a report from a healthcare professional of a patient suffering jaw disorder and oral mucosal blistering while taking Suboxone;

j. On July 20, 2018, FDA received a report from Indivior of a patient suffering tooth loss, toothache, and periodontal disease while taking Suboxone;

k. On September 2, 2018, FDA received a report from a patient suffering a swollen tongue, pain in jaw, gingival pain, glossodynia, and tongue discomfort while taking Suboxone;

l. On September 5, 2018, FDA received a report from Indivior of a patient suffering stomatitis, oral discomfort, glossodynia, glossitis, tongue discomfort, gingival recession, and tooth disorder while taking Suboxone;

m. On September 25, 2018, FDA received five different reports from Indivior of adverse dental events in patients taking Suboxone:

   i. One patient suffered tooth pain;

   ii. One patient suffered oral discomfort;

   iii. One patient suffered oral discomfort, oral pain, and oral hypoesthesia;

   iv. One patient suffered dry mouth; and

   v. One patient suffered tooth disorder and jaw disorder;

n. On September 26, 2018, FDA received five different reports from Indivior of adverse dental events in patients taking Suboxone:

i. One patient suffered oral hypoesthesia and oropharyngeal pain;

ii. One patient suffered dry mouth;

iii. One patient suffered jaw disorder;

iv. One patient suffered dental caries, loose tooth, and tooth discoloration; and

v. One patient suffered toothache;

o. On December 17, 2018, FDA received a report from Indivior of a patient suffering glossodynia while taking Suboxone;

p. On December 19, 2018, FDA received a report from Indivior of a patient suffering tooth loss and tooth fracture while taking Suboxone.

100. As of the end of 2018, Defendants were aware of at least 100 adverse events related to oral health associated with Suboxone use. The adverse-event reports continued in 2019:

a. On May 22, 2019, FDA received a report from Ranbaxy of a patient suffering tongue disorder while taking Suboxone and other prescription medication;

b. Also on May 22, 2019, FDA received a report from a patient suffering taste disorder while taking Suboxone;

c. On June 28, 2019, FDA received a report from Reckitt Benckiser of a patient suffering tongue blistering, tongue eruption, and tongue discomfort while taking Suboxone;

d. On August 23, 2019, FDA received a report from Reckitt Benckiser of a patient suffering tooth disorder while taking Suboxone;

e. On October 8, 2019, FDA received six different reports from Reckitt Benckiser of a patient suffering adverse dental events while taking Suboxone:

i. One patient suffered oral pain and a swollen tongue;

ii. One patient suffered tooth disorder and oral mucosal blistering;

iii. One patient suffered oral mucosal erythema, a swollen tongue, stomatitis, mouth swelling, and oral candidiasis;

iv. One patient suffered oral discomfort;

v. One patient suffered toothache and tooth disorder; and

vi. One patient suffered toothache and jaw disorder.

f. On February 24, 2020, FDA received a report from Reckitt Benckiser of a patient suffering tooth injury while taking Suboxone;

g. On March 13, 2020, FDA received a report from Reckitt Benckiser of a patient suffering tooth injury while taking Suboxone;

h. On September 14, 2020, FDA received a report from Purdue of a patient suffering poor dental condition while taking Suboxone and other prescription medication;

i. On September 23, 2020, FDA received a report from Alkermes of a patient suffering toothache while taking Suboxone and other prescription medication;

j. On October 8, 2020, FDA received six different reports from Reckitt Benckiser of a patient suffering adverse dental events while taking Suboxone:

i. One patient suffered dry mouth;

ii. One patient suffered a swollen tongue, pharyngeal swelling, oral pain, and oropharyngeal pain;

iii. One patient suffered tooth discoloration;

iv. One patient suffered taste disorder;

v. One patient suffered tooth loss; and

vi. One patient suffered oral discomfort;

k. On October 9, 2020, FDA received a report from Apotex of a patient suffering glossodynia and oral pain while taking Suboxone and other prescription medication;

l. On October 14, 2020, FDA received a report from Purdue of a patient suffering tooth extraction while taking Suboxone and other prescription medication;

m. On October 27, 2020, FDA received a report from Purdue of a patient suffering tooth loss and tooth disorder while taking Suboxone and other prescription medication;

n. On November 11, 2020, FDA received a report from Purdue of a patient suffering taste disorder while taking Suboxone and other prescription medication;

o. On December 20, 2020, FDA received a report from Specgx of a patient suffering oral pain while taking Suboxone and other prescription medication.

101. These additional 25 adverse-event reports in 2019–2020 meant that as of the end of 2020, Defendants were aware of at least 125 adverse events related to oral health associated with Suboxone use. The adverse-event reports continued in 2021:

a. On January 28, 2021, FDA received a report from Purdue of a patient suffering dental caries while taking Suboxone and other prescription medication;

b. On March 3, 2021, FDA received a report from Purdue of a patient suffering toothache while taking Suboxone and other prescription medication;

c. On March 16, 2021, FDA received a report from Purdue of a patient suffering tooth loss while taking Suboxone and other prescription medication;

d. On March 23, 2021, FDA received a report from Reckitt Benckiser of a patient suffering tooth loss and dental caries while taking Suboxone;

e. On April 24, 2021, FDA received a report from Abbvie of a patient suffering oral pain while taking Suboxone and other prescription medication;

f. On May 30, 2021, FDA received a report from Purdue of a patient suffering oropharyngeal discomfort while taking Suboxone and other prescription medication;

g. On June 22, 2021, FDA received a report from Purdue of a patient suffering dental caries while taking Suboxone and other prescription medication;

h. On October 5, 2021, FDA received a report from Purdue of a patient suffering tooth abscess and tooth loss while taking Suboxone and other prescription medication;

i. On October 7, 2021, FDA received a report from Reckitt Benckiser of a patient suffering pain in jaw while taking Suboxone;

j. Also on October 7, 2021, FDA received a report from Reckitt Benckiser of a patient suffering tooth fracture, dental caries, and tooth loss while taking Suboxone;

k. FDA received a third report on October 7, 2021, from a patient suffering dental caries while taking Suboxone and other prescription medication.

102. Before the FDA released its Safety Communication on January 12, 2022, Defendants were aware of at least 136 reports of adverse dental events in patients taking Suboxone tablets or film, but took no steps to alert patients or prescribers of the danger to oral health that Suboxone posed until after the FDA required them to do so.

103. The adverse-event reporting continued in 2022 after the FDA issued its Safety Communication:

a. On January 17, 2022, FDA received a report from a patient suffering tooth loss and bone loss while taking Suboxone;

b. On January 28, 2022, FDA received a report from a healthcare professional of a patient suffering tooth extraction, tooth infection, dental caries, mastication disorder, and tooth loss while taking Suboxone; the report also indicated that the patient was suffering from decreased self esteem;

c. On February 8, 2022, FDA received a report from a patient suffering gingivitis, gingival disorder, tooth disorder, pain in jaw, tooth infection, and tooth abscess while taking Suboxone;

d. On March 22, 2022, FDA received a report from a patient suffering a tooth disorder while taking Suboxone;

e. On March 28, 2022, FDA received a report from a patient suffering tooth disorder, dental caries, periodontal disease, infection, abscess, and mastication disorder while taking Suboxone;

f. On April 1, 2022, FDA received a report from a patient suffering mastication disorder, tooth fracture, and tooth loss while taking Suboxone;

g. On April 26, 2022, FDA received a report from a patient suffering tooth loss while taking Suboxone;

h. On May 8, 2022, FDA received a report from a patient suffering tooth disorder and loose tooth while taking Suboxone;

i. On June 2, 2022, FDA received a report from a patient suffering tooth loss while taking Suboxone;

j. On June 28, 2022, FDA received a report from Jazz of a patient suffering tooth loss while taking Suboxone and other prescription medication.

