IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

LARRY GENE COOPER	§	
	§	
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., AND NOVO NORDISK PHARMACEUTICAL INDUSTRIES, LP,	§	**CA NO. _____**
	§	
Defendants.	§	

PLAINTIFF'S ORIGINAL COMPLAINT

COMES NOW, LARRY GENE COOPER Plaintiff herein and hereinafter referred to as "Plaintiff", and complains of 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 SEATTLE, INC., AND NOVO DORDISK, Defendants herein and hereinafter collectively referred to as "Defendants", and shows the Court the following:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides, which Texas.

2. This Court has personal jurisdiction over Defendants, consistent with the United States Constitution and Texas Civil Practice And Remedies Code Sec. 17.041 et sec (Texas' "Long-Arm Jurisdiction" statue) and by virtue of Defendants' doing business in the State of Texas by including but not limited to but not limited to committing a tort in whole or in part in this state.

PARTIES

Plaintiff

3. Plaintiff is a citizen of the United States, a citizen of Texas, and is a resident of Harris County, Texas and intends on residing there as his/her permanent residence.

Defendants

4. Defendant Novo Nordisk Inc. is a Delaware corporation with a principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey.

5. Upon information and belief, Defendant Novo Nordisk Inc. is wholly owned by Defendant Novo Nordisk US Commercial Holdings, Inc.

6. Upon information and belief, Defendant Novo Nordisk US Commercial Holdings Inc. is a Delaware corporation with a principal place of business at 103 Foulk Road, Wilmington, Delaware.

7. Upon information and belief, Defendant Novo Nordisk US Commercial Holdings Inc. is wholly owned by Defendant Novo Nordisk US Holdings Inc. 24. Upon information and belief, Defendant Novo Nordisk US Holdings Inc. is a Delaware corporation with a principal place of business at 103 Foulk Road, Wilmington, Delaware.

8. Upon information and belief, 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 a principal place of business in Bagsværd, Denmark.

10. Defendant Novo Nordisk A/S and its subsidiaries and affiliates named herein are collectively referenced as "the Novo Nordisk Defendants."

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

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

13. The Novo Nordisk Defendants' website states that Novo Nordisk's Seattle research center "serves as the foundation of the company's U.S. research and development efforts for diabetes, obesity, liver disease and other therapeutic areas."6

14. Novo Nordisk Pharmaceutical Industries LP is a Delaware corporation with a principal place of business at 3611 and 3612 Powhatan Road, Clayton, North Carolina.

15. 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."7 Upon information and belief, this refers to Novo Nordisk's manufacturing facility in Clayton, North Carolina, operated by Novo Nordisk Pharmaceutical Industries LP.

16. Defendant Novo Nordisk Pharmaceutical Industries LP is the labeler for Ozempic, and Defendants Novo Nordisk A/S and Novo Nordisk Inc. are identified on Ozempic's label.8 The Novo Nordisk Defendants also designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic.

NATURE OF THE CASE

17. This is an action for damages suffered by Plaintiff who was severely injured as a result of her use of Ozempic an injectable prescription medication used to control blood sugar in adults with type 2 diabetes.

18. Plaintiff began using Ozempic in January 2023 and continued using it for approximately 10 months, stopping its use in or around October 2023.

19. Plaintiff's physician(s) (collectively "prescribing physician(s)") prescribed Ozempic that was used by Plaintiff As a result of using Defendants' Ozempic, Plaintiff was caused to suffer from severe gastrointestinal events and digestive events, and as a result suffered severe and permanent personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

20. As a result of using Defendants' Ozempic, Plaintiff was caused to suffer from severe gastrointestinal events and digestive events, hospitalizations, extreme vomiting and severe abdominal pain.

21. Plaintiff's injuries were caused by Defendants' Ozempic.

22. Ozempic is also known as semaglutide. Ozempic works by stimulating insulin production and reducing glucose production in the liver, helping to lower blood sugar levels.

23. Ozempic belongs to a class of drugs called GLP-1 receptoargonists.

24. Defendants acknowledge that gastrointestinal events are well known side effects of the GLP-1 class. However, Defendants have downplayed the severity of the gastrointestinal events and digestive events caused by Ozempic, never, for example, warning of the risk of gastroparesis ("paralyzed stomach") or gastroenteritis, and never warning of the risk of gall bladder removal surgery and associated complications.

25. 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 preventing the stomach from emptying properly. Gastroparesis can interfere with normal digestion, 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.[1]

26. Gastroenteritis refers to inflammation of the stomach and intestines. While viral gastroenteritis[2] 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.[3] Notably, vomiting and diarrhea can cause dehydration, which is the main complication of gastroenteritis, and which can lead to death.[4]

27. A cholecystectomy is a surgery to remove the gallbladder. The gallbladder is a pear-shaped organ that sits just below the liver on the upper right side of the abdomen. The gallbladder collects and stores a digestive fluid made in the liver called bile.[5]

28. Long term side effects of gall bladder removal include food intolerance, nausea, vomiting, heartburn, flatulence, indigestion, diarrhea, jaundice, and severe abdominal pain. These symptoms can present early, typically in the post-operative period, but can also manifest months to years after surgery.

[1] https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787 (last visited on 8/1/23).
[2] https://www.merckmanuals.com/home/digestive-disorders/gastroenteritis/drug-related-gastroenteritis- andchemical- related-gastroenteritis
[3] https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847 (last visited on 8/1/23).
[4] https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847 (last visited on 8/1/23).
[5] https://www.mayoclinic.org/tests-procedures/cholecystectomy/about/pac-20384818 (last visited 8/1/2023).

FACTUAL BACKGROUND

A. FDA's Approval of Ozempic

29. On December 5, 2016, the Novo Nordisk Defendants announced submission of a new drug application (NDA) to the FDA for regulatory approval of once-weekly injectable semaglutide, a new glucagon-like peptide-1 (GLP-1) medication for treatment of type 2 diabetes. In the announcement, Defendants represented that in clinical trials "once-weekly semaglutide had a safe and well tolerated profile with the most common adverse event being nausea."[6]

30. On December 5, 2016, Defendant Novo Nordisk Inc. submitted NDA 209637, requesting that the FDA grant it approval to market and sell Ozempic (semaglutide) 0.5 mg or 1 mg injection in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On December 5, 2017, the FDA approved NDA 209637.[7]

31. On March 20, 2019, Defendant Novo Nordisk Inc. submitted supplemental new drug application (sNDA) 209637/S-003 for Ozempic (semaglutide) 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.[8] On January 16, 2020, the FDA approved sNDA 209637/S-003.[9]

32. On May 28, 2021, Defendant Novo Nordisk Inc. submitted sNDA 209637/S-009, requesting approval for a higher 2 mg dose of Ozempic (semaglutide) injection. On March 28, 2022, the FDA approved sNDA 209637/S-009.13[10]

[6] https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183 (last visited on 8/1/23).
[7] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf (last visited on 8/1/23).
[8] https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-bloodsugar-control-and cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html (last visited on 8/1/23).
[9] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf (last visited on 8/1/23).
[10] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209637Orig1s009ltr.pdf (last visited on 8/1/23).

