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

DAVID SORENSEN, *Plaintiff*, v. **INDIVIOR, INC.,** **INDIVIOR PLC,** **INDIVIOR SOLUTIONS, INC.,** **AQUESTIVE THERAPEUTICS, INC.,** **MONOSOL RX, INC.,** **MONOSOL, LLC,** **RECKITT BENCKISER LLC, AND** **RECKITT BENCKISER HEALTHCARE (UK) LTD.,** *Defendants*.	
COMPLAINT WITH JURY DEMAND	

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 addition, 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®.

3. Defendants manufacture, promote, and sell Suboxone as a prescription drug that treats opioid use disorder. Suboxone reduces 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 designed to be ingested through oral absorption either as a tablet or film. Buprenorphine is acidic. And the inclusion of buprenorphine in a dissolvable form leads to dental erosion and decay.

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

5. Suboxone 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 Sept. 22, 2023).

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 prescribing information to warn of the risks dental problems. *See* Suboxone Prescribing Information (available at https://www.indivior.com/admin/resources/dam/id/1073/Suboxone_PI.pdf) (last accessed Sept. 22, 2023).

9. But the medication guide for Suboxone 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 Sept. 22, 2023).

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

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 David Sorensen is a resident and a citizen of the State of Ohio, Cuyahoga County. Plaintiff suffered damage to Plaintiff's teeth as a direct result of using Defendants' prescription drug Suboxone.

13. Plaintiff became addicted to opioids prescribed by a physician for pain management.

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

15. During the relevant time periods, Plaintiff and Plaintiff's physicians were given no warning and had no knowledge of the serious risk of dental erosion and decay Suboxone posed. Specifically, and as discussed more fully below, there was no warning or indication that Suboxone causes permanent damage to the teeth.

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

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

Defendants

18. Defendant Indivior, Inc. is a corporation organized under the laws of Delaware with its principal place of business at 10710 Midlothian Turnpike, Suite 125, North Chesterfield, Virginia 23235. On information and belief, Indivior, Inc. is a wholly owned subsidiary of Indivior PLC.

19. Defendant Indivior PLC is a British corporation organized under the laws of the United Kingdom, with its principal place of business at 234 Bath Road, Slough, Berkshire, United Kingdom, SL1 4EE. On information and belief, Indivior PLC is formerly known as Reckitt Benckiser Pharmaceuticals, Inc. Indivior, PLC demerged from Reckitt Benckiser 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 Sept. 22, 2023).

20. Defendant Indivior Solutions, Inc. is a corporation organized under the laws of Ohio 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.

21. Defendant Aquestive Therapeutics, Inc. 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 formerly known as MonoSol Rx, Inc. and is the exclusive global manufacturer of Suboxone sublingual film.

22. Defendant MonoSol Rx, Inc. is a corporation organized under the laws of Delaware with its principal place of business at 30 Technology Drive, Warren, New Jersey 07059.

23. Defendant MonoSol LLC is a limited liability company organized under the laws of Delaware with its principal place of business at 707 East 80th Place, Suite 301 Merrillville, Indiana 46410.

24. Defendant Reckitt Benckiser LLC is a limited liability company organized under the laws of New Jersey with its principal place of business at Morris Corporate Center IV 399 Interpace Parkway, P.O. Box 225 Parsippany, New Jersey 07054.

25. Defendant Reckitt Benckiser Healthcare (UK) Ltd. is a corporation organized under the laws of New Jersey with its principal place of business at Morris Corporate Center IV 399 Interpace Parkway, P.O. Box 225 Parsippany, New Jersey 07054.

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

27. Each Defendant derives substantial revenue from interstate and international commerce, including significant revenue derived from products sold in this district.

28. Defendants were responsible for the sales and marketing in the United States of the drug Suboxone.

29. On information and belief, Defendants have transacted and conducted business within this state and have derived substantial revenue from goods and products disseminated and used throughout this state and the United States.

30. 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, throughout the United States and in this state.

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

32. 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

33. 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.

34. Venue is proper in this Court under 28 U.S.C. § 1391(a) because Plaintiff was injured in and resides in this district. Venue is also proper under 28 U.S.C. § 1391(b), because Defendants conduct business in this district and a substantial part of the acts and omissions giving rise to this complaint occurred in this district.

NATURE OF THE CASE

35. Plaintiff brings this case against Defendants for damages associated with Plaintiff's use of Suboxone, 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 use of Suboxone.

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

37. Defendants' fraudulent and illegal conduct with respect to Suboxone caused hundreds, if not thousands, of individuals—including Plaintiff—to develop severe and permanent damage to their teeth.