104. Of the adverse events reported to FDA before the mandated label change, 40% were classified as serious. Over one-third reported the problem as affecting two or more teeth. Some of the adverse events were reported in patients with no prior history of dental issues.

105. The FDA's safety communication identified hundreds of adverse-event reports related to buprenorphine products dissolved in the mouth.

106. Published literature reports that a slim fraction of adverse events are actually reported to the FDA. *See, e.g.*, Ahmad SR, *Adverse Drug Monitoring at the Food and Drug Administration*. J Gen Intern Med. 2003 Jan; 18(1): 57–60 (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1494803/) (last accessed September 10, 2024) (summarizing research that puts reporting of adverse events at between 1% and 13%); Hibbert PD, Molloy, CJ, Schultz TJ, et al. *Comparing rates of adverse events detected in incident reporting and the Global Trigger Tool*. Int J Qual Health Care 2023 Jul; 35(3) (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10367579/) (last accessed September 10, 2024) (finding an average of 7% of adverse events actually reported internationally).

107. Defendants were or should have been aware that only a small fraction of the actual adverse events regarding the use of Suboxone film or tablet were actually received by FDA.

108. Defendants also should have known that adverse events were being underreported given that the medical professionals who treat the injuries resulting from Suboxone use—primarily dentists—are not the same medical professionals who prescribe the drug. A dentist may not be aware that a patient is taking Suboxone, in which case the dentist would have no reason to report the event to the FDA. The adverse-event reports received by Defendants and/or reported to FDA should therefore have been afforded an even greater significance in light of the fact that the diagnosing provider may not even be aware that the patient is taking the product.

109. For the patient population Defendants have targeted, the risk of being lost to follow-up care is higher than for patients not suffering from opioid use disorder. Patients suffering from opioid use disorder experience barriers related to stigma, insurance, and finances generally. Bremer, W, Plaisance K, Walker D, et al. *Barriers to opioid use disorder treatment: A comparison of self-reported information from social media with barriers found in literature*. Front Pub Health 2023; 11: 1141093 (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10158842/) (last accessed September 10, 2024). The adverse-event reports received by Defendants and/or reported to FDA should therefore have been afforded an even greater significance in light of the practical realities of existence for the people Defendants selected to target for these drugs.

110. On information and belief, Defendants or their affiliated companies received adverse-event reports of dental harm in Suboxone tablet and/or film patients outside the United States and did not report that newly acquired information to FDA.

111. For example, the following adverse events implicating dental health were reported to Canadian officials regarding Suboxone tablets for years that, that, on information and belief, were not reported to FDA or American patients and prescribers:

a. On May 26, 2015, Health Canada received four reports of patients suffering oral disorder while taking Suboxone;

b. On February 17, 2020, Health Canada received nineteen reports of patients suffering tooth infection while taking Suboxone;

c. On June 11, 2021, Health Canada received two reports of patients suffering toothache while taking Suboxone;

d. On February 9, 2022, Health Canada received a report of a patient suffering tooth loss while taking Suboxone;

e. On September 8, 2022, Health Canada received a report of a patient suffering tooth erosion while taking Suboxone;

f. On September 8, 2022, Health Canada received a report of a patient suffering tooth loss while taking Suboxone;

g. On September 8, 2022, Health Canada received a report of a patient suffering oral infection while taking Suboxone; and

h. On May 16, 2023, Health Canada received a report of a patient suffering oral discomfort while taking Suboxone.

Despite the newly acquired information Defendants had from adverse-event reporting and published medical literature, they did not make any changes to the Suboxone film label until the FDA required them to do so.

112. The FDA has established reporting categories for post-approval changes to a drug's label. The Changes Being Effected or CBE supplement allows for changes in the labeling of a drug product to reflect newly acquired information without prior

approval from the FDA. 21 C.F.R. § 314.70(c)(3). The manufacturer may make these changes based on newly acquired information, which can include reevaluation of prior clinical trials, mounting adverse-event reports, and the peer-reviewed literature. The manufacturer is, at all times, responsible for the content of its label and may execute a CBE to the label *with or without* FDA approval.

113. The CBE process allows for drug manufacturers to change a drug label more quickly than the supplemental new drug application ("sNDA") process based on newly acquired information about the drug.

114. FDA has routinely approved manufacturers' CBEs imposing testing regimes for harms associated with a drug's use.

115. Before and during Plaintiff's treatment, the peer-reviewed literature, together with the mounting adverse event reports in the United States and internationally, required Defendants to implement a CBE warning physicians and consumers of the risk of dental erosion and decay. Defendants failed to modify the label to warn of risks associated with dental erosion and decay until June 2022 (only after the FDA mandated such a warning) rather than availing themselves of the CBE process, which at all relevant times they had the power to do.

116. These data from publications and adverse-event reporting, coupled with the fact that acidic compounds are well known to adversely impact dental integrity, triggered Defendants' obligation to implement a CBE to warn of the risks of dental problems long before the FDA required it.

117. It was not impossible for Defendants to use the CBE process to strengthen the Suboxone film label at any time between 2010 and the eventual mandated label change in 2022.

118. Based on the FDA's requirement in 2022 that Defendants change the Suboxone film label to warn of the serious dental risks the product poses, there is no reason to doubt that the FDA would have approved the label change had Defendants initiated it sooner (either through an sNDA or via a CBE). For the same reason, there is no reason to doubt that the FDA would have approved the initial label for Suboxone film to warn of the dental risks posed by the product.

Adverse event-reporting relating to dental events continues

119. Even after the FDA forced Defendants to include reference to potential dental injuries in the label, additional information about the risk of dental injuries continued to pile up.

120. The following adverse events implicating dental health were reported to FDA regarding Suboxone film after Defendants modified the Suboxone film label on June 17, 2022:

a. On January 30, 2023, FDA received a report from a patient suffering dental caries, bone disorder, and jaw disorder while taking Suboxone;

b. On February 11, 2023, FDA received a report from a patient suffering dysgeusia, gingival recession, and exposed bone in jaw while taking Suboxone and other prescription medications;

c. On March 13, 2023, FDA received a report from Alvogen of a patient suffering oral hypoaesthesia while taking Suboxone and other prescription medications;

d. On March 22, 2023, FDA received a report from Celltrion of a patient suffering glossodynia, oral pain, and tooth infection while taking Suboxone and other prescription medications;

e. On March 30, 2023, FDA received a report from Novartis of a patient suffering glossodynia, oral pain, and tooth infection while taking Suboxone and other prescription medications;

f. On April 20, 2023, FDA received a report from Reckitt Benckiser of a patient suffering dental caries while taking Suboxone;

g. On May 30, 2023, FDA received a report from a patient suffering toothache, mastication disorder, and tooth fracture while taking Suboxone;

h. On July 21, 2023, FDA received a report from Reckitt Benckiser of a patient suffering tooth loss and mastication disorder while taking Suboxone and other prescription medications;

i. On September 5, 2023, FDA received a report from Pfizer of a patient suffering toothache while taking Suboxone and other prescription medications;

j. On October 6, 2023, FDA received three different reports from Reckitt Benckiser and one report from a patient suffering adverse dental events while taking Suboxone:

   i. One patient suffered from tooth loss, pain in jaw, tooth discoloration, face swelling, teeth hyperaesthesia, tooth fracture, dry mouth, bruxism, toothache, gingival bleeding, and dental caries;

   ii. One patient suffered from dry mouth, dental restoration failure, bruxism, dental caries, tooth injury, gingivitis, toothache, and tooth loss;

   iii. One patient suffered from tooth loss and bone loss;

   iv. One patient suffered from dental caries, osteonecrosis of jaw, tooth loss, and mastication disorder;

k. On November 10, 2023, FDA received a report from a patient suffering tooth loss, mastication disorder, and bone disorder while taking Suboxone and other prescription medications;

l. On December 8, 2023, FDA received a report from Reckitt Benckiser of a patient suffering tooth loss while taking Suboxone;