33. On March 28, 2022, the Novo Nordisk Defendants announced the FDA's approval of sNDA 209637/S-009 for a higher 2 mg dose of Ozempic (semaglutide) injection. In the press release, Defendants represented Ozempic as having "proven safety and efficacy" and advertised that "plus it can help many patients lose some weight."[11] As with its prior press releases, Defendants disclosed Important Safety Information and a provided link to the Medication Guide and Prescribing Information, but severe gastrointestinal events including but not limited to but not limited to gastroparesis and gastroenteritis were not identified as risks.

B. Defendants' Marketing and Promotion of Ozempic

33. On December 5, 2017, the Novo Nordisk Defendants announced the FDA's approval of Ozempic (semaglutide) 0.5 mg or 1 mg injection in a press release stating that: "Novo Nordisk expects to launch OZEMPIC® in the U.S. in Q1 2018, with a goal of ensuring broad insurance coverage and patient access to the product. OZEMPIC® will be priced at parity to current market-leading weekly GLP-1 receptor agonists and will be offered with a savings card program to reduce co-pays for eligible commercially-insured patients. Additionally, as part of the access strategy, Novo Nordisk is working with appropriate health insurance providers to establish innovative contracting solutions."[12]

34. On February 5, 2018, the Novo Nordisk Defendants announced that they had started selling Ozempic in the United States and 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."[13]

[11] https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-higher-dose-ozempic-2-mgproviding-increased-glycemic-control-for-adults-with-type-2-diabetes-301512209.html (last visited on 8/1/23).
[12] https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-ozempic-semaglutideinjection-for-the-treatment-of-adults-with-type-2-diabetes-300567052 html (last visited on 8/1/23).
[13] https://www.prnewswire.com/news-releases/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatmentoptions-for-adults-with-diabetes-

35. The Novo Nordisk Defendants promoted the safety, efficacy and sale of Ozempic in the United States on its websites, in press releases, through in-person presentations, through the drug's label, in print materials, on social media, and through other public outlets.

36. On July 30, 2018, the Novo Nordisk Defendants launched their first television ad for Ozempic to the tune of the 1970s hit pop song "Magic" by Pilot wherein the Novo Nordisk Defendants advertised that "adults lost on average up to 12 pounds" when taking Ozempic, even though it is not a weight loss drug.[14]

37. On March 28, 2022, Novo Nordisk announced the FDA's approval of sNDA 209637/S-009 for a higher 2 mg dose of Ozempic (semaglutide) injection. In the press release, Novo Nordisk represented Ozempic as having "proven safety" and advertised that "plus it can help many patients lose some weight."[15]

38. 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 drugs (Ozempic, Wegovy) with the majority of the spending allocated specifically to advertising Ozempic.[16]

39. In 2022, Novo Nordisk spent $180.2 million on Ozempic ads, including but not limited to an estimated $157 million on national television ads for Ozempic, making Ozempic the sixth most advertised drug that year. As a result of its GLP-1RA treatments, including but not limited to Ozempic, Novo Nordisk forecasts sales growth of 13% to 19% for 2023.[17]

300592808.html (last visited on 8/1/23).
[14] https://www.ispot.tv/ad/d6Xz/ozempic-oh (last visited on 8/1/23).
[15] *Novo Nordisk receives FDA approval of higher-dose Ozempic® 2 mg providing increased glycemic control for adults with type 2 diabetes*, Cision PR Newswire (March 28, 2022), available at https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-higher-dose-ozempic-2-mgproviding-increased-glycemic-control-for-adults-with-type-2-diabetes-301512209.html (visited on 10/16/23).
[16] https://medwatch.com/News/Pharma __Biotech/article15680727.ece (last visited on 8/1/23).
[17] Adams B, Fierce Pharma, *The top 10 pharma drug ad spenders for 2022*, https://www.fiercepharma.com/specialreports/top-10-pharma-drug-brand-ad-spenders-2022 (visited on 9/26/23).

40. On July 6, 2023, it was reported that the Novo Nordisk Defendants had spent $11,000,000 on food and travel for doctors as part of the Novo Nordisk Defendants' efforts to promote Ozempic.[18]

41. As a result of the Novo Nordisk Defendants' advertising and promotion efforts, Ozempic has been widely used throughout the United States. The number of prescriptions filled reached an all-time high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.[19] In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.[20]

42. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,[21] and currently has over 1.2 billion views.[22]

43. On June 15, 2023, a news report was published about the "thousands of weight-loss ads on social media for the drugs Ozempic and Wegovy." And while many of those ads were found to be from online pharmacies, as of June 2023 the Novo Nordisk Defendants were still running online social-media ads for its semaglutide products despite claiming in May that it would stop running adds due to a shortage of the drug. [23]

44. On July 10, 2023, a global media company declared Ozempic as "2023's buzziest drug" and one of the "Hottest Brands, disrupting U.S. culture and industry."[24]

45. At all times pertinent hereto the Novo Nordisk Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Ozempic.

[18] https://finance.yahoo.com/video/novo-nordisk-spent-11-million-155418308.html (last visited on 8/1/23).
[19] https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/ (last visited on 8/1/23).
[20] https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance/ (last visited on 8/1/23).
[21] https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss html (last visited on 8/1/23).
[22] https://www.tiktok.com/tag/ozempic (last visited on 8/1/23).
[23] https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602 (last visited on 8/1/23).
[24] https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing- 2023/2500571 (last visited on 8/1/23).

C. The Medical Literature and Clinical Trials Gave Defendants Notice of Gastroparesis Being Causally Associated with GLP-1Ras

46. As previously noted, Ozempic (semaglutide) belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

47. Medications within the GLP-1RA class of drugs mimic the activities of physiologic GLP-1, which is a gut hormone that activates the GLP-1 receptor in the pancreas to stimulate the release of insulin and suppress glucagon.[25]

48. Because the risk of gastroparesis is common to the entire class of drugs, any published literature regarding the association between gastroparesis and *any* GLP-1RA (such as tirzepatide, exenatide, liraglutide, albiglutide, dulaglutide, lixisenatide, and semaglutide) should have put Defendants on notice of the need to warn patients and prescribing physicians of the risk of gastroparesis associated with these drugs.