RELEVANT FACTUAL BACKGROUND

Opioid use disorder and treatment options

38. 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 addicted to opioid painkillers and healthcare providers began to prescribe them at greater rates.[1]

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

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

41. 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 on July 7, 2023.[4]

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[1] United States Department of Health & Human Services, Opioid Facts and Statistics (available at https://www.hhs.gov/opioids/statistics/index.html) (last accessed Sept. 22, 2023).

[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 Sept. 22, 2023).

[4] United States Department of Health & Human Services, Renewal of Determination that a Public Health Emergency Exists (July 7, 2023) (available at https://aspr.hhs.gov/legal/PHE/Pages/Opioid-7July2023.aspx) (last accessed Sept. 22, 2023).

42. 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]

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

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

45. Buprenorphine is a synthetic opioid that treats acute pain, chronic pain, and opioid use disorder. It was developed in the late 1960s.

46. Buprenorphine is an addictive drug.

47. 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 addiction by partially activating those receptors, reducing cravings and withdrawal symptoms.

48. Buprenorphine administration is possible via many means. For chronic pain relief, a transdermal patch is an option. Oral forms include a buccal film and sublingual tablets. Parenteral routes include a subdermal or subcutaneous implant and intravenous or intramuscular injections.

49. Defendants' drug Suboxone is a combination of buprenorphine and naloxone administered through a film that is placed sublingually or buccally.

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[5] United States Department of Health & Human Services, Opioid Facts and Statistics (available at https://www.hhs.gov/opioids/statistics/index.html) (last accessed Sept. 22, 2023).

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

50. Defendant Indivior, then known as Reckitt, developed two buprenorphine products for the treatment of opioid addiction: Subutex—a single-entity buprenorphine product intended for a brief induction stage—and Suboxone—a buprenorphine-naloxone combination for post-induction maintenance treatment.

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

52. The FDA approved Suboxone tablets in 2002 as an orphan drug to manage opioid dependence. 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).

53. The Suboxone tablet's orphan-drug exclusivity expired on October 8, 2009.

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

54. In early 2006, in an effort to avoid generic competition with its Suboxone product, Indivior—then known as Reckitt—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 thus not automatically substitutable by pharmacists due to the difference in dosage form.

55. 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. Defendants also asserted that the film's individual packaging reduced the risk for accidental pediatric exposure to the drug.

56. 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.

57. Defendants filed a patent application (US12/537,571) for sublingual and buccal film compositions on August 7, 2009. The application was granted on July 2, 2013 (US 8,475,832 B2). The 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).

58. 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 prior to expiration of its market exclusivity for the purpose of stymieing generic competition and preserving monopoly profits.

59. 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 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.

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

61. 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. The indictment alleged that Indivior's "Here to Help" web and phone program was

marketed by the company as a resource for addiction patients. But in reality, the program connected patients to doctors the company knew were prescribing Suboxone and other opioids to more patients than 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 Reckitt 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.

62. 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 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

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

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

65. 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."

66. 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."

67. 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.

68. Suboxone has a low pH. According to a letter the authors of the Suzuki article received from Timothy Baxter (then of Reckitt),[6] Suboxone 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).

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

69. These publications confirmed what the adverse-event reporting for Suboxone had already shown: that dental erosion and decay were associated with ingesting this medication.

Adverse events related to Suboxone put Defendants on notice of adverse dental events associated with the use of this drug.

70. 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.

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

72. Defendants also knew that Suboxone was "acidic," stating the specific pH level in their letter to dental researchers in 2013 as noted above.

73. But despite knowing that Suboxone was acidic, the mounting adverse events (listed below), and the ongoing development of the published literature regarding dental damage from Suboxone use, 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)). The following adverse events implicating dental health were reported to FDA regarding Suboxone:[7]

[7] *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 Sept. 22, 2023).

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;

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;

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

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

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

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

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

s. 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;

t. 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;

74. By the end of 2010, Defendants were aware of at least 20 adverse events related to oral health associated with Suboxone 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.

75. As of the end of 2011, Defendants were aware of at least 36 adverse events related to oral health associated with Suboxone 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.

76. As of the end of 2013, Defendants were aware of at least 46 adverse events related to oral health associated with Suboxone 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;

77. Before Reckitt Benckiser became Indivior, it was aware of at least 61 adverse events related to oral health associated with Suboxone use. The adverse-event reports continued following the demerger of Indivior:

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.

78. 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.

79. 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.

80. 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 Juen 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.