m. On January 2, 2024, FDA received a report from a patient suffering tooth loss while taking Suboxone;

n. On January 3, 2024, FDA received a report from Reckitt Benckiser of a patient suffering tooth loss while taking Suboxone;

o. On January 16, 2024, FDA received a report from a patient suffering dental caries while taking Suboxone and other prescription medications;

p. On January 22, 2024, FDA received a report from Reckitt Benckiser of a patient suffering tooth loss, toothache, tongue hemorrhage, brittle teeth, dysgeusia, dental carries, tooth socket hemorrhage, and tongue injury while taking Suboxone;

q. On January 29, 2024, FDA received a report from a patient suffering tooth loss and dental caries while taking Suboxone;

r. On March 14, 2024, FDA received a report from Purdue of a patient suffering tooth injury while taking Suboxone;

s. On March 17, 2024, FDA received a report from a patient suffering dental caries and tooth disorder while taking Suboxone;

t. On March 22, 2024, FDA received a report from a patient suffering dental caries, tooth fracture, and a loose tooth while taking Suboxone and other prescription medications;

u. On March 28, 2024, FDA received a report from a patient suffering loose tooth, tooth fracture, dental caries, and tooth loss while taking Suboxone;

v. On April 26, 2024, FDA received a report from Purdue of a patient suffering dental caries while taking Suboxone;

w. On April 29, 2024, FDA received a report from a patient suffering tooth loss while taking Suboxone;

x. On May 1, 2024, FDA received two reports from a patient suffering adverse dental events while taking Suboxone:

    i. One patient suffered from tooth extraction, dental caries, and while taking Suboxone and other prescription medications;

ii. One patient suffered from tooth injury, endodontic procedure, tooth extraction, and dental caries;

y. On May 23, 2024, FDA received a report from a patient suffering toothache, dental caries, tooth loss, and pain while taking Suboxone;

z. On June 3, 2024, FDA received a report from a patient suffering dental caries, tooth injury, tooth loss, and loose tooth while taking Suboxone and other prescription medications;

aa. On June 12, 2024, FDA received a report from FDA-CTU of a patient suffering dental caries while taking Suboxone;

bb. On June 13, 2024, FDA received a report from Reckitt Benckiser of a patient suffering dental caries, brittle teeth, periodontitis, and tooth loss while taking Suboxone; and

cc. On June 19, 2024, FDA received a report from Reckitt Benckiser of a patient suffering tooth fracture while taking Suboxone.[11]

Epidemiology confirms the association between transmucosal buprenorphine use and dental erosion and decay.

121. In December 2022, a research letter published in the Journal of the American Medical Association reported on a pharmacoepidemiologic study for dental adverse events associated with the use of sublingual buprenorphine-containing medication such as Suboxone and transdermal alternatives. The study examined a cohort of patients from 2006–2020. It included 21,404 new users of sublingual buprenorphine/naloxone, 5,385 users of transdermal buprenorphine, and 6,616 users of oral naltrexone. The study found "an increase in the risk of adverse dental outcomes associated with sublingual buprenorphine/naloxone compared with transdermal buprenorphine or oral naltrexone." The adjusted HRs were 1.42 (95% CI, 1.17-1.73) for sublingual buprenorphine/naloxone vs. transdermal buprenorphine

[11] On information and belief, the data in FAERS is available only through June 2024.

and 1.67 (95% CI, 1.41-1.98) for sublingual buprenorphine/naloxone vs. oral naltrexone. The incidence of dental caries or tooth loss was 8.2 per 1000 person-years with sublingual buprenorphine/naloxone, 3.5 per 1000 person-years with transdermal buprenorphine, and 3.8 per 1000 person-years with oral naltrexone. For dental caries or tooth loss, the HRs were 1.57 (95% CI, 1.11-2.23) for sublingual buprenorphine/naloxone vs. transdermal buprenorphine and 1.71 (95% CI, 1.29-2.27) for sublingual buprenorphine/naloxone vs. oral naltrexone. Etminan J, Rezaeianzadeh R, Kezouh A, et al. *Association Between Sublingual Buprenorphine-Naloxone Exposure and Dental Disease*. JAMA (Dec. 13, 2022) (available at https://jamanetwork.com/journals/jama/fullarticle/2799415) (last accessed September 10, 2024).

122. Two months later, Indivior touted "another strong year of execution of [its] strategic priorities" including "excellent momentum from [its] increased efforts to access the millions of opioid use disorder patients" across the nation. Indivior PLC Q4 Financial Results (Feb. 16, 2023) (available at https://www.indivior.com/resources/dam/id/1125/Indivior_Q4_2022_Financial_Results_Final.pdf) (last accessed September 10, 2024).

Defendants failed to warn patients and prescribers about the risk

123. At all relevant times, Defendants failed to adequately warn or instruct patients, the medical community, or prescribers in the United States that Suboxone film causes, is linked to, and is associated with dental erosion and decay.

124. At all relevant times, Defendant failed to adequately warn or instruct patients, the medical community, or prescribers in the United States that patients receiving Suboxone film should undergo regular dental monitoring for adverse impact.

125. At all relevant times, Defendants failed and continue to fail to instruct prescribers that Suboxone film causes, is linked to, and is associated with xerostomia or dry mouth.

126. At all relevant times, Defendants failed and continue to fail to instruct prescribers to conduct saliva quality, pH, and buffering capacity testing before and during Suboxone film usage.

127. Until June 2022, Defendants failed to instruct patients or prescribers that patients should wait one hour after the film dissolves to brush their teeth. Brushing teeth while the mouth remains acidic exacerbates the demineralization caused by transmucosal buprenorphine-containing products including Suboxone film. The tooth minerals released by the hydrogen ions in the product are brushed away, preventing remineralization and further weakening the enamel softened by the acid bath of Suboxone film.

128. At all relevant times, the labeling for Suboxone film failed and continues to fail to provide adequate warnings and instructions, failed and continues to fail to caution that patients should be closely monitored, and failed and continues to fail to adequately inform patients and physicians that permanent dental erosion and decay are associated with Suboxone film use.

129. At all relevant times, Defendants also failed to alert patients of the need for dental monitoring while receiving Suboxone film and whether risks for dental injuries increase with longer durations.

130. As explained above, the FDA has established reporting categories for post-approval changes to a drug's label. The CBE supplement allows for changes in the labeling of a drug product to reflect newly acquired information without prior approval from the FDA.

131. Defendants should have sought to include a warning about adverse dental risks in the label for Suboxone film based on information acquired about the Suboxone tablet.

132. Defendants should have changed the Suboxone film label to include warnings and instructions addressing the risk of injury associated with the drug as newly acquired information continued to become available post-approval of the film.

133. By failing to use the FDA's CBE supplement to warn Plaintiff, consumers, and physicians of the risk of permanent dental erosion and decay associated with using Suboxone film, Defendants acted in a gross and flagrant character, evincing reckless disregard of the safety and welfare of persons exposed to this dangerous drug.

134. By failing to provide an adequate warning presently, Defendants continue to act in a gross and flagrant character, evincing reckless disregard of the safety and welfare of persons exposed to this dangerous drug.

135. By failing to acknowledge the serious and severe dental injuries that Suboxone film causes, Defendants continue to act in a gross and flagrant character, evincing

reckless disregard of the safety and welfare of persons exposed to this dangerous drug.

136. Additionally, by failing to use the FDA's CBE supplement to warn Plaintiff, consumers, and physicians of the risk of permanent dental erosion and decay associated with using Suboxone film, Defendants showed wantonness, recklessness, or a grossly careless disregard for the public's safety and welfare.

137. The label still does not provide an adequate warning that Suboxone film can cause dental erosion and decay or xerostomia, even after the mandated label change. This inadequacy demonstrates Defendants' continued wantonness, recklessness, or grossly careless disregard for the public's safety and welfare.