49. In addition to pancreatic effects, the published medical literature shows that GLP-1 slows gastric emptying. As early as 2010, a study published in The Journal of Clinical Endocrinology & Metabolism indicated this effect.[26]

50. Defendants knew or should have known of this risk of gastroparesis from the clinical trials, medical literature, and case reports.

51. A 2016 trial funded by Novo Nordisk measuring semaglutide and cardiovascular outcomes in patients with type 2 diabetes found more gastrointestinal disorders in the semaglutide group than in the placebo group, including but not limited to a severe adverse event report of impaired gastric emptying with semaglutide 0.5 mg together with other serious

[25] Hinnen D, *Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes*, 30(3) Diabetes Spectr., 202–210 (August 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556578/ (visited on 9/26/23).

[26] Deane AM et al., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia*, 95(1) J Clinical Endo Metabolism, 225-221 (January 1, 2010), available at https://academic.oup.com/jcem/article/95/1/215/2835243 (visited on 9/26/23); American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-takingpopular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery (visited on 9/26/23).

gastrointestinal adverse events such as abdominal pain (upper and lower), intestinal obstruction, change of bowel habits, vomiting, and diarrhea.[27]

52. Two subjects in a semaglutide trial pool by Novo Nordisk reported moderate adverse events of impaired gastric emptying and both subjects permanently discontinued treatment due to the adverse events. Three subjects also reported mild adverse events of impaired gastric emptying in the semaglutide run-in period of trial 4376. The cardiovascular outcomes trials included two cases of gastroparesis with the first subject being diagnosed with severe gastroparesis after one month in the trial and second subject being diagnosed with gastroparesis after approximately two (2) months in the trial.

53. A study published in 2017 evaluated the effect of GLP-1RAs on gastrointestinal tract motility and residue rates and explained that "GLP-1 suppresses gastric emptying by inhibiting peristalsis of the stomach while increasing tonic contraction of the pyloric region." The study authors concluded that the GLP-1RA drug liraglutide "exhibited gastric-emptying delaying effects" and "the drug also inhibited duodenal and small bowel movements at the same time."[28]

54. Another study in 2017 reviewed the survey results from 10,987 patients and 851 physicians and found that "GI-related issues were the top two patient-reported reasons for GLP-1RA discontinuation in the past 6 months, with 'Made me feel sick' as the most frequently reported reason (64.4%), followed by 'Made me throw up' (45.4%)."[29] As explained above, these are symptoms of gastroparesis.

[27] Marso, SP, et al., Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes, N. Eng. J. Med. 375:1834-1844 (November 2016), available at https://www.nejm.org/doi/10.1056/NEJMoa1607141 (visited on 10/19/23).
[28] Nakatani Y et al., *Effect of GLP-1 receptor agonist on gastrointestinal tract motility and residue rates as evaluated by capsule endoscopy*, 43(5) Diabetes & Metabolism, 430-37 (October 2017), available at https://www.sciencedirect.com/science/article/pii/S1262363617301076 (visited on 9/26/23).
[29] Sikirica M et al., *Reasons for discontinuation of GLP1 receptor agonists: data from a real-world cross-sectional survey of physicians and their patients with type 2 diabetes*, 10 Diabetes Metab. Syndr. Obes., 403-412 (September 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5630073/

55. A 2019 study of the GLP-1RA drug dulaglutide identified adverse events for impaired gastric emptying and diabetic gastroparesis.

56. In August of 2020, medical literature advised that some "patients do not know they have diabetic gastroparesis until they are put on a glucagon-like peptide 1 (GLP-1) receptor agonist such as ... semaglutide ... to manage their blood glucose." The article went on to explain that "[t]his class of drugs can exacerbate the symptoms of diabetic gastroparesis. ... Thus, GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis."[30]

57. In a September 2020 article funded and reviewed by Novo Nordisk, scientists affiliated with Novo Nordisk reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes. More patients permanently discontinued taking oral semaglutide (11.6%) than placebo (6.5%) due to adverse events. The most common adverse events associated with semaglutide were nausea (2.9% with semaglutide versus 0.5% with placebo), vomiting (1.5% with semaglutide versus 0.3% with placebo), and diarrhea (1.4% with semaglutide versus 0.4% with placebo). Injectable semaglutide had a discontinuation rate of 11.5-14.5% (versus 5.7-7.6% with placebo) over a two-year period. The authors acknowledged the potential for severe gastrointestinal events, warning that "[f]or patients reporting severe adverse gastrointestinal reactions, it is advised to monitor renal function when initiating or escalating doses of oral semaglutide." For patients with other comorbidities, the study warned that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs." The study further identified as one "key clinical take-home point" that "patients

[30] Young CF, Moussa M, Shubrook JH, *Diabetic Gastroparesis: A Review*, Diabetes Spectr. (2020), Aug; 33(3): 290–297, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/ (visited on 9/26/23).

should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs."[31]

58. A July 2021 article funded and reviewed by Novo Nordisk considered 23 randomized control trials conducted across the United States, Japan, and China and concluded that "gastrointestinal disturbances" were "well-known" side effects associated with semaglutide use. When compared with placebos, the subcutaneous (injection) form of the drug induced nausea in up to 20% of patients (versus up to 8% on the placebo group), vomiting in up to 11.5% of patients (versus up to 3% in the placebo group) and diarrhea in up to 11.3% of patients (versus up to 6% in the placebo group). Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for gastrointestinal related adverse events, with some trials experiencing 100% discontinuation due to gastrointestinal related adverse events. The mean value of gastrointestinal related adverse events that led to discontinuation averaged 57.75%. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"[32]

59. An October 2021 article in the Journal of Investigative Medicine ("JIM") concluded that because gastroparesis can be associated with several medications, "[i]t is crucial to identify the causative drugs as discontinuation of the drug can result in resolution of the symptoms[.]" In diabetics, making this determination can be particularly "tricky" because both diabetes and GLP-1RAs can cause delayed gastric emptying. As such, "the timeline of drug initiation and symptom onset becomes of the upmost importance." The authors reviewed two case reports (discussed below) and concluded that history taking and making an accurate diagnosis of diabetic

[31] Mosenzon O, Miller EM, & Warren ML, *Oral semaglutide in patients with type 2 diabetes and cardiovascular disease, renal impairment, or other comorbidities, and in older patients*, Postgraduate Medicine (2020), 132:sup2, 37-47, available at https://doi.org/10.1080/00325481.2020.1800286 (visited on 9/26/23).
[32] Smits MM & Van Raalte DH (2021), *Safety of Semaglutide*, Front. Endocrinol., 07 July 2021, doi: 10.3389/fendo.2021.645563, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8294388/ (visited on 9/26/23).

gastroparesis versus medication-induced gastroparesis is critical.[33]

