

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MIQUANA RENTERIA,

Plaintiff,

vs.

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

Defendants.

COMPLAINT and

DEMAND FOR JURY TRIAL

Plaintiff Miquana Renteria (Plaintiff), submits her Complaint and Demand for Jury Trial as follows:

1. Plaintiff brings this action against Defendants for their failure to warn Plaintiff about the true risks of their weight loss drug, Ozempic, as well as negligence and deceptive and/or unfair marketing and sales practices.
2. Plaintiff is a citizen and resident of Texas.

3. Defendant Novo Nordisk Inc. (“Novo Nordisk”) is a Delaware corporation that has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536. Novo Nordisk has conducted business and derived substantial revenue from within the Commonwealth of Pennsylvania.

4. Defendant Novo Nordisk Inc. is wholly owned by Defendant Novo Nordisk US Commercial Holdings, Inc.

5. Defendant Novo Nordisk US Commercial Holdings Inc. is a Delaware corporation with its principal place of business at 103 Foulk Road, Wilmington, Delaware 19803.

6. Defendant Novo Nordisk US Commercial Holdings Inc. is wholly owned by Defendant Novo Nordisk US Holdings Inc.

7. Defendant Novo Nordisk US Holdings Inc. is a Delaware corporation with its principal place of business at 103 Foulk Road, Wilmington, Delaware 19803.

8. Defendant Novo Nordisk US Holdings Inc. is wholly owned by Defendant Novo Nordisk A/S.

9. Defendant Novo Nordisk A/S is a public limited liability company organized under the laws of Denmark with its principal place of business in Bagsværd, Denmark.

10. Defendant Novo Nordisk North America Operations A/S is a company organized under the laws of Denmark with its principal place of business in Bagsværd, Denmark.

11. Novo Nordisk Research Center Seattle, Inc. is a Delaware corporation with its principal place of business at 530 Fairview Ave. N., Seattle, Washington.

12. Novo Nordisk Pharmaceutical Industries LP is a Delaware partnership with its principal place of business at 3611-3612 Powhatan Road, Clayton, North Carolina.

13. Novo Holdings A/S is a company organized under the laws of Denmark with its principal place of business in Hellerup, Denmark.

14. Novo Holdings Equity US Inc. is a Delaware corporation with its principal place of business at 200 Clarendon Street Floor 45 Boston, MA 02142 USA.

15. Novo Ventures (US) Inc. is a Massachusetts corporation with its principal place of business at 501 2nd Street Suite 300 San Francisco, CA 94107.

16. Defendant Novo Nordisk A/S and its subsidiaries and affiliates named herein are collectively referenced as “the Novo Nordisk Defendants” and “Novo Nordisk.”

17. The Novo Nordisk Defendants’ website states that “the vast majority of our U.S. injectable diabetes and obesity products are produced and packaged at

the Clayton aseptic fill-finish site.” Upon information and belief, this refers to Novo Nordisk’s manufacturing facility in Clayton, North Carolina, operated by Novo Nordisk Pharmaceutical Industries LP.

18. Upon information and belief, Defendant Novo Nordisk Pharmaceutical Industries LP is the labeler for Ozempic and Wegovy, and Defendants Novo Nordisk A/S and Novo Nordisk Inc. are identified on Ozempic and Wegovy’s label. The Novo Nordisk Defendants also designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic and Wegovy.

19. Upon information and belief, Defendants failed to warn the end users of Ozempic and Wegovy of the complications and devastating effects of which the company knew or should have known.

20. Upon information and belief, Defendants’ marketing was deceptive and misleading about the true risks associated with use of Ozempic and Wegovy of which the company knew or should have known.

21. This Court has subject matter jurisdiction under 28 U.S.C. §1332(a) as the matter in controversy exceeds the value of \$75,000, exclusive of interest and costs and is between citizens of different states and/or a foreign state.

22. This Court has personal jurisdiction over Defendants consistent with the United States Constitution and 42 Pa. Consol. Stat. Ann. §5322

(Pennsylvania’s “long arm” statute), as Plaintiff’s claims arise out of Defendants’ transaction of business, their tortious acts within the Commonwealth of Pennsylvania, their doing a series of similar acts for the purpose of thereby realizing pecuniary benefit, and by virtue of Defendants’ substantial, continuous, and systematic contacts with the Commonwealth of Pennsylvania.