81. 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.

82. 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, 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.

83. 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;

84. 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.

85. 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 Sept. 22, 2023) (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 Sept. 22, 2023) (finding an average of 7% of adverse events actually reported internationally).

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

87. 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 Sept. 22, 2023). 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.

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

88. 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.

89. 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.

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

91. Before and during Plaintiff's treatment, the peer-reviewed literature, together with the mounting adverse event reports, required Defendants to implement a CBE warning physicians and consumers of the risk of dental erosion and decay. Defendants failed to use the CBE process 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).

92. 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.

Epidemiology confirms the association between Suboxone use and dental erosion and decay.

93. 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 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 Sept. 22, 2023).

94. 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 Sept. 22, 2023).

Defendants failed to warn patients and prescribers about the risk of adverse dental events associated with Suboxone use.

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

96. 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 should undergo regular dental monitoring for adverse impact.

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

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

99. 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.

100. Defendants should have changed the Suboxone label to include warnings and instructions addressing the risk of injury associated with the drug as soon as they had notice of adverse reports relating to the same.

101. 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, Defendants acted in a gross and flagrant character, evincing reckless disregard of the safety and welfare of persons exposed to its dangerous drug.

102. 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, Defendants showed wantonness, recklessness, or a grossly careless disregard for the public's safety and welfare.

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

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

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

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

106. At all relevant times, Defendants had a duty to revise the Suboxone 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 use.

107. On information and belief, despite understanding Suboxone could cause dentition-related injuries, Defendants knowingly withheld and/or misrepresented information from consumers and physicians concerning the safety and efficacy of Suboxone, including, but not limited to, raw data sets, documents, data analyses,

and/or other information related to the risk of Suboxone users suffering dental erosion and decay as a result of their Suboxone use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious dental injuries as a result of taking Suboxone.

108. 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 as a safe and effective drug for medication-assisted treatment of addiction.

How Defendants' misconduct endangered American consumers

109. On information and belief, had Defendants exercised reasonable care in testing and studying Suboxone, it would have discovered—before seeking FDA approval—that sublingual or buccal administration of buprenorphine and/or naloxone use can cause dental erosion and decay.

110. On information and belief, despite post-approval adverse-event reports and other clinical evidence, Defendants failed to continue to test and study the safety and efficacy of Suboxone.

111. On information and belief, from the date Defendants received FDA approval to market Suboxone in the United States through June 2022, Defendant made, distributed, marketed, and sold Suboxone without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Suboxone 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 with regard to dental erosion and decay.

112. On information and belief, Defendants concealed and/or failed to completely disclose their knowledge that Suboxone 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.

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

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

115. 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 use.

116. 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 use.

117. 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 when potentially serious dental complications developed while using Suboxone.

118. 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 as compared to other similarly efficacious pharmaceutical products, treatment options, and/or delivery mechanisms.

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

120. Despite adverse-event reports from healthcare professionals and consumers, Defendants did not adequately warn of the risk of serious and irreversible dental injury associated with using Suboxone until the label change in June 2022.

Equitable tolling of statutes of limitations

121. 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.

122. 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.

123. 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.

124. 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.

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

126. Due to the absence of any warning by Defendants as to the significant permanent health and safety risks posed by Suboxone, Plaintiff was unaware that

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

127. Due to the absence of any instructions for how to identify and/or monitor Suboxone patients for potential dental complications, Plaintiff was unaware that Suboxone could cause serious and permanent dental injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

128. 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, Defendant is estopped from relying on any statute-of-limitations defenses.

CLAIM 1: STRICT PRODUCTS LIABILITY

129. Plaintiff incorporates all prior allegations.

130. 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 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.

131. 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 were inadequate.

132. 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.

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

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

135. Defendants marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug, Suboxone, to health care providers empowered to prescribe and dispense Suboxone 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, which resulted in injury to Plaintiff.

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

137. Despite the fact that Defendants knew or should have known that Suboxone caused unreasonable and dangerous side effects, it continued to promote and market

Suboxone without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

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

139. The Suboxone 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. Despite this knowledge and information, Defendants failed and neglected—until June 2022—to issue adequate warnings that Suboxone causes serious and potentially irreversible dental injuries and/or instructions concerning the need for dental monitoring and potential discontinuation of use of Suboxone.

140. Defendants' failure to provide adequate warnings or instructions rendered Suboxone 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.