60. Case Report #1 in JIM involved a 52-year-old female with long-standing (10 years) well-controlled, type 2 diabetes who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis symptoms. The patient was referred with a 7-month history of post-prandial epigastric pain, accompanied by fullness, bloating, and nausea. A gastric emptying study showed a 24% retention of isotope in the patient's stomach at four hours, indicative of delayed gastric emptying. The patient discontinued semaglutide and her symptoms resolved after six weeks. The case report authors concluded that "thorough history taking revealed the cause [of gastroparesis] to be medication induced."[34]

61. Case Report #2 in JIM involved a 57-year-old female with a long-standing (16 years) type 2 diabetes who had been taking weekly dulaglutide injections (another GLP-1RA) for 15 months and suffering from abdominal bloating, nausea, and vomiting for 12 of those months. A gastric emptying study showed 35% retention of isotope in the patient's stomach at four hours, indicating delayed gastric emptying. After discontinuing dulaglutide, the patient experienced a gradual resolution of symptoms over a four-week period.[35]

62. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[36]

63. An October 2022 study analyzed 5,442 GLP-1RA adverse gastrointestinal events. 32% were serious, including but not limited to 40 deaths, 53 life-threatening conditions, and 772 hospitalizations. The primary events were nausea and vomiting. There were also adverse events

[33] Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (visited on 9/26/23).
[34] Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (visited on 9/26/23).
[35] Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (visited on 9/26/23).
[36] Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).

for impaired gastric emptying.[37]

64. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[38]

65. In February 2023, a longitudinal study of GLP-1RA (dulaglutide) reported adverse events for nausea and vomiting, and one adverse event of impaired gastric emptying.[39]

66. On March 28, 2023, a case study concluded that impaired gastric emptying is "a significant safety concern, especially since it is consistent with the known mechanism of action of the drug."[40]

67. On June 29, 2023, the American Society of Anesthesiologists ("ASA") warned that patients taking semaglutide and other GLP-1RAs should stop the medication at least a week before elective surgery because these medications "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." The ASA also warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[41]

[37] Shu, *Gastrointestinal adverse events associated with semaglutide: A pharmacovigilance study based on FDA adverse event reporting system*, Front. Public Health (Oct. 20, 2022). (https://doi.org/10.3389%2Ffpubh.2022.996179).
[38] Mirsha, *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).
[39] Chin, *Safety and effectiveness of dulaglutide 0.75 mg in Japanese patients with type 2 diabetes in real-world clinical practice: 36 month postmarketing observational study*, J Diabetes Investig (Feb. 2023) (https://doi.org/10.1111%2Fjdi.13932).
[40] Klein, Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report, Can J. Anesth (Mar. 28, 2023) (https://doi.org/10.1007/s12630-023-02440-3).
[41] American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at https://www.asahq.org/aboutasa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stopbefore-elective-surgery (visited on 9/26/23).

68. News sources have identified the potential for serious side effects in users of Ozempic, including but not limited to gastroparesis, leading to hospitalization.[42] For example, NBC News reported in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable, and one user said that five weeks into taking the medication she found herself unable to move off the bathroom floor because she had "vomited so much that [she] didn't have the energy to get up."[43] CNN reported in July that one Ozempic user diagnosed with gastroparesis vomits so frequently that she had to take a leave of absence from her teaching job.[44]

69. A July 25, 2023, article in Rolling Stone magazine—"*Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell'*"—highlighted three patients who have suffered severe gastrointestinal related events, including but not limited to gastroparesis, as a result of their use of GLP-1RAs. Patient 1 (female, age 37) reported incidents of vomiting multiple times per day and being unable to eat. The patient's physician diagnosed her with severe gastroparesis and concluded that her problems were caused and/or exacerbated by her use of a GLP-1RA medication. Patient 2 (female) used Ozempic for one year and reported incidents of vomiting, including but not limited to multiple times per day. The patient's physician diagnosed her with severe gastroparesis related to her Ozempic use. Patient 3 (female, age 42) experienced severe nausea both during and after she discontinued use of a GLP-1RA. In a statement to

[42] Penny Min, *Ozempic May Cause Potential Hospitalizations*, healthnews (June 26, 2023), available at https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/ (visited on 9/26/23); Elizabeth Laura Nelson, *These Are the 5 Most Common Ozempic Side Effects, According to Doctors*, Best Life (April 3, 2023), available at https://bestlifeonline.com/ozempic-side-effects-news/ (visited on 9/26/23); Cara Shultz, *Ozempic and Wegovy May Cause Stomach Paralysis in Some Patients*, People (July 26, 2023), available at https://people.com/ozempic-wegovy-weight-loss-stomach-paralysis-7565833 (visited on 9/26/23); CBS News Philadelphia, *Popular weight loss drugs Ozempic and Wegovy may cause stomach paralysis, doctors warn* (July 23, 2023), available at https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomachparalysis/(visited on 9/26/23).

[43] Bendix A, Lovelace B Jr., *What it's like to take the blockbuster drugs Ozempic and Wegovy, from severe side effects to losing 50 pounds*, NBC News (Jan. 29, 2023), available at https://www.nbcnews.com/health/health-news/ozempicwegovy-diabetes-weight-loss-side-effects-rcna66493 (visited on 9/26/23).

[44] Brenda Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugsgastroparesis/index.html (visited on 9/26/23).

Rolling Stone, Novo Nordisk acknowledged that "[t]he most common adverse reactions, as with all GLP-1 RAs, are gastrointestinal related." Novo Nordisk further stated that while "GLP-1 RAs are known to cause a delay in gastric emptying, … [s]ymptoms of delayed gastric emptying, nausea and vomiting are listed as side effects." Novo Nordisk did not claim to have warned consumers about gastroparesis, or other severe gastrointestinal issues.[45]

70. On July 25, 2023, CNN Health reported that patients taking Ozempic have 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." Another patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.[46]

71. On July 26, 2023, a New York hospital published an article to its online health blog section "What You Need to Know About Gastroparesis" entitled "Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines." It was reported that a growing number of gastroparesis cases had been seen in people taking GLP-1RAs. The article noted that the weight loss drugs can delay or decrease the contraction of muscles that mix and propel contents in the gastrointestinal tract leading to delayed gastric emptying. One concern raised was that patients and doctors often assume the symptoms of gastroparesis are reflux or other gastrointestinal conditions, meaning it may take a long time for someone to be diagnosed correctly.[47]

[45] CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-lossside-effects-1234794601 (visited on 9/26/23).
[46] Brenca Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN Health (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugsgastroparesis (last visited on 9/26/23).
[47] *Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines*, Montefiore Health Blog article (released July 26, 2023), available at https://www.montefiorenyack.org/health-blog/what-you-need-know-aboutgastroparesis (last visited on 9/26/2023).