23. Venue is proper under 28 U.S.C. § 1391(b)(2) as a substantial part of the events or omissions giving rise to the claim occurred in this District., Defendants routinely market their products at issue in this District and conduct business in this District related to their products at issue in the state of Pennsylvania.

24. Defendants produce, market and sell the weight loss product Ozempic.

25. In their press release touting the Ozempic product, Defendants represented Ozempic as having “proven safety and efficacy” and they continued to advertise that “it can help many patients lose some weight.” As with its prior press releases, Defendants disclosed Important Safety Information and provided link to the Medication Guide and Prescribing Information. However, severe gastrointestinal events, including gastroparesis and gastroenteritis, were not identified as risks.

26. Since Defendants discovered GLP-1 agonists potential use for weight loss, Defendants began working to change medical consensus as it relates to obesity. Conventionally, evidence-based approaches to obesity focused on lifestyle: eating whole, nutrition foods, exercising, reducing stress, and obtaining adequate sleep. In contrast, Defendants have spent millions of dollars marketing the belief that sustained weight loss is only achievable by using Defendants' medications at a cost of more than \$1000 a month.

27. Throughout their marketing, Defendants fail to disclose the true serious side effects of Ozempic and Wegovy, including but not limited to hospitalization and death.

28. Defendants also fail to disclose in their label and patient brochure for Ozempic and/or Wegovy that in order to maintain any weight loss, the patient must stay on the drug permanently or most patients will regain most of the weight within one year and virtually all the weight will be regained within five years.

29. When the Novo Nordisk Defendants announced that they had started selling Ozempic in the United States, they touted the medication as a "new treatment option[]" that "addresses the concerns and needs of people with diabetes[.]" The Novo Nordisk Defendants offered an "Instant Savings Card to reduce co-pays to as low as \$25 per prescription fill for up to two years."

30. Indeed, some patients will regain even more weight after stopping the drug, so that they end up heavier than before starting Ozempic and/or Wegovy. This is also not disclosed in the label or patient brochure.

31. Novo Nordisk was not permitted to market Ozempic for weight loss without F.D.A. approval for that specific indication, but before Wegovy ever received separate approval for treatment of weight loss, Novo Nordisk had already begun mentioning weight loss in their Ozempic commercials.

32. Over the next five years, the Novo Nordisk Defendants spent \$884,000,000 on running television ads in the United States to promote its semaglutide Ozempic, Wegovy, and another of its lesser known GLP-1 agonists, Rybelsus, with most advertisements allocated towards Ozempic.

33. By 2021, Defendants' aggressive marketing of the weight loss benefits of Ozempic, sophisticated use of social media, and America's socially ingrained desire to be thin had reached a tipping point.

34. Defendants have spent millions of dollars across multiple platforms to deliver their message to physicians, healthcare providers, and consumers that Ozempic was a safe way for consumers to lose weight, all without disclosing the serious risk of gastrointestinal events, including gastroparesis and gastroenteritis.

35. Defendants' sophisticated marketing and advertising has resulted in widespread use of Ozempic and Wegovy by consumers, and substantial sales and profits to Defendants.

36. Defendants knew from their required premarket and post-market research and analytics that Ozempic and Wegovy could cause malnutrition, cyclical vomiting, and gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, esophageal and bowel injury, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, and intraoperative aspiration.

37. The Novo Nordisk Defendants have repeatedly failed to warn about the known dangerous side effects of Ozempic and Wegovy. This includes malnutrition, cyclical vomiting, and gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, esophageal and bowel injury, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, and intraoperative aspiration. All of these conditions can, and have, lead to hospitalization and/or death in patients across America.

38. Some doctors estimate that as many as 10% of patients discontinue use of these drugs due to the severity of side effects.

39. Thousands of adverse event reports have been filed by the public with the FDA Adverse Event Reporting System. As of June 2022, the FDA has posted

an alert that both Ozempic and Wegovy had potential safety signals for intestinal blockage.