141. Defendants failed to provide timely and adequate warnings to physicians and consumers, including Plaintiff and to Plaintiff's intermediary 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 physicians to the dangerous risks of Suboxone including, among other things, dental erosion and decay;

b. Defendants failed to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of, among other things, potentially irreversible dental erosion and decay; and

c. Defendants continued to promote and sell Suboxone, even after they knew or should have known of the unreasonable risks of dental injuries from the drug.

142. Defendants had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Suboxone, and/or that there existed safer and more or equally effective alternative drug products, treatment options, and/or delivery mechanisms.

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

144. By failing to adequately test and research harms associated with Suboxone, and by failing to provide appropriate warnings and instructions about Suboxone use, patients and the medical community—including Plaintiff and Plaintiff's prescribing doctors—were inadequately informed about the true risk-benefit profile of Suboxone and were not sufficiently aware that serious dental injuries were associated with use of Suboxone. Nor were the medical community, patients, patients' families, or

regulators appropriately informed that serious dental injuries might be a side effect of Suboxone and should or could be reported as an adverse event.

145. The Suboxone 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, they failed to provide adequate warnings to users or consumers of the product and continued to improperly advertise, market, and/or promote Suboxone.

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

147. The foreseeable risk of serious dental injuries caused by Suboxone 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.

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

149. 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, 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

150. Plaintiff incorporates all prior allegations.

151. 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 when used as intended or in a way that Defendant could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Suboxone.

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

153. Defendants had a duty to warn Plaintiff, Plaintiff's physicians, and consumers of Suboxone'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 could cause such injuries.

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

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

b. Disseminating information to Plaintiff and Plaintiff's 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 reflected 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, including, without limitations, the possible adverse side effects and health risks caused by using Suboxone;

f. Failure to adequately warn of the risks that Suboxone 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;

j. Failing to provide instructions on ways to safely use Suboxone to avoid injury;

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

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

m. 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, as it became or could have become known to Defendants;

n. 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; and

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

156. Suboxone was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert patients and prescribing physicians of the dangerous risks associated with Suboxone, 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.

157. Suboxone 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 but failed to provide adequate warning to patients and prescribing physicians of the product, including Plaintiff and Plaintiff's prescribing physician, knowing the product could cause serious injury.

158. Plaintiff was prescribed and used Suboxone for its intended purpose.

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

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

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

162. The warnings that were given by Defendants failed to properly warn Plaintiff and prescribing physicians of the prevalence of dental injuries.

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

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

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

166. 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

167. Plaintiff incorporates all prior allegations.

168. 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, 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.

169. Defendants, as manufacturer, designer, distributer, marketer, and promoter of pharmaceutical drugs, had a duty to design a product free from a defective condition that was unreasonably dangerous to Plaintiff.

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

171. 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, 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.

172. 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.

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

174. 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.

175. The Suboxone 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.

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

177. The Suboxone 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.

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

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

180. The Suboxone 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.

181. The Suboxone 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 drug makes the product unreasonably dangerous.

182. The design defects render Suboxone more dangerous than other drugs and therapies designed to treat opioid use disorder and causes an unreasonable increased risk of injury, including but not limited to dental injuries.

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

184. Suboxone is defective and unreasonably dangerous to Plaintiff and other consumers in that, despite early indications and concerns that Suboxone use could result in dental erosion and decay, Defendant 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.

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

186. Suboxone 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.

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

188. 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, 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

189. Plaintiff incorporates all prior allegations.

190. 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 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 physicians, obtained accurate information and adequate instructions for the safe use or non-use of Suboxone.

191. 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 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.

192. 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 so as to avoid the aforementioned risks to individuals when Suboxone 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;

c. Failing to adequately test or study Suboxone, 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;

e. Promoting, advertising, marketing, and selling Suboxone 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.

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

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

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

196. 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

197. Plaintiff incorporates all prior allegations.

198. 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.

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

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

201. Defendants marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug to healthcare providers empowered to prescribe and dispense Suboxone 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, which resulted in injury to Plaintiff.

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

203. Defendants were or should have been in possession of evidence demonstrating that Suboxone use could interfere with dental health, including dental erosion and decay. Nevertheless, Defendants continued to market Suboxone by providing false and misleading information regarding its safety and effectiveness.

204. Defendants failed to provide warnings that would have dissuaded health care professionals from using Suboxone, thus preventing health care professionals, including Plaintiff's prescribing physician, and consumers, including Plaintiff, from weighing the true risks against the benefits of using Suboxone.

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

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

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

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

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

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

211. 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.

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

PRAYER FOR RELIEF

Plaintiff respectfully prays 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 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: September 25, 2023

/s/ Ashlie Case Sletvold
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