72. In an October 5, 2023, Research Letter published in the Journal of the American Medical Association ("JAMA"), the authors examined gastrointestinal adverse events associated with GLP-1RAs used for weight loss in clinical setting and reported that use of GLP-1Ras compared with use of bupropion-naltrexone was associated with increased risk of pancreatitis, gastroparesis, and bowel obstruction.[48] The study found that patients prescribed GLP-1Ras were at 4.22 times higher risk of intestinal obstruction and at 3.67 times higher risk of gastroparesis.

73. The medical literature listed above is not a comprehensive list, and several other case reports have indicated that GLP-1RAs can cause gastroparesis and impaired gastric emptying.[49]

74. Defendants knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae, but they ignored the causal association. Defendants' actual and constructive knowledge derived from their clinical studies, case reports, medical literature, including but not limited to the medical literature and case reports referenced above in this Complaint.

75. On information and belief, Defendants not only knew or should have known that their GLP-1RAs cause delayed gastric emptying, resulting in risks of gastroparesis, but they may have sought out the delayed gastric emptying effect due to its association with weight loss. For example, a recent study published in 2023 notes that "it has been previously proposed that long-acting GLP-1RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying,]" and the study authors suggested "further exploration of

[48] Mohit Sodhi, et al., *Risk of Gastrointestinal Adverse Events Associated with Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss*, JAMA (published online October 5, 2023), available at https://jamanetwork.com/journals/jama/fullarticle/2810542 (last visited 10/19/23).

[49] Cure, *Exenatide and Rare Adverse Events*, N. Eng. J. Med. (May 1, 2008) (https://doi.org/10.1056/nejmc0707137); Rai, *Liraglutide-induced Acute Gastroparesis*, Cureus (Dec. 28, 2018) (https://doi.org/10.7759%2Fcureus.3791); Guo, *A Post Hoc Pooled Analysis of Two Randomized Trials*, Diabetes Ther (2020) (https://doi.org/10.1007%2Fs13300-020-00869-z); Almustanyir, *Gastroparesis With the Initiation of Liraglutide: A Case Report*, Cureus (Nov. 28, 2020) (https://doi.org/10.7759/cureus.11735); Ishihara, *Suspected Gastroparesis With Concurrent Gastroesophageal Reflux Disease Induced by Low-Dose Liraglutide*, Cureus (Jul. 16, 2022) (https://doi.org/10.7759/cureus.26916); Preda, *Gastroparesis with bezoar formation in patients treated with glucagon-like peptide-1 receptor agonists: potential relevance for bariatric and other gastric surgery*, BJS Open (Feb. 2023) (https://doi.org/10.1093%2Fbjsopen%2Fzrac169).

peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake."[50]

D. Defendants Failed to Warn of the Risk of Severe Gastrointestinal Events and Digestive Events From Ozempic

76. Gastroparesis is a disorder that slows or stops the movement of food from the stomach to the small intestine, even though there is no blockage in the stomach or intestines. Gastroparesis may also be called delayed gastric emptying.[51]

77. Gastroenteritis refers to inflammation of the stomach and intestines. Its symptoms include (but are not limited to) vomiting and diarrhea, which can cause dehydration.[52] Gastroenteritis may be caused by ingesting medications.[53]

78. A cholecystectomy is a surgery to remove the gallbladder. The gallbladder is a pearshaped organ that sits just below the liver on the upper right side of the abdomen. The gallbladder collects and stores a digestive fluid made in the liver called bile.[54]

79. Long term side effects of gallbladder removal include food intolerance, nausea, vomiting, heartburn, flatulence, indigestion, diarrhea, jaundice, and severe abdominal pain. These symptoms can present early, typically in the post-operative period, but can also manifest months to years after surgery.

80. The Novo Nordisk Defendants' main promotional website for Ozempic (ozempic.com) includes a variety of information about the benefits of Ozempic relating to blood sugar, cardiovascular health and weight loss, as well as "Important Safety Information" – however, Defendants do not disclose any risks associated with severe gastrointestinal events, including

[50] Jensterle M et al., *Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity*, 25(4) Diabetes Obes. Metab. 975-984 (April 2023), available at https://dompubs. onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944 (visited on 9/26/23).
[51] https://www.niddk nih.gov/health-information/digestive-diseases/gastroparesis (last visited on 8/1/23).
[52] https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847 (last visited on 8/1/23).
[53] https://www.merckmanuals.com/home/digestive-disorders/gastroenteritis/drug-related-gastroenteritis-and- chemicalrelated-gastroenteritis (last visited on 8/1/23).
[54] https://www.mayoclinic.org/tests-procedures/cholecystectomy/about/pac-20384818 (last visited 8/1/2023).

but not limited to but not limited to gastroparesis and gastroenteritis and gall bladder removal, within the "Important Safety Information" section of their promotional website.

81. Similarly, the Prescribing Information discloses warnings, precautions, and adverse reactions associated with Ozempic, but it does not disclose the risk of severe gastrointestinal events and digestive events, including but not limited to but not limited to gastroparesis and gastroenteritis and gall bladder removal. Instead, it discloses delayed gastric emptying under the "Drug Interaction" 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."[55] 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.

82. None of Defendants' additional advertising or promotional materials warned prescription providers or the general public of the risk of severe gastrointestinal events and digestive events, including but not limited to gastroparesis and gastroenteritis and gall bladder removal.

83. 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 but not limited to gastroparesis and gastroenteritis.

84. Upon information and belief, Defendants knew of the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues and digestive

[55] https://www.novo-pi.com/ozempic.pdf (last visited on 8/1/23).

issues, including but not limited to gastroparesis and gastroenteritis and gall bladder removal. Defendants' knowledge derived from their clinical studies, case reports, and the medical literature, including but not limited to the medical literature and case reports referenced above in this Complaint.

85. 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 and digestive issues including but not limited to gastroparesis and gastroenteritis and gall bladder removal.

86. Upon information and belief, Defendants knew of the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues and digestive issues. Defendants' knowledge derived from their clinical studies, case reports, and the medical literature, including but not limited to the medical literature and case reports referenced above in this Complaint.

87. 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 but not limited to gastroparesis and gastroenteritis and gall bladder removal.

88. 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 but not limited to gastroparesis and gastroenteritis and gall bladder removal, rendered the warnings for this medication inadequate.

89. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from severe gastrointestinal issues and digestive issues, as well as other severe and personal

injuries which are permanent and lasting in nature, physical pain, and mental anguish, including but not limited to 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.