Defendants had a duty to protect American consumers, but failed to fulfill it.

138. At all relevant times, Defendants had a duty to design a safe drug and craft an adequate label with respect to Suboxone film.

139. At all relevant times, Defendants had a duty to ensure that the warnings in the Suboxone film label were adequate—at all times—for as long as the drug remained available for sale in the United States.

140. At all relevant times, Defendants had a responsibility to conduct post-marketing surveillance and to continue to study the safety and efficacy of Suboxone film after the drug was approved, for as long as the drug remained available for sale in the United States.

141. At all relevant times, Defendants had a duty to revise the Suboxone film label to include a warning regarding the risk of serious and permanent dental erosion and

decay as soon as there was reasonable evidence of a causal association between such injuries and Suboxone film use.

142. At all relevant times, Defendants had a duty to revise the Suboxone film label to include a warning regarding the risk of xerostomia as soon as there was reasonable evidence of a causal association between dry mouth and Suboxone film use.

143. On information and belief, despite understanding Suboxone film could cause dentition-related injuries, Defendants knowingly withheld and/or misrepresented information from consumers and physicians concerning the safety and efficacy of Suboxone film, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Suboxone film users suffering dental erosion and decay as a result of their Suboxone film use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious dental injuries as a result of using Suboxone film as prescribed.

144. With knowledge of the true relationship between long-term use of Suboxone and dental deterioration, rather than adequately warn of the risks or remove the drug from the market, Defendants promoted Suboxone film as a safe and effective drug for medication-assisted treatment of opioid dependence.

How Defendants' misconduct endangered American consumers

145. On information and belief, had Defendants exercised reasonable care in testing and studying Suboxone film, they would have discovered—before seeking FDA approval—that sublingual or buccal administration of buprenorphine and/or

naloxone at the pH Defendants selected for the product can cause dental erosion and decay.

146. On information and belief, despite post-approval adverse-event reports (in the United States and internationally) and other clinical evidence, Defendants failed to continue to test and study the safety and efficacy of Suboxone film, including but not limited to as a long-term maintenance drug.

147. On information and belief, from the date Defendants received FDA approval to market Suboxone film in the United States through June 2022, Defendants made, distributed, marketed, and sold Suboxone film without adequate warnings to Plaintiff's prescribing physicians or Plaintiff that Suboxone film was associated with and/or could cause serious dental injuries in patients who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Suboxone film with regard to dental erosion and decay.

148. On information and belief, Defendants concealed and/or failed to completely disclose their knowledge that Suboxone film was associated with and/or could cause dental injuries, as well as its knowledge that it had failed to fully test or study said risk.

149. On information and belief, Defendants ignored the association between the use of Suboxone film and the risk of developing permanent dental loss, including, but not limited to, dental decay and erosion.

150. On information and belief, Defendants failed to warn Plaintiff and Plaintiff's healthcare providers regarding the true risk of dental damage of Suboxone film, but

similar efficacy compared to other products, treatment options, and/or delivery mechanisms such as Sublocade (a monthly buprenorphine extended-release injection manufactured by Defendants and approved by the FDA in 2017).

151. On information and belief, Defendants failed to provide adequate instructions to healthcare professionals and patients in the United States regarding how to safely monitor and identify signs of potentially serious dental complications associated with Suboxone film use.

152. On information and belief, Defendants failed to provide adequate instructions to healthcare professionals and patients in the United States regarding the risk of xerostomia associated with Suboxone film use as it relates to increasing the risk of dental erosion and decay.

153. On information and belief, Defendant failed to warn healthcare professionals and patients in the United States, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely monitor and identify signs of potentially serious dental complications associated with Suboxone film use.

154. On information and belief, Defendant failed to warn and/or to provide adequate instructions to healthcare professionals and patients in the United States, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely stop receiving Suboxone film when potentially serious dental complications developed while using Suboxone film.

155. On information and belief, Defendants failed to warn healthcare professionals and patients in the United States, including Plaintiff's prescribing physicians and

Plaintiff, of the *true* risk of dental damage to patients receiving Suboxone film as compared to other similarly efficacious pharmaceutical products, treatment options, and/or delivery mechanisms.

156. Defendants' failures to provide adequate instructions and/or disclose information—which Defendants possessed regarding the failure to adequately test and study Suboxone film for the risk of serious dental complications—further rendered the Suboxone Film Package Insert, and other educational and/or promotional materials, inadequate.

157. Despite adverse-event reports from healthcare professionals and consumers, Defendants did not warn of the risk of serious and irreversible dental injury associated with using Suboxone film until the label change in June 2022. Even after the label change, the warning on the label is inadequate to warn healthcare professionals and consumers of the risk of dental injury.

Delay in safer injectable to maximize profits from oral monopoly

158. Oral absorption is not the only way to administer buprenorphine for opioid use disorder.

159. Injectable buprenorphine was first introduced in the United Kingdom in 1977, when Reckitt & Colman registered the Temgesic Injection. Christian Heidbreder et al., *History of the discovery, development, and FDA-approval of buprenorphine medications for the treatment of opioid use disorder*, Drug and Alcohol Dependence Rep., 2023, at 2 (available at

www.ncbi.nlm.nih.gov/pmc/articles/PMC10040330/pdf/main.pdf) (last accessed September 10, 2024). Temgesic was used to treat pain. *Id.*

160. Injectable buprenorphine has been available in the United States since 2002. *Buprenex (Buprenorphine Hydrochloride) Injectable*, U.S. Food & Drug Admin. (Feb. 11, 2002) (available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/018401_s014_BuprenexTOC.cfm#:~:text=Approval%20Date%3A%2002%2F11%2F2002) (last accessed September 10, 2024).

161. Buprenex was not withdrawn from the market for reasons of safety or effectiveness.[12]

162. Polymer extended-release injections for drug delivery have been technologically feasible since the 1990s. *See, e.g.*, Patent No. US 5384333 A, Biodegradable injectable drug delivery polymer (Jan. 24, 1995) (available at https://patents.google.com/patent/US5384333A/en) (last accessed September 10, 2024).

163. The FDA approved a polymer extended-release injectable naltrexone (trade name Vivitrol) for treating alcohol dependence nearly two decades ago. *See* Division Director's Approval Letter for Vivitrol (Apr. 13, 2006) (available at www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021897s000_MedR_P1.pdf) (last

[12] *See* FDA Notice, Determination that BUPRENEX (Buprenorphine Hydrochloride) Injection, 0.3 Milligram/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness (Nov. 22, 2023) (available at https://federalregister.gov/documents/2023/11/22/2023-25857/determination-that-buprenex-buprenorphine-hydrochloride-injection-03-milligrammilliliter-was-not) (last accessed May 17, 2024).

accessed September 10, 2024). Alkermes, Inc. applied for a patent for that delivery system in 2005. Patent No. US 7919499 B2, Ehrich, Naltrexone Long Acting Formulations and Methods of Use, Alkermes, Inc. (Apr. 5, 2011) (available at https://patents.google.com/patent/US7919499B2/en) (last accessed September 10, 2024);

164. The technology for an extended-release buprenorphine injection was available decades before Sublocade was submitted for FDA approval in 2017.

165. In the early 1990s, Biotek, Inc. received Phase I and II funding from the federal Small Business Innovation Research Program (SBIR) for a "Sustained-Action Buprenorphine" project. The purpose of the project was to develop "a sustained-action formulation of microencapsulated buprenorphine that is effective for one month and to prepare documentation to support an IND [investigational new drug] application for initial clinical trials." Sustained-Action Buprenorphine, SBIR-STTR (available at https://legacy.www.sbir.gov/content/sustained-action-buprenorphine-0) (last accessed September 11, 2024). *See also* Sustained-Action Buprenorphine, SBIR-STTR (available at https://legacy.www.sbir.gov/content/sustained-action-buprenorphine-2) (last accessed September 11, 2024).