40. On September 22, 2023, FDA updated the label for Ozempic to include “ileus,” the medical term for blocked intestines.

41. Wegovy, chemically identical to Ozempic, already carried a warning on ileus.

42. As early as 2014, Defendants knew that Saxenda (liraglutide), Ozempic’s predecessor, caused serious side effects and warned the end user of same.

43. As early as 2019, Defendants knew that Rybelsus (Semaglutide), Ozempic’s predecessor, caused serious side effects and warned the end user of same.

44. These side effects for Rybelsus included: nausea, abdominal pain, diarrhea, decreased appetite, vomiting, constipation, pancreatitis, diabetic retinopathy complication, hypoglycemia; acute kidney injury, and hypersensitivity reactions.

45. According to the FDA Adverse Event Reporting System, Defendants were aware of reports of intestinal obstruction no later than 2019 for Ozempic and/or Wegovy. These reports to the FDA also stated that many of these patients reporting intestinal obstruction or blockage were hospitalized.

46. The Prescribing Information for Ozempic discloses warnings, precautions, and adverse reactions associated with Ozempic, but it does not disclose the risk of severe gastrointestinal events, including gastroparesis and gastroenteritis. Instead, it discloses delayed gastric emptying under the “Drug Interactions” heading and notes that Ozempic “may impact absorption of concomitantly administered oral medications.” Further, under the “Mechanism of Action” section, the Prescribing Information states that “[t]he mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase.” These statements do not disclose gastroparesis or delayed gastric emptying as risks of taking Ozempic, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Ozempic.

47. The Prescribing Information for Wegovy discloses warnings, precautions, and adverse reactions associated with taking Wegovy, but it does not disclose the risk of severe gastrointestinal events, including gastroparesis and gastroenteritis. Instead, it discloses delayed gastric emptying under the “Drug Interactions” heading and notes that Wegovy “may impact absorption of concomitantly administered oral medications.” These statements do not disclose gastroparesis or delayed gastric emptying as risks of taking Wegovy, nor do they disclose gastroparesis as a chronic condition that can result because of taking Wegovy.

48. Despite their experience and knowledge, Defendants have downplayed the severity of the gastrointestinal events caused by Ozempic, never, for example, warning of the risk of gastroparesis (“paralyzed stomach”), gastroenteritis, or intestinal blockage or obstruction.

49. Gastroparesis is a condition that affects normal muscle movement in the stomach. Ordinarily, strong muscular contractions propel food through the digestive tract. However, in a person suffering from gastroparesis, the stomach’s motility is slowed down or does not work at all, preventing the stomach from emptying properly. Gastroparesis can interfere with normal digestion, and can cause nausea, vomiting, abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, vomiting undigested food, undigested food that hardens and remains in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, malnutrition, and a decreased quality of life. There is no cure for gastroparesis.

50. Gastroenteritis refers to inflammation of the stomach and intestines. While viral gastroenteritis is also known as stomach flu, gastroenteritis may also be caused by ingesting medications. Its symptoms include vomiting, nausea, diarrhea, stomach cramps, muscle aches, headaches, and fever. Notably, vomiting and diarrhea can cause dehydration, which is the main complication of gastroenteritis, and which can lead to death.

51. At all relevant time periods, Defendants do not disclose any risks associated with severe gastrointestinal events, including the risk of gastroparesis, gastroenteritis, and intestinal blockage or obstruction within the “Important Safety Information” section of their promotional website.

52. At all relevant time periods, none of Defendants’ additional advertising or promotional materials warned prescription providers or the general public of the risk of severe gastrointestinal events, including gastroparesis, gastroenteritis, or intestinal blockage or obstruction.

53. On June 29, 2023, the American Society of Anesthesiologists issued a warning that patients taking Ozempic should stop the medication at least a week before elective surgery because Ozempic and other GLP-1 agonists “delay gastric (stomach) emptying” and “the delay in stomach emptying could be associated with an increased risk of regurgitation and aspiration of food into the airways and lungs during general anesthesia and deep sedation.”