NEGLIGENCE AND GROSS NEGLIGENCE

90. Plaintiff incorporates the foregoing herein as if fully set forth herein at length, and further alleges the following:

91. Defendants were negligent in the preparation, design, research, development, manufacturing, inspection, labeling, marketing, promotion, and selling of Ozempic, in that Defendants:

a. Failed to use due care in the preparation of Ozempic to prevent the aforementioned risks to individuals when the drugs were ingested;

b. Failed to use due care in the design of Ozempic to prevent the aforementioned risks to individuals when the drugs were ingested;

c. Failed to conduct adequate pre-clinical testing and research to determine the safety of Ozempic;

d. Failed to conduct adequate post-marketing surveillance to determine the safety of Ozempic;

e. Failed to accompany Ozempic with proper warnings regarding all possible adverse side effects associated with the use of such products and the comparative severity and duration of such adverse effects;

f. Failed to use due care in the development of Ozempic to prevent the aforementioned risks to individuals when the drugs were ingested;

g. Failed to use due care in the manufacture of Ozempic to prevent the aforementioned risks to individuals when the drugs were ingested;

h. Failed to use due care in the inspection of Ozempic to prevent the aforementioned risks to individuals when the drugs were ingested;

i. Failed to use due care in the labeling of Ozempic to prevent the aforementioned risks to individuals when the drugs were ingested;

j. Failed to use due care in the marketing of Ozempic to prevent the aforementioned risks to individuals when the drugs were ingested;

k. Failed to use due care in the promotion of Ozempic to prevent the aforementioned risks to individuals when the drugs were ingested;

l. Failed to use due care in the selling of Ozempic to prevent the aforementioned risks to individuals when the drugs were ingested;

m. Failed to provide adequate training and information to healthcare providers for the appropriate use of Ozempic;

n. Failed to warn Plaintiff and the healthcare providers, prior to actively encouraging and promoting the sale of Ozempic, either directly or indirectly, orally or in writing, about the need for comprehensive, regular medical monitoring to insure early discovery of unreasonable, dangerous injuries, such as gastroparesis and its sequelae; and

o. Were otherwise careless and negligent.

92. Despite the fact that Defendants knew or should have known that Ozempic's use had and caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, Defendants continued to promote and market Ozempic by providing false and misleading information with regard to its safety and efficacy to prescribers and their patients, including but not limited to Plaintiff, when safer and more effective methods of treatment were available.

93. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of their failure to exercise ordinary care as described herein.

94. As a result of Defendants' conduct, Plaintiff suffered injuries and damages from her ingestion of Defendants' Ozempic. All Defendants are liable to Plaintiff jointly and severally for all general, special, and equitable relief to which Plaintiff is entitled by law.

95. At all times pertinent hereto, when viewed objectively from Defendants' standpoint, Defendants recommending, promoting, or advertising Ozempic for safe weight loss, and especially for an indication/use not approved by the United States Food and Drug Administration, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others and Plaintiff and of which Defendants has actual, subjective awareness of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others, including but not limited to Plaintiff. Plaintiff is therefore entitled to exemplary damages.

PRODUCT LIABILITY

96. Plaintiff incorporates the foregoing herein as if fully set forth herein at length, and further alleges the following:

97. The Texas Civil Practices and Remedies Code Sec 82.001 et sec imposes a duty on producers, manufacturers, distributors, lessors, and sellers of a product to exercise all reasonable care when producing, manufacturing, distributing, leasing, and selling their product.

98. At all times pertinent hereto Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Ozempic that was used by Plaintiff.

99. Ozempic was expected to and did reach the usual consumers, handlers, and persons coming into contact with Ozempic without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendants.

100. At all times pertinent hereto and at the time Ozempic left Defendants' control, Defendants knew or should have known that Ozempic was unreasonably dangerous because they did not adequately warn of the risk of gastroparesis and its sequelae, especially when used in the form and manner as provided by Defendants.

101. Despite the fact that Defendants knew or should have known that Ozempic caused unreasonably dangerous injuries, Defendants continued to market, distribute, and/or sell Ozempic to consumers, including but not limited to Plaintiff, without adequate warnings.

102. Despite the fact that Defendants knew or should have known that Ozempic caused unreasonably dangerous injuries, Defendants continued to market Ozempic to prescribing physicians, including but not limited to Plaintiff's prescribing physician(s), without adequate warnings.

103. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of their failure to provide adequate warnings, as set forth herein.

104. At all times pertinent hereto given its increased safety risks, Ozempic was not fit for the ordinary purpose for which it was intended.

105. At all times pertinent hereto given its increased safety risks, Ozempic did not meet the reasonable expectations of an ordinary consumer, and particularly Plaintiff.

106. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and distribution of Ozempic into the stream of commerce, including but not limited to a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as gastroparesis and its sequelae.

107. At all times pertinent hereto Plaintiff was using Ozempic for the purposes and in a manner normally intended, namely as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus.

108. Ozempic as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was and is defective due to inadequate warnings or instructions because Defendants knew or should have of the risks of serious side effects, including but not limited to gastroparesis and its sequalae, as well as other severe and permanent health consequences which are permanent and lasting in nature, and Defendants failed to adequately warn of said risks.

109. Ozempic as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was and is defective due to inadequate post-marketing surveillance and/or warnings because after Defendants knew or should have known of the risks of serious side effects, including but not limited to gastroparesis and its sequalae, as well as other severe and permanent health consequences which are permanent and lasting in nature, and Defendants failed to provide adequate warnings to users and/or prescribers of the product, and continued to advertise, market and/or promote Ozempic.

110. The label for Ozempic was inadequate because it did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic, including but not limited to the increased risk of gastroparesis and its sequelae.

111. The label for Ozempic was inadequate because it did not warn and/or adequately warn that Ozempic had not been sufficiently and/or adequately tested for safety risks, including but not limited to gastroparesis and its sequelae. The Ozempic label was inadequate because it did not warn and/or adequately warn of all possible adverse side effects of Ozempic, including but not limited to the increased risk of gastroparesis and its sequelae.

112. The label for Ozempic was inadequate because it did not warn and/or adequately warn of the severity and duration of adverse effects, as the warnings given did not accurately reflect

the symptoms or severity of the side effects, including but not limited to the increased risk of gastroparesis and its sequelae..

113. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) was inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic, including but not limited to the increased risk of gastroparesis and its sequelae.

114. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) was inadequate because Defendants failed to warn and/or adequately warn that Ozempic had not been sufficiently and/or adequately tested for safety risks, including but not limited to gastroparesis and its sequelae.

115. Plaintiff had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and Plaintiff's reliance upon Defendants' warnings was reasonable.

116. Plaintiff's prescribing physician(s) had no way to determine if the Ozempic label adequately warned of the severity and duration of adverse effects, as the warnings given did not accurately reflect the symptoms or severity of the side effects, including but not limited to the increased risk of gastroparesis and its sequelae, and the physician's reliance upon Defendants' warnings was reasonable.

117. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of Ozempic's increased risks of gastroparesis and its sequalae, the prescribing physician would not have prescribed Ozempic and/or would have provided Plaintiff with the information and warned Plaintiff about the dangers of Ozempic, and specifically, Ozempic's increased risks of gastroparesis and its sequalae, so as to allow Plaintiff to make an informed decision regarding

Plaintiff's use of Ozempic.

118. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Ozempic had not been sufficiently and/or adequately tested for safety risks, including but not limited to gastroparesis and its sequelae, the prescribing physician would not have prescribed Ozempic and/or would have provided Plaintiff with information and warned Plaintiff about the lack of sufficient and/or adequate testing of Ozempic so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic.

119. If Plaintiff had been warned of the increased risks of gastroparesis and its sequelae, which are causally associated with Ozempic, then Plaintiff would not have used Ozempic and/or suffered from gastroparesis and its sequelae.

120. If Plaintiff had been warned that Ozempic had not been sufficiently and/or adequately tested for safety risks, including but not limited to gastroparesis and its sequalae, then Plaintiff would not have used Ozempic and/or suffered gastroparesis and its sequelae.

121. If Plaintiff had been warned of the increased risks of gastroparesis and its sequelae, which is causally associated with Ozempic, then Plaintiff would have informed Plaintiff's prescribers that Plaintiff did not want to take Ozempic.

122. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Ozempic due to the risks of gastroparesis and its sequelae and the lack of adequate testing for safety risks including but not limited to gastroparesis and its sequelae, then Plaintiff's prescribing physician(s) would not have prescribed Ozempic.

123. By reason of the foregoing, Defendants are liable to Plaintiff for the design, marketing, promoting, distribution and/or sale of an unreasonably dangerous product, Ozempic.

124. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product, Ozempic, which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore liable for Plaintiff's injuries.

125. Defendants' inadequate warnings for Ozempic were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

126. Said inadequate warnings for Defendants' drugs Ozempic were a substantial factor in causing Plaintiff's injuries.

127. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including but not limited to gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including but not limited to physical pain, mental anguish, 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.

128. As a result of the foregoing acts and omissions Plaintiff did incur medical, health, incidental, and related expenses, and requires and/or will require more health care and services. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

129. At all times pertinent hereto Defendants:

a. At all times pertinent hereto, and specifically before or after pre-market approval or licensing of Ozempic, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the risk of serious side effects of Ozempic, including but not limited to gastroparesis and its sequelae, and was causally related to the Plaintiff's injury.

b. At all times pertinent hereto Defendants recommended, promoted, or advertised the Ozempic for an indication not approved by the United States Food and Drug Administration.

c. At all times pertinent hereto the product was used by Plaintiff as Defendants recommended, promoted, or advertised and Plaintiff's injury is causally related to the recommended, promoted, or advertised use of Ozempic;

d. Based on the information about Ozempic provided by Defendants to Plaintiff's prescriber, Plaintiff was prescribed and used Ozempic as prescribed for an indication not approved by the United States Food and Drug Administration and Plaintiff's injury is causally related to the recommended, promoted, or advertised use of Ozempic;

130. Defendants committed various acts and omissions of negligence and gross negligence, which both individually and collectively, were the proximate cause of the injuries and damages suffered by Plaintiff as set forth above.

STRICT PRODUCTS LIABILITY
(Defective Product)

131. Plaintiff incorporates the foregoing herein as if fully set forth herein at length, and further alleges:

132. Defendants are liable under the theory of Strict Product Liability as set forth in the Restatement (Second) of Torts § 402A. Defendants were at all times engaged in the business of manufacturing, creating, designing, testing, labeling, packaging, supplying, marketing, promoting, selling, advertising, warning, and otherwise distributing Ozempic in interstate commerce, which they sold and distributed throughout the United States.

133. Ozempic was expected to and did reach Plaintiff without substantial change in its condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned and otherwise distributed.

134. Plaintiff used Ozempic in a manner for which it was intended or in a reasonably foreseeable manner.

135. Defendants' Ozempic caused increased risks of personal injury and harm upon consumption, and therefore constitutes a product unreasonably dangerous for normal use due to their defective design, defective manufacture, Defendants' misrepresentations and inadequate facts disclosed to Plaintiff.

136. Ozempic manufactured and/or supplied by Defendants were defective due to:

a. Defective design or formulation in that when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation;

b. Defective marketing in that Defendants made inappropriate, misleading, inaccurate and incomplete representations about this product in advertisements, news, commercials, and direct to consumer advertisements. These deceptive marketing representations were made to the FDA, healthcare providers, pharmacists and the public. These deceptive marketing representations were made in order to induce sales and increase profits;

c. Defective design or formulation, in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect, and more dangerous than other Ozempic medications;

d. Inadequate warnings or instructions because the defendants knew or should have known that the product created a risk of dangerous side effects and other related conditions and diseases;

e. Inadequate pre-marketing testing which, if conducted properly, would have revealed the serious problems with this drug prior to the first sale; and/or

f. Inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of dangerous side effects and other related conditions and diseases, they failed to provide adequate warnings to users or consumers of the product and continued to promote the product.

137. Defendants, therefore, are strictly liable to Plaintiff.

138. As a direct and proximate result Defendants' manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distribution of Ozempic in interstate commerce, Plaintiff has suffered injuries and

damages, and is at an increased risk of developing further injuries and damages and has suffered compensatory damages in an amount to be proven at trial.

STRICT PRODUCTS LIABILITY
(Defective Marketing and Inadequate Warnings)

139. Plaintiff incorporates the foregoing herein as if fully set forth herein at length, and further alleges:

140. Defendants are manufacturers and/or suppliers of Ozempic using retail or sample distribution. The Ozempic manufactured and/or supplied by Defendants were not accompanied by proper warnings regarding dangerous side effects and posed potentially fatal health risks associated with the use of Ozempic in that the warnings given did not accurately reflect the symptoms, scope or severity of such injuries and health risks.

141. Defendants failed to effectively warn consumers, pharmacists, physicians and healthcare providers that even under close medical monitoring, the potential for serious health complications existed, and there was no way to know which patients would suffer such complications.

142. Defendants failed to perform adequate testing in that adequate testing would have shown that Ozempic pose significant risks of serious health events including but not limited to but not limited to and related conditions and diseases, with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made.

143. Defendants knew, or should have known, that Ozempic was dangerously defective products which pose unacceptable risks unknown and unknowable by the consuming public of serious health events and related conditions and diseases. Ozempic was defective due to inadequate warnings because after Defendants knew or should have known of the risk of dangerous side effects and potentially fatal health risks, they failed to provide adequate warnings

to consumers of the product and continued to aggressively promote and market the dangerously defective drugs.

144. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered injuries and damages, and is at an increased risk of developing further injuries and damages and has suffered compensatory damages in an amount to be proven at trial.