166. Biotek, Inc. filed a patent in 2002 for an extended-release monthly buprenorphine injection, which was granted in 2006. Patent No. US 7041320 B1, Nuwayser, High drug loaded injectable microparticle compositions and methods of treating opioid drug dependence (May 9, 2006) (available at

https://patents.google.com/patent/US7041320B1/en) (last accessed September 11, 2024).

167. By 2004, it was established that buprenorphine injections using polymer microcapsule depot sustained-release technology are safe and effective for treating opioid use disorder. Bai-Fong X Sobel, et al., *Open-label trial of an injection depot formulation of buprenorphine in opioid detoxification*, 73 Drug and Alcohol Dependence 11 (Jan. 2004) (available at https://www.sciencedirect.com/science/article/abs/pii/S0376871603002424?via%3Dihub) (last accessed September 11, 2024) ("Depot buprenorphine appeared to provide effective relief from opioid withdrawal, with no participant requiring additional medication for withdrawal relief following depot administration. The depot was safe and well-tolerated, with no significant side effects, signs of intoxication, or respiratory depression. In the opioid challenge sessions, depot buprenorphine appeared to produce substantial opioid blockade that persisted for 6 weeks post-depot administration. Results from the present study suggest that depot buprenorphine offers significant promise for enhancing the delivery of effective opioid agonist treatment while minimizing risk for abuse of the medication."); Stacey C Sigmon, et al., *Evaluation of an injection depot formulation of buprenorphine: placebo comparison*, 99 Addiction 1439 (Aug. 25, 2004) (available at https://pubmed.ncbi.nlm.nih.gov/15500597/) (last accessed September 11, 2024) ("Results from this double-blind, placebo-controlled study indicate that depot

buprenorphine is effective in providing both withdrawal suppression and opioid blockade.").

168. On information and belief, the Sobel and Sigmon publications were funded by the Phase I and II funding from SBIR for Biotek's monthly injectable buprenorphine product (Norvex). These clinical studies suggested that Biotek's monthly extended-release injectable buprenorphine was highly promising for treating opioid use disorder.

169. On information and belief, Biotek did not proceed to Phase III clinical trials with Norvex or seek FDA approval to market this delivery method for buprenorphine despite the promising results of the Phase I and II trials.

170. The FDA approved Defendant Indivior Inc.'s Sublocade, an extended-release monthly injection of buprenorphine, in 2017. The buprenorphine is incorporated into a polymer solution, becomes incorporated within the polymer matrix, and is slowly released in the body as the polymer biodegrades. The NDA for Sublocade was submitted on May 30, 2017. Application No. 209819Orig1s000, Center for Drug Evaluation and Research (May 30, 2017) (available at www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209819Orig1s000ClinPharmR.pdf) (last accessed September 11, 2024). The FDA swiftly granted approval on November 30, 2017. *Id.*

171. On information and belief, Defendants could have sought FDA approval to introduce Sublocade—a safer buprenorphine-containing product—to the market long before 2017 but delayed seeking approval for this safer alternative to maintain the

monopoly of the film occasioned by its successful product hop from tablets and orphan-drug exclusivity through 2017.

172. Based on the fact that the FDA approved Sublocade, Plaintiff allege that the FDA would have approved Sublocade earlier had Defendants sought approval of this safer technology for delivering buprenorphine that does not require multiple daily acid baths for patients' teeth.

173. On information and belief, Defendants started developing Sublocade before introducing Suboxone film to the market. Christian Heidbreder, et al., *supra,* at 6. By 2007, the appropriate dosage for clinical studies had been determined. *Id.* But Defendants delayed clinical trials until November 2010. *See Single-dose, Study of RBP-6000 in Opioid Dependent Individuals*, ClinicalTrials.gov (available at https://clinicaltrials.gov/study/NCT02765867?term=Indivior&page=4&rank=31) (last accessed September 11, 2024).

174. Reckitt Benckiser Pharmaceuticals (now Indivior Inc.) filed the patent for Sublocade on June 6, 2011—six years before seeking FDA approval for Sublocade. U.S. Patent 8,921,387 B2, Norton et al., Injectable Flowable Composition Comprising Buprenorphine (filed June 6, 2011; granted Dec. 30, 2014) (available at https://patentimages.storage.googleapis.com/4e/bd/eb/b24cfbd3a27853/US8921387.pdf) (last accessed September 11, 2024).

175. On information and belief, Defendants delayed developing the safer injectable because of the desire to maintain the profits they reaped from monopolizing the oral-

dissolvables market for buprenorphine and the belief that developing and/or launching the safer injectable would harm sales of Suboxone film.

176. In November 2010, Indivior Inc. sponsored a clinical trial to evaluate the safety, tolerability, and pharmacokinetic profile of injectable buprenorphine. *Single-dose, Study of RBP-6000 in Opioid Dependent Individuals*, *supra.* The trial was completed in May 2011. *Id.*

177. In March 2012, Indivior Inc. sponsored a clinical trial to determine whether individuals who had been using Suboxone or Subutex could transition to RBP-6330 (injectable buprenorphine). *Transfer of Subjects From Subutex/Suboxone to RBP-6300,* ClinicalTrials.gov (available at https://www.clinicaltrials.gov/study/NCT01582347?term=Indivior&page=4&rank=39) (last accessed September 11, 2024). The study was completed in November 2012. *Id.*

178. In July 2012, Indivior Inc. sponsored a clinical trial to study depot buprenorphine in individuals who had not taken Suboxone versus individuals who had taken Suboxone tablets. *Single Ascending Dose Study of RBP-6000 (SAD)*, ClinicalTrials.gov (available at https://www.clinicaltrials.gov/study/NCT03002961?term=Indivior&page=3&rank=39) (last accessed September 11, 2024). The trial was completed in October 2013. *Id.*

179. In October 2012, Indivior Inc. sponsored a clinical trial to study the subcutaneous injections of depot buprenorphine on individuals who had taken Subutex, another of Defendants' products. *Multiple Dose Pharmacokinetics Depot*

Buprenorphine in Opioid-Dependent Subjects, ClinicalTrials.gov (available at https://clinicaltrials.gov/study/NCT01738503?term=Indivior&page=4&rank=37) (last accessed September 11, 2024). The study was completed in May 2014. *Id.*

180. Defendants knew Sublocade was safer than Suboxone film before introducing Suboxone film to the market.

181. Because Sublocade is injected subcutaneously, it does not create an acidic environment in the mouth.

182. It has been known for over half a century that acids destroy tooth enamel and dentin. *See* James L. McDonald, Jr. & George K. Stookey, *Laboratory Studies Concerning the Effect of Acid-Containing Beverages on Enamel Dissolution and Experimental Dental Caries*. 52 J. Dental Rsch. 211 (1973) (available at https://journals.sagepub.com/doi/abs/10.1177/00220345730520020401) (last accessed September 11, 2024). This information was available to Defendants before the development of Suboxone film or Sublocade, making it clear that non-acidic, subcutaneously administered Sublocade would not cause the same damage to users' teeth as Suboxone film.

183. One side effect of Suboxone film is xerostomia, or dry mouth. *Buprenorphine*, Substance Abuse and Mental Health Servs. Admin. (available at https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine) (last accessed September 11, 2024). Xerostomia "is associated with a low pH of the saliva and a decreased buffering capacity[,]" which is "strongly associated with dental erosion." Ana Carolina

Magalhães, et al., *Insights into preventive measures for dental erosion*, 17 J. Applied Oral Sci. 75, 79 (2009) (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4327581/) (last accessed September 11, 2024). This means that a known side effect of buprenorphine (of which Defendants still fail to warn at all) also increases the risk of dental erosion that Suboxone film already poses (of which Defendants still fail to adequately warn). Sublocade does not pose this risk.