54. On July 25, 2023, it was reported that patients taking Ozempic had been diagnosed “with severe gastroparesis, or stomach paralysis, which their doctors think may have resulted from or been exacerbated by the medication they were taking, Ozempic.” Additionally, “[t]he US Food and Drug Administration said it has received reports of people on the Ozempic experiencing stomach paralysis[.]”

55. Case reports continue to be published regarding the use of semaglutide and intraoperative aspirations. In June 2021, a comprehensive meta-analysis showed nearly a four-fold increased risk of DVT when taking semaglutide. DVT, or deep vein thrombosis, is associated with pulmonary embolism and other serious complications, including death.

56. At all relevant time periods, the Novo Nordisk Defendants made, distributed, marketed, and/or sold Ozempic and/or Wegovy without adequate warning to Plaintiff's prescribing physician(s) and/or Plaintiff that Ozempic and/or Wegovy was associated with and/or could cause severe gastrointestinal issues including gastroparesis, gastroenteritis, and intestinal blockage or obstruction, ileus, malnutrition, esophageal and bowel injury, DVT, intraoperative aspiration, and death.

57. Defendants knew of the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues including gastroparesis, gastroenteritis, and intestinal blockage or obstruction, ileus, malnutrition, esophageal and bowel injury, DVT, intraoperative aspiration, and death. Defendants' knowledge derived from their clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced above in this Complaint.

58. Upon information and belief, Defendants ignored the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues including gastroparesis, gastroenteritis, and intestinal blockage or obstruction, ileus, malnutrition, esophageal and bowel injury, DVT, intraoperative aspiration, and death.

59. Defendants' failure to disclose information that they possessed regarding the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues including gastroparesis, gastroenteritis, and intestinal blockage or obstruction, ileus, malnutrition, esophageal and bowel injury, DVT, intraoperative aspiration, and death, rendered the warnings for this medication inadequate.

60. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from severe gastrointestinal issues, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

61. Defendants also fail to provide adequate instructions for use and warnings and precautions for Ozempic and Wegovy, including failing to warn that a patient needs to remain permanently on the drug or the weight will be regained

within a one to five year period. Nor do the Defendants provide instructions on how to safely use the drug to mitigate harms, including how to safely monitor the patient for adverse effects and how to safely take the patient off the drug without causing a worsening of those adverse events, such as severe gastrointestinal issues including gastroparesis, gastroenteritis, and intestinal blockage or obstruction, ileus, malnutrition, esophageal and bowel injury, DVT, intraoperative aspiration, and death.

62. Defendants knew from their required premarket and post-market research and analytics that Ozempic and Wegovy could cause malnutrition, cyclical vomiting, and gastroparesis, gastroenteritis, and intestinal obstruction/blockage.

63. The Novo Nordisk Defendants have repeatedly failed to warn about the known dangerous side effects of Ozempic and Wegovy. This includes gastroparesis, gastroenteritis, intestinal blockage or obstruction, and malnutrition. All of these conditions can, and have, lead to hospitalization and/or death in patients across America.

64. Despite their experience and knowledge, Defendants have downplayed the severity of the gastrointestinal events caused by Ozempic, never, for example, warning of the risk of gastroparesis (“paralyzed stomach”), gastroenteritis, or intestinal blockage or obstruction.

65. Gastroparesis is a condition that affects normal muscle movement in the stomach. Ordinarily, strong muscular contractions propel food through the digestive tract. However, in a person suffering from gastroparesis, the stomach's motility is slowed down or does not work at all, preventing the stomach from emptying properly. Gastroparesis can interfere with normal digestion, and can cause nausea, vomiting, abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, vomiting undigested food, undigested food that hardens and remains in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, malnutrition, and a decreased quality of life. There is no cure for gastroparesis.

66. Gastroenteritis refers to inflammation of the stomach and intestines. While viral gastroenteritis is also known as stomach flu, gastroenteritis may also be caused by ingesting medications.¹⁵⁸ Its symptoms include vomiting, nausea, diarrhea, stomach cramps, muscle aches, headaches, and fever.¹⁵⁹ Notably, vomiting and diarrhea can cause dehydration, which is the main complication of gastroenteritis, and which can lead to death.