184. Defendants have received more than 100 adverse-event reports of dry mouth/xerostomia with the use of their buprenorphine-containing product, Suboxone tablets. These adverse-event reports began before Suboxone film was approved.

185. Apart from avoiding the threat of dental destruction, research also indicates that Sublocade is more effective in treating opioid use disorder than sublingual formulations like Suboxone film. Lee JD, Malone M, McDonald R, et al. *Comparison of treatment retention of adults with opioid addiction managed with extended-release buprenorphine vs daily sublingual buprenorphine-naloxone at time of release from jail*. JAMA Netw Open, 2021 Sep; 4(9): e2123032 (comparing injection to sublingual and finding 69% of injection patients remained in treatment after eight weeks compared with only 35% in the sublingual group) (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8427378/) (last accessed September 11, 2024).

186. On information and belief, Defendants delayed submitting Sublocade for FDA approval or introducing it to the market to financially benefit from their orphan-drug

monopoly on Suboxone film; the film's exclusivity period ran from its approval in 2010 for seven years, and Sublocade was introduced in 2017.

187. On information and belief, Defendants delayed launching Sublocade until the near conclusion of the *de facto* exclusivity period that resulted from Defendants' patent litigation, which delayed generic versions of Suboxone film from entering the market until 2019. *See* Barenie, *et al.*, *Factors Affecting Buprenorphine Utilization and Spending in Medicaid, 2002–2018*, 24(2) Value in Health 182–187 (2021) (available at www.valueinhealthjournal.com) (last accessed September 11, 2024).

188. Had Defendants not withheld Sublocade, Plaintiff would have taken it and avoided the dental injuries Plaintiff sustained.

189. Defendants knew the safer injection was less likely to cause dental damage than Suboxone film.

Equitable tolling of statutes of limitations

190. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold information from Plaintiff, Plaintiff's healthcare providers, and the general public concerning the known hazards associated with the use of Suboxone film.

191. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold safety-related warnings from Plaintiff, Plaintiff's healthcare providers, and the general public concerning the known hazards associated with the use of Suboxone film.

192. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold instructions from Plaintiff, Plaintiff's healthcare providers, and

the general public concerning how to identify, mitigate, and/or treat known hazards associated with the use of Suboxone film.

193. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to ignore relevant safety concerns and to deliberately *not* study the safety and efficacy of Suboxone film, particularly for long-term use as a maintenance drug.

194. Defendants failed to disclose a known risk and, instead, affirmatively misrepresented that Suboxone film was safe for its intended use indefinitely. Defendants disseminated labeling, marketing, promotion, and/or sales information to Plaintiff, Plaintiff's healthcare providers, and the general public regarding the safety of Suboxone film knowing such information was false, misleading, and/or inadequate to warn of the safety risks associated with Suboxone film use. Defendants did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning the Suboxone film's safety.

195. Defendants marketed Suboxone film as a maintenance drug, knowing that Suboxone film patients would use the product for extended time periods, yet failed to warn of the risk of prolonged use of Suboxone film posed to dental health.

196. Due to the absence of any warning by Defendants as to the significant permanent health and safety risks posed by Suboxone film, Plaintiff was unaware that Suboxone film could cause serious and permanent dental injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

197. Due to the absence of any instructions for how to identify and/or monitor Suboxone film patients for potential dental complications, Plaintiff was unaware that

Suboxone film could cause serious and permanent dental injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

198. Due to the absence of any warnings regarding extended use of Suboxone film, Plaintiff and Plaintiff's healthcare providers were unaware of the increasing risk of dental injuries with extended use of the product.

199. Given Defendants' conduct and deliberate actions designed to deceive Plaintiff, Plaintiff's healthcare providers, and the general public with respect to the safety and efficacy of Suboxone film, Defendant is estopped from relying on any statute-of-limitations defenses.

CLAIM 1: STRICT PRODUCTS LIABILITY—FAILURE TO WARN

200. Plaintiff incorporates all prior allegations.

201. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Suboxone film and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

202. Defendants, as manufacturers and distributers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data that it distributed regarding the risks associated with the use of Suboxone film were inadequate.

203. Plaintiff did not have the same knowledge as Defendants, and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians.

204. Defendants had a duty to provide adequate warnings and instructions for Suboxone film, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately understand, test, and monitor their product.

205. Defendants had a continuing duty to provide consumers, including Plaintiff and Plaintiff's treating physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Suboxone film as it became or could have become available to Defendants.

206. Defendants marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug, Suboxone film, to health care providers empowered to prescribe and dispense Suboxone film to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of Suboxone film, which resulted in injury to Plaintiff.

207. Defendants knew or should have known through testing, scientific knowledge, advances in the field, published research, and/or their own post-marketing studies, that Suboxone film created a risk of serious dental issues.

208. Defendants knew or should have known through testing, scientific knowledge, advances in the field, published research, and/or their own post-marketing studies,

that the risk of serious dental injuries from using Suboxone film increases with prolonged use.

209. Despite the fact that Defendants knew or should have known that Suboxone film caused unreasonable and dangerous side effects, they continued to promote and market Suboxone film without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

210. Defendants knew or should have known that consumers, Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Defendants' failures.

211. The Suboxone film supplied to Plaintiff by Defendants was defective, unreasonably dangerous, and had inadequate warnings or instructions at the time it was sold, and Defendants also acquired additional knowledge and information confirming the defective and unreasonably dangerous nature of Suboxone film. Despite this knowledge and information, Defendants failed and neglected—until June 2022—to issue any warning that Suboxone film causes serious and potentially irreversible dental injuries and/or instructions concerning the need for dental monitoring and potential discontinuation of use of Suboxone film.

212. To this day, Defendants continue to fail to warn of the risk of xerostomia (and its relationship to dental erosion and decay).

213. To this day, Defendants continue to fail to warn that prolonged use of Suboxone film increases the risk of dental erosion and decay, despite marketing the product as

a maintenance drug that may be used (according to the product's Prescribing Information) "indefinitely."

214. Defendants' failure to provide adequate warnings or instructions rendered Suboxone film unreasonably dangerous in that it failed to perform as safely as an ordinary patient, prescriber, and/or other consumer would expect when used as intended and/or in a manner reasonably foreseeable by Defendants, and in that the risk of danger outweighs the benefits.

215. Defendants failed to provide timely and adequate warnings to physicians and consumers, including Plaintiff and to Plaintiff's treating physicians, in the following ways:

a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's treating physicians to the dangerous risks of Suboxone film including, among other things, dental erosion and decay;

b. Defendants failed to provide adequate post-marketing warnings and instructions (including regarding the increasing risk with long-term usage) after Defendants knew or should have known of the significant risks of, among other things, potentially irreversible dental erosion and decay;

c. Defendants failed and continue to fail to report the incidence rate of dental injuries associated with Suboxone film use;

d. Defendants continued and continue to promote and sell Suboxone film without adequate warnings, even after they knew or should have known of the unreasonable risks of dental injuries from the drug; and

e. Defendants failed to instruct prescribers to conduct saliva quality, pH, and buffering capacity testing before and during Suboxone film usage.

216. Defendants had an obligation to provide Plaintiff and Plaintiff's treating physicians with adequate clinically relevant information and data and warnings

regarding the adverse health risks associated with exposure to Suboxone film, and/or that there existed safer and more or equally effective alternative drug products, treatment options, and/or delivery mechanisms.

217. By failing to provide Plaintiff and Plaintiff's treating physicians with adequate clinically relevant information, data, and warnings regarding the adverse health risks associated with exposure to Suboxone film, and/or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

218. By failing to adequately test and research harms associated with Suboxone film, and by failing to provide appropriate warnings and instructions about Suboxone film use (including incidence rates), patients and the medical community—including Plaintiff and Plaintiff's treating physicians—were inadequately informed about the true risk-benefit profile of Suboxone film and were not sufficiently aware that serious dental injuries were associated with use of Suboxone film. Nor were the medical community, patients, patients' families, or regulators appropriately informed that serious dental injuries might be a side effect of Suboxone film and should or could be reported as an adverse event.

219. The Suboxone film designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks and severe and permanent dental injuries from receiving Suboxone film, they failed to provide adequate warnings to

users or consumers of the product and continued to improperly advertise, market, and/or promote Suboxone film.

220. Suboxone film is defective and unreasonably dangerous to Plaintiff and other consumers regardless of whether Defendants had exercised all possible care in its preparation and sale.

221. The foreseeable risk of serious dental injuries caused by Suboxone film could have been reduced or avoided by Plaintiff, prescribers, and/or other consumers if Defendants had provided reasonable instructions or warnings of these foreseeable risks of harm.

222. The foreseeable risk of serious dental injuries caused by Suboxone film could have been reduced or avoided by Plaintiff, prescribers, and/or other consumers if Defendants had provided reasonable instructions or warnings to taper and discontinue Suboxone film use in patients experiencing dental deterioration.

223. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard for the health and safety of Plaintiff and the general public.

224. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Suboxone film, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and

aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

CLAIM 2: PRODUCTS LIABILITY—NEGLIGENT FAILURE TO PROVIDE ADEQUATE WARNINGS AND INSTRUCTIONS

225. Plaintiff incorporates all prior allegations.

226. At all relevant times, Defendants had a duty to exercise reasonable care and had the duty of an expert in all aspects of the warning and post-sale warning to assure the safety of Suboxone film when used as intended or in a way that Defendants could reasonably have anticipated (including as to the duration of use), and to assure that the consuming public, including Plaintiff and Plaintiff's treating physicians, obtained accurate information and adequate instructions for the safe use or non-use of Suboxone film.

227. Defendants' duty of care was that a reasonably careful designer, manufacturer, seller, importer, distributor, and/or supplier would use under like circumstances.

228. Defendants had a duty to warn Plaintiff, Plaintiff's treating physicians, and consumers of Suboxone film's dangers and serious side effects, including serious dental erosion and decay and other clinically relevant information, as it was reasonably foreseeable to Defendants that Suboxone film could cause such injuries.

229. At all relevant times, Defendants failed to exercise reasonable care and knew, or in the exercise of reasonable care should have known, that Suboxone film had inadequate instructions and/or warnings.

230. Defendants' actions and omissions were and are negligent and careless, resulting in a breach of the duties set forth above. These acts and omissions include, but are not limited to:

a. Failing to accompany their product with proper and adequate warnings, labeling, or instructions concerning the potentially dangerous, defective, unsafe, and deleterious propensity of Suboxone film and of the risks associated with its use;

b. Disseminating information to Plaintiff and Plaintiff's treating physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

c. Failing to provide warnings or other information that accurately reflect the symptoms, scope, severity, and permanence of the side effects and health risks;

d. Failure to accompany the product with proper or adequate rate of incidence or prevalence of dental-related injuries;

e. Failing to adequately test and/or warn about the use of Suboxone film, including, without limitations, the possible adverse side effects and health risks caused by using Suboxone film;

f. Failure to adequately warn of the risks that Suboxone film could interfere with dental health;

g. Failure to adequately warn of the risk of serious dental erosion and decay;

h. Failure to adequately warn and advise of adverse reactions involving dental health;

i. Failure to instruct patients, prescribers, and consumers of the need for dental monitoring when ingesting Suboxone film;

j. Failure to warn of the consequences that might result from failure to follow the instructions related to dental health;

k. Failing to provide instructions on ways to safely use Suboxone film to avoid injury (including as to duration of use);

l. Failing to warn of the risk of xerostomia or dry mouth;

m. Failing to instruct providers to conduct saliva quality, pH, and buffering capacity testing before and during Suboxone film usage;

n. Failing to explain the mechanism, mode, and types of adverse events associated with Suboxone film;

o. Failing to provide adequate training or information to medical care providers for appropriate use of Suboxone film and patients receiving Suboxone film;

p. Failing to provide patients and/or physicians with adequate clinically relevant information, data, and warnings regarding the adverse health risks associated with exposure to Suboxone film, as it became or could have become known to Defendants;

q. Failing to advise patients and/or physicians that there existed safer and more or equally effective alternative products, treatment options, and/or delivery mechanisms that do not carry the risks posed by Suboxone film; and

r. Representing to physicians, including but not limited to Plaintiff's treating physicians, that this drug was safe and effective for use.

231. Suboxone film was defective and unreasonably dangerous when it left the possession of Defendants in that it contains warnings insufficient to alert patients and treating physicians of the dangerous risks associated with Suboxone film, including but not limited to the risk of dental injuries despite Defendants' knowledge of the risk of these injuries over other products, treatment options, and/or delivery mechanisms available.

232. Suboxone film was defective due to inadequate post-marketing warnings and instructions because Defendants knew or should have known of the risk and danger of serious harm from the use of Suboxone film but failed and continue to fail to provide adequate warnings to patients and treating physicians of the product, including

Plaintiff and Plaintiff's treating physicians, knowing the product could cause serious injury.

233. Plaintiff was prescribed and used Suboxone film for its intended purpose.

234. Plaintiff could not have known about the dangers and hazards presented by Suboxone film.

235. The warnings given by Defendants were and are not accurate, clear, or complete and/or were and are ambiguous.

236. The warnings, or lack thereof, that were and are given by Defendants failed to properly warn treating physicians, including Plaintiff's treating physicians, of the risk of serious dental erosion and decay, and failed to instruct treating physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk by using Suboxone film.

237. The warnings that were given by Defendants failed and continue to fail to properly warn Plaintiff and Plaintiff's treating physicians of the prevalence of dental injuries.

238. Plaintiff and Plaintiff's treating physicians reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn Plaintiff and Plaintiff's treating physicians of the dangers associated with Suboxone film. Had Plaintiff received adequate warnings regarding the risks of Suboxone film, Plaintiff would not have used Suboxone film. But Defendants failed to communicate adequate warnings and/or instructions for use of Suboxone film.

239. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Suboxone film was a proximate cause of Plaintiff's injuries and damages, which were foreseeable.

240. Plaintiff's injuries and damages are severe and permanent and will continue into the future. As a result, Plaintiff seek actual and punitive damages from Defendants.

241. As a direct and proximate result of Defendants' negligence, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

CLAIM 3: STRICT PRODUCTS LIABILITY—DEFECTIVE DESIGN

242. Plaintiff incorporates all prior allegations.

243. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Suboxone film, and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

244. Defendants, as manufacturers, designers, distributers, marketers, and promoters of pharmaceutical drugs, had a duty to design a product free from a defective condition that was unreasonably dangerous to Plaintiff.

245. Defendants breached this duty by designing Suboxone film in such a way that posed an unreasonable risk of dental injuries and by placing and keeping Suboxone film on the market despite Suboxone film's defective condition.

246. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended, and foreseeable use. Defendants knew or should have known that Suboxone film, which they developed, manufactured, labeled, marketed, sold, and/or promoted, was defectively designed in that it posed a serious risk of severe and permanent dental injuries.

247. Defendants had a continuing duty to use reasonable care to design a product that is not unreasonably dangerous to users and to adequately understand, test, and monitor their product.

248. Defendants breached that duty when they created a product unreasonably dangerous for its intended and foreseeable use.

249. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

250. The Suboxone film supplied to Plaintiff by Defendants was defective in design or formulation because, when it left the hands of the manufacturer or supplier, it was in an unreasonably dangerous and defective condition because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner

reasonably foreseeable to Defendants, posing a risk of serious and potentially irreversible dental damage to Plaintiff and other consumers.

251. The Suboxone film administered to Plaintiff was expected to, and did, reach Plaintiff without substantial change in the condition in which it is sold.