67. Defendants do not disclose any risks associated with severe gastrointestinal events, including the risk of gastroparesis, gastroenteritis, and intestinal blockage or obstruction within the "Important Safety Information" section of their promotional website.

68. None of Defendants' additional advertising or promotional materials warned prescription providers or the general public of the risk of severe gastrointestinal events, including gastroparesis, gastroenteritis, or intestinal blockage or obstruction.

69. From the date the Novo Nordisk Defendants received FDA approval to market Ozempic until the present time, the Novo Nordisk Defendants made, distributed, marketed, and/or sold Ozempic without adequate warning to Plaintiff's prescribing physician(s) and/or Plaintiff that Ozempic was associated with and/or could cause severe gastrointestinal issues including gastroparesis, gastroenteritis, and intestinal blockage or obstruction. Defendants knew of the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues, including gastroparesis and gastroenteritis. Defendants' knowledge derived from their clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced above in this Complaint.

70. Upon information and belief, Defendants ignored the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues, including gastroparesis and gastroenteritis.

71. Defendants' failure to disclose information that they possessed regarding the association between the use of GLP-1 receptor agonists and the risk

of developing severe gastrointestinal issues, including gastroparesis and gastroenteritis, rendered the warnings for this medication inadequate.

72. Plaintiff, in consultation with her doctor, began taking Ozempic in 2022 for weight loss.

73. In August 2022, she was treated for chest pain.

74. In September 2022, she was again treated for chest pain along with nausea and vomiting.

75. In October 2022, she was treated for chest pain, epigastric pain, nausea and vomiting, and diagnosed with gastritis.

76. In November 2022, Plaintiff was admitted to the hospital with a diagnosis of gastritis, hiatal hernia and uncontrolled vomiting. She further reported being afraid to eat.

77. In April 2023, Plaintiff was diagnosed with cholecystitis, or inflammation of the gallbladder.

78. In May 2023, Plaintiff had her gallbladder removed.

79. At all times material to the above, the Ozempic label failed to adequately warn Plaintiff and/or her medical provider of the true risks of taking Ozempic.

80. At all times material to the above, the Ozempic marketing and advertising failed to adequately warn Plaintiff and her medical providers of the true risks of taking Ozempic.

FIRST CAUSE OF ACTION
Negligence/Failure to Warn

81. Plaintiff incorporates the above allegations as if fully set forth herein.

82. Defendants had a duty to exercise reasonable care in the manufacture, marketing, advertisement, supply, storage, transport, packaging, sale, and distribution of Wegovy and/or Ozempic products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that did not cause users to suffer from unreasonable, dangerous side effects without an adequate warning—when used alone or in foreseeable combination with other drugs.

83. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known of the hazards and dangers associated with Wegovy and/or Ozempic, and specifically that use of these drugs could cause malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, and death.

84. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known that the use of Wegovy and/or Ozempic could cause Plaintiff's injuries, and thus, created a dangerous and unreasonable risk of injury to the users of these products that Defendants did not warn of.

85. Defendants knew, or in the exercise of reasonable care, should have known that users and consumers were unaware of the risks and magnitude of the risks associated with the use of Wegovy and/or Ozempic.

86. Defendants breached their duty of care to Plaintiff and Plaintiff's treating physicians, in the advertising, warning, testing, monitoring, and pharmacovigilance of Ozempic and Wegovy.

87. A reasonable manufacturer, designer, distributor, promoter, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions. As a direct and proximate result of Defendants' negligent testing, monitoring, and pharmacovigilance of Ozempic and Wegovy, Defendants introduced a drug into this Commonwealth that they knew or should have known would cause serious and severe complications in people, including severe gastrointestinal injuries such as severe nausea, diarrhea, abdominal pain and cyclical vomiting., and Plaintiff has been injured catastrophically and sustained severe and permanent pain, suffering, and

impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

88. The aforementioned negligence and wrongs done by Defendants were aggravated by the kind of grossly negligent conduct and disregard for the rights of others, the public, and Plaintiff, for which the law allows the imposition of exemplary or punitive damages, in that Defendants' conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants proceeded with a reckless disregard to the rights, safety, or welfare of others, including Plaintiff.

89. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania law.

90. As a direct and proximate result of one or more of the above-stated negligent acts by Defendants, Plaintiff suffered bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

SECOND CAUSE OF ACTION
Negligence-Design Defect

91. Plaintiff incorporates the above allegations as if fully set forth herein.

92. Defendants are liable to Plaintiff for the injuries and damages sustained due to Defendants' negligent design and/or formulation of Wegovy and/or Ozempic.

93. At all relevant times to this lawsuit, Defendants owed a duty to consumers including Plaintiff and his health care providers, to assess, manage, and communicate the risks, dangers, and adverse effects of Wegovy and/or Ozempic. Defendants' duties included, but were not limited to, carefully and properly designing, testing, studying, and manufacturing Wegovy and/or Ozempic.

94. Defendants negligently and carelessly breached the above-described duties to Plaintiff by, among other acts and omissions, negligently and carelessly:

- (a) Failing to use ordinary care in designing, testing, and manufacturing Wegovy and/or Ozempic;
- (b) Failing to design Wegovy and/or Ozempic as to properly minimize the adverse effects to the gastrointestinal and immune system;
- (c) Failing to counteract in the design the known adverse effects on the gastrointestinal and immune system;
- (d) Designing a product where the benefits were greatly outweighed by the risks of malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, intraoperative aspiration and death;
- (e) Designing a product without taking into consideration the proper dosage that could avoid malnutrition, cyclical vomiting, gastroparesis,

gastroenteritis, intestinal, obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, intraoperative aspiration and death;

(f) Wegovy and/or Ozempic was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

95. At all reasonable times, given their lack of efficacy and increased safety risks, Wegovy and/or Ozempic did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff, or in the alternative, his medical providers.

96. Wegovy and/or Ozempic was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, more dangerous than an ordinary consumer would expect, and more dangerous than other similar drugs.

97. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of Wegovy and/or Ozempic at all times relevant, Defendants designed and brought the product to market and continued to market the drug when there were safer alternatives available, including but not limited to alternate dosing, reduced exposure, among others.

98. As a result of Defendants' negligent and reckless design, Plaintiff sustained severe and ongoing injuries.

99. As a direct and proximate result of one or more of the above-stated negligent acts by Defendants, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

THIRD CAUSE OF ACTION
Negligent Misrepresentation

100. Plaintiff incorporates the above allegations as if fully set forth herein.

101. At all relevant times, Defendants negligently provided Plaintiff, Plaintiff's healthcare providers, the general medical community, and the public with false, fraudulent, and/or incorrect information or omitted or failed to disclose material information concerning Wegovy and/or Ozempic, including, but not limited to, misrepresentations and marketing regarding the safety and known risks of Wegovy and/or Ozempic.

102. At all relevant times, Defendants negligently provided Plaintiff, Plaintiff's healthcare providers, the general medical community, and the public with false, fraudulent, and/or incorrect information or omitted or failed to disclose material information concerning Wegovy and/or Ozempic, including, but not limited to, misrepresentations and marketing regarding the long term effects of Ozempic and/or Wegovy.

103. The information distributed by Defendants to the public, the medical community, Plaintiff and his healthcare providers, including advertising campaigns, labeling materials, print advertisements, commercial media, and marketing was false and misleading and contained omissions and concealment of truth about the dangers of Wegovy and/or Ozempic.

104. Defendants' conduct had the capacity to deceive and/or purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiff's health care providers; to falsely assure them of the quality of Wegovy and/or Ozempic and induce the public and medical community, including Plaintiff and Plaintiff's healthcare providers to request, recommend, purchase, and prescribe Wegovy and/or Ozempic.

105. Defendants had a duty to accurately and truthfully represent and market to the medical and healthcare community, medical pharmaceutical manufacturers, Plaintiff, Plaintiff's healthcare providers and the public, the known risks of Wegovy and/or Ozempic, including its propensity to cause malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, and death.

106. Defendants made continued omissions in the Wegovy and/or Ozempic labeling, including promoting it as safe and effective while failing to warn of its propensity to cause malnutrition, cyclical vomiting, and gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, and death.