252. The Suboxone film administered to Plaintiff was in a condition not contemplated by Plaintiff in that it was unreasonably dangerous, posing a serious risk of permanent dental erosion and decay.

253. Suboxone film causes serious dental injuries, and/or could interfere with normal dental health, harming Plaintiff and other consumers.

254. Plaintiff, ordinary consumers, and prescribers would not expect Suboxone film to cause dental erosion and decay.

255. The Suboxone film supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it had not been adequately tested, was in an unreasonably dangerous and defective condition, and posed a risk of serious dental injuries to Plaintiff and other consumers.

256. The Suboxone film supplied to Plaintiff by Defendants was defective in design or formulation in that its limited and unproven effectiveness and low efficacy did not outweigh the risks of serious dental injuries posed by the drug. Balancing the limited utility and high risk of the drug's use, the design of the Suboxone film drug makes the product unreasonably dangerous.

257. The design defects render Suboxone film more dangerous than other buprenorphine-containing products and causes an unreasonable increased risk of

injury, including but not limited to dental injuries, particularly for patients who take the product for months or years as a maintenance drug.

258. Defendants knew or should have known through testing, scientific knowledge, advances in the field, published research, their own post-marketing studies, or otherwise, that Suboxone film created a risk of serious dental erosion and decay.

259. Suboxone film is defective and unreasonably dangerous to Plaintiff and other consumers in that, despite early indications and concerns that Suboxone film use could result in dental erosion and decay, Defendants failed to adequately test or study the drug, including but not limited to: pharmacokinetics and pharmacodynamics of the drug, its effects on dental health, the potential effects and risks of long-term use, the potential for inter-patient variability, the potential for a safer effective dosing regimen, and/or the alternative delivery mechanisms that would avoid the risk of dental injury.

260. Defendants knew or should have known that consumers, and Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Suboxone film's defective design.

261. Suboxone film is defective and unreasonably dangerous to Plaintiff and other consumers even if Defendants had exercised all possible care in the preparation and sale of Suboxone film.

262. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of Plaintiff and the general public.

263. As a direct and proximate result of Defendants' conduct, including the lack of adequate testing and research and the defective and dangerous nature of Suboxone film, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

CLAIM 4: PRODUCTS LIABILITY—NEGLIGENT DESIGN DEFECT

264. Plaintiff incorporates all prior allegations.

265. At all relevant times, Defendants had a duty to exercise reasonable care and had the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, testing, and research to assure the safety of Suboxone film when used as intended or in a way that Defendants could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and Plaintiff's treating physicians, obtained accurate information and adequate instructions for the safe use or non-use of Suboxone film.

266. At all relevant times, Defendants failed to exercise reasonable care and meet the duties of an expert and knew, or in the exercise of reasonable care should have known, that Suboxone film was not properly manufactured, designed, compounded, tested, inspected, packaged, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, monitored, or a combination of these acts.

267. Defendants' actions and omissions were negligent and careless, resulting in a breach of the duties set forth above. These acts and omissions include, but are not limited to:

a. Failing to use due care in developing, testing, designing, monitoring, and manufacturing Suboxone film so as to avoid the aforementioned risks to individuals when Suboxone film was being used for treatment;

b. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Suboxone film;

c. Failing to adequately test or study Suboxone film, including but not limited to pharmacokinetics and pharmacodynamics of the drug, its effects on dental health, the potential effects of long-term use, the potential for inter-patient variability, the potential for a safer effective dosing regimen, and/or the alternative delivery mechanisms that would avoid the risk of dental injury;

d. Failing to independently and vigilantly protect against unreasonable health risks posed by Suboxone film;

e. Promoting, advertising, marketing, and selling Suboxone film without advising that there existed safer and more or equally effective alternative drug products, treatment options, and/or delivery mechanisms; and

f. Designing, manufacturing, and placing into the stream of commerce a product that was unreasonably dangerous for its reasonably foreseeable use, which Defendants knew or should have known could cause injury to Plaintiff.

268. Defendants' negligence and Suboxone film's failures arise under circumstances precluding any reasonable inference other than a defect in Suboxone film.

269. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Suboxone film was a proximate cause of Plaintiff's injuries and damages, which were foreseeable.

270. Plaintiff's injuries and damages are severe and permanent and will continue into the future. As a result, Plaintiff seek actual and punitive damages from Defendants.

271. As a direct and proximate result of Defendants' negligence, Plaintiff suffered bodily injury with resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer losses in the future.

CLAIM 5: PUNITIVE DAMAGES

272. Plaintiff incorporates all prior allegations.

273. Defendants' acts and omissions constituted oppression, fraud, malice, and/or recklessness and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendants' officers, directors, and/or managing agents.

274. Defendants' actions amounted to actual malice or reckless indifference to the likelihood of harm associated with their acts and omissions.

275. Defendants misled both the medical community and the public, including Plaintiff and Plaintiff's treating physicians, by making false, misleading, or incomplete representations about the safety and effectiveness of Suboxone film and by failing to provide adequate instructions and training concerning its use.

276. Defendants marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug to healthcare providers empowered to

prescribe and dispense Suboxone film to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data and misled the medical community about the need for and the risk-benefit balance of Suboxone film, which resulted in injury to Plaintiff.

277. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Suboxone film despite available information demonstrating that the drug could interfere with dental health.

278. Defendants were or should have been in possession of evidence demonstrating that Suboxone film use could interfere with dental health, including dental erosion and decay. Nevertheless, Defendants continued to market Suboxone film as a long-term maintenance drug for opioid dependence by providing false and misleading information regarding its safety and effectiveness.

279. Defendants failed to provide warnings that would have dissuaded health care professionals from using Suboxone film, preventing health care professionals, including Plaintiff's treating physicians, and consumers, including Plaintiff, from weighing the true risks against the benefits of using Suboxone film.

280. Defendants knew or should have known that consumers, and Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Suboxone film's negligent failure to warn, negligent design, and/or negligent marketing, and consciously, deliberately, and callously disregarded that knowledge in favor of maximizing sales and profits.

281. Defendants knew or should have known that consumers, and Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of delaying the entry of extended-release injectable buprenorphine (Sublocade) to the market and consciously, deliberately, and callously disregarded that knowledge in favor of maximizing sales and profits.

282. As a direct and proximate result of Defendants' acts and omissions, Plaintiff suffer from dental erosion and decay caused by Plaintiff receiving Suboxone film.

283. As a result of Plaintiff's injuries, Plaintiff endured substantial pain and suffering, have incurred significant expenses for medical care, and will remain economically challenged and emotionally harmed.

284. Plaintiff suffered and will continue to suffer economic loss and emotional harm.

285. Defendants' actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff and the public.

286. Plaintiff's injuries and damages are severe, permanent, and will continue into the future. As a result, Plaintiff seek actual and punitive damages from Defendants.

287. Defendants' conduct was committed with knowing, conscious, deliberate, or reckless disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them and those similarly situated from similar conduct in the future.

288. Consequently, Defendants are liable for punitive damages in an amount to be determined by the jury:

PRAYER FOR RELIEF

Plaintiff respectfully pray for the following relief:

a. Enter judgment in Plaintiff's favor on each claim;

b. Award Plaintiff compensatory damages for each of the following categories of harm:

   i. Medical expenses (both to purchase Suboxone film and resulting from its use);

   ii. Pain and suffering;

   iii. Mental anguish, anxiety, and discomfort;

   iv. Physical impairment; and

   v. Loss of enjoyment of life;

c. Award Plaintiff pre- and post-judgment interest;

d. Award exemplary and punitive damages;

e. Award reasonable and necessary attorneys' fees, costs, and expenses, of suit along with pre-judgment interest on those sums; and

f. Award such other relief to which Plaintiff may be justly entitled.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: November 14, 2024

Respectfully submitted,

/s/ Jessica Wieczorkiewicz

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