107. Defendants made additional misrepresentations beyond the product labeling by representing Wegovy and/or Ozempic as a safe and effective treatment for diabetes and weightloss with only minimal risks.

108. Defendants misrepresented and overstated the benefits of Wegovy and/or Ozempic to Plaintiff, Plaintiff's treaters, and the medical community without properly advising of the known risks to patients.

109. Defendants made the misrepresentations alleged herein with the intent to induce consumers, like Plaintiff, to take their weight-loss products.

110. In reliance upon the false, deceptive and negligent misrepresentations and omissions and marketing made by Defendants, Plaintiff and Plaintiff's healthcare providers were induced to, and did use and prescribe Wegovy and/or Ozempic, and relied upon the affirmative misrepresentations and/or negligent omissions in doing so.

111. As a direct and proximate result of the foregoing negligent

misrepresentations and marketing and conduct with capacity to deceive and/or intention to deceive, Plaintiff suffered serious and ongoing injuries.

112. As a direct and proximate result of the foregoing misrepresentations, marketing, and deceitful intentions, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses.

113. Defendants knew or should have known that Plaintiff, Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true material facts which were intentionally and/or negligently concealed and misrepresented by Defendants.

114. Plaintiff and his healthcare providers would not have used or prescribed Wegovy and/or Ozempic had the true facts not been concealed by Defendants.

115. Defendants had sole access to many of the material facts concerning the defective nature of Wegovy and/or Ozempic and its propensity to cause serious and dangerous side effects.

116. At the time Plaintiff was prescribed and administered Wegovy and/or Ozempic, Plaintiff and Plaintiff's healthcare providers were unaware of Defendants' negligent misrepresentations and omissions.

117. Defendants failed to exercise ordinary care in making representations

concerning Wegovy and/or Ozempic while they were involved in their manufacture, design, sale, testing, quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate commerce, because Defendants negligently misrepresented Wegovy and/or Ozempic's high risk of unreasonable and dangerous adverse side effects.

118. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the misrepresentations and omissions made by Defendants, where the concealed and misrepresented facts were critical to understanding the true and full dangers inherent in the use of the Wegovy and/or Ozempic.

119. Plaintiff and Plaintiff's healthcare providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

FOURTH CAUSE OF ACTION
Consumer Protection Act

120. Plaintiff incorporates the above allegations as if fully set forth herein.

121. Defendants financed, assisted, supported and participated in the promotion and use of Wegovy and/or Ozempic in order to create a demand for the drug.

122. Defendants deliberately and/or negligently misrepresented the safety of Wegovy and/or Ozempic and concealed the risks attendant to use of the drugs. Through their misrepresentations, Defendants' conduct had the tendency or

capacity to deceive, and affected the decisions of consumer and their health care providers to purchase, prescribe and use Wegovy and/or Ozempic, and to exclude the options of not using a drug product for treatment.

123. All Defendants, while engaged in the conduct and practices identified above, committed one or more violations of state laws related to unfair or deceptive acts or practices, including, but not limited to, the following:

- a. Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of Wegovy and/or Ozempic;
- b. Representing that Wegovy and/or Ozempic have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have;
- c. Representing that Defendants' authors, key opinion leaders, consultants, and speakers do not have a sponsorship, approval, status, affiliation or connection that they do have;
- d. Representing that Wegovy and/or Ozempic are of a particular standard, quality or grade;
- e. Engaging in other fraudulent or deceptive conduct which creates likelihood of confusion or of misunderstanding, as alleged in this Complaint.

124. Plaintiff has suffered injuries and damages as a direct and proximate result of Defendants' statements in the advertising and promotional activities to Plaintiff and Plaintiff's medical providers, as described above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for damages as allowed by law:

- A. compensatory damages;
- B. statutory damages;
- C. exemplary/punitive damages sufficient to punish and deter Defendants
and others;
- D. pre- and post-judgment interest;
- E. costs as permitted by law;
- F. such further and other relief as may be just and proper.

Plaintiff demands trial by jury on all issues so triable.

RESPECTFULLY SUBMITTED AND DATED this 26th day of March,
2024.

By: /s/ Scott D. Levensten
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