BREACH OF EXPRESS WARRANTY

145. Plaintiff incorporates the foregoing herein by reference as if fully set forth herein at length, and further alleges:

146. Defendants, through description, affirmation of fact, and promise expressly warranted to the FDA, prescribing physicians, and the general public, including but not limited to Plaintiff, that their Ozempic products were both efficacious and safe for the intended use. These warranties came in the form of:

a. Publicly-made written and verbal assurances of the safety and efficacy of Ozempic;

b. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create and increase demand for Ozempic, which utterly failed to warn of the risks inherent to the ingestion of such products;

c. Verbal assurances made by Defendants regarding Ozempic, and the downplaying of any risk associated with the drug;

d. False and misleading written information, supplied by Defendants, and published in the *Physicians Desk Reference* on an annual basis, upon which physicians were forced to rely in prescribing Ozempic during the period of Plaintiff's ingestion of Ozempic, including but not limited to but not limited to information relating the recommended dose, administration and duration of the use of the drugs;

e. Promotional pamphlets and brochures published and distributed by Defendants and directed to consumers; and

f. Advertisements.

147. The documents referred to in this paragraph were created by and at the direction of Defendants.

148. At the time of these express warranties, Defendants had knowledge of the purpose for which Ozempic was to be used and warranted it to be in all aspects safe, effective, and proper for such purpose. Defendants' Ozempic do not conform to these express representations in that they are neither safe nor effective and use of such drugs produce serious adverse side effects.

149. As such, Defendants' products were neither in conformity to the promises, descriptions or affirmations of fact made about these drugs nor adequately contained, packaged, labeled or fit for the ordinary purposes for which such goods are used.

150. Defendants breached their express warranties to Plaintiff by:

a. Manufacturing, marketing, packaging, labeling, and selling Ozempic to Plaintiff in such a way that misstated the risks of injury, without warning or disclosure thereof by package and label of such risks to Plaintiff or the prescribing physician or pharmacist, or without so modifying or excluding such express warranties;

b. Manufacturing, marketing, packaging, labeling, and selling Ozempic to Plaintiff, which failed to counteract the negative health effects of obesity in a safe and permanent manner and without injury; and

c. Manufacturing, marketing, packaging, labeling, and selling Ozempic to Plaintiff, thereby causing Plaintiff serious physical injury and pain and suffering.

151. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered injuries and damages, and is at an increased risk of developing further injuries and damages and has suffered compensatory damages in an amount to be proven at trial.

NEGLIGENT MISREPRESENTATIONS

152. Plaintiff incorporates the foregoing herein by reference as if fully set forth herein at length, and further alleges:

153. At the time the Defendants manufactured, designed, marketed, sold, and distributed Ozempic for use by Plaintiff, Defendants knew or should have known of the use for which Ozempic was intended and knew or should have known of the serious risks and dangers associated with such use of Ozempic.

154. Defendants owed a duty to prescribing physicians and ultimate end users, including but not limited to Plaintiff, to accurately and truthfully represent the risks and benefits of Ozempic. Defendants breached that duty by misrepresenting the risks and benefits of Ozempic to the prescribing physicians and ultimate users, including but not limited to Plaintiff.

155. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered injuries and damages, and is at an increased risk of developing further injuries and damages and has suffered compensatory damages in an amount to be proven at trial.

FRAUD

156. Plaintiff incorporates the foregoing herein by reference as if fully set forth herein at length, and further alleges:

157. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell Ozempic owed a duty to provide accurate and complete information regarding these products.

158. Defendants' advertising program, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of Ozempic was safe for human use, had no unacceptable side effects, and would not interfere with daily life.

159. Defendants intentionally encouraged consumers and Plaintiff to remain on Ozempic for a longer duration than they know or should have known were safe and effective to remain on such products and at higher dosage levels than necessary.

160. On information and belief, Plaintiff avers that Defendants purposefully concealed, failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of Ozempic. Defendants, through promotional practices as well as the publication of medical literature, deceived potential users and prescribers of the drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying the known adverse and serious health effects. Defendants falsely and deceptively kept relevant information from potential Ozempic users and minimized prescriber concerns regarding the safety and efficacy of their drugs.

161. Defendants did not properly study nor report accurately the results of their human animal and cell studies in terms of risks and benefits of its Ozempic. Defendants also fraudulently and intentionally polluted the scientific literature related to Ozempic. Defendants hired physicians and scientists to write inaccurate and misleading scientific articles for the purpose of creating confusion so as to pollute existing scientific and medical knowledge pertaining to menopausal Ozempic and their particular products. Defendants then used and relied on these inaccurate and fraudulently prepared scientific papers to defend and justify the marketing, promotions, and labeling of Ozempic. At all times, Defendants knew that what they were publishing or having published was inaccurate and that this information would mislead the members of the medical and scientific communities who were studying or more importantly, prescribing Ozempic.

162. The scientific and medical communities were misled as to the true nature of the risk and benefits of Defendants' Ozempic in particular and in general as to the treatment needs and

options for the symptoms of its approved uses, Type 2 Diabetes. Even then the doctors in those communities had been so conditioned by the false science published and or funded for years by Defendants that it was difficult for many of those doctors to accept the truth about the risks and lack of benefits associated with Ozempic.

163. The misconceptions as to the true risks and benefits of Defendants' Ozempic were pervasive throughout the medical and scientific communities due to the marketing methods employed by Defendants that included but were not limited to the following:

a. The publication of fraudulent scientific papers in scientific and medical literature;

b. Providing false and misleading information to doctors during sales and detailing calls at the doctors' offices or at medical or scientific conferences and meetings;

c. Funding third-party organizations to disseminate false and misleading scientific and medical information through its publications and its members to physicians and patients;

d. Funding continuing medical education to disseminate false and misleading information to doctors;

e. Paying specialists in the field of treatment and management of Type 2 Diabetes to meet with prescribing doctors for the purpose of disseminating false and misleading information about the risks and benefits of the drugs;

f. Providing false and misleading information to the FDA to support inaccurate risk and benefit information contained in the product labeling; and

g. Disseminating direct to consumers advertising to drive patients to their doctors' offices to ask for the drugs based on false and misleading information regarding the risks and benefits of the drugs.

164. In particular, in the materials disseminated by Defendants, they falsely and deceptively misrepresented or omitted a number of material facts regarding Ozempic, including but not limited to but not limited to, the following:

a. The presence and adequacy of the testing of Ozempic, both pre-and post-marketing;

b. The severity and frequency of adverse health effects caused by Ozempic including but not limited to but not limited to the increased risk of gastroparesis and its sequelae;

c. The range of injuries caused by Ozempic; and

d. The lack of any reliable science to support representations about the benefits of Ozempic.

165. As a result of these efforts, it was accepted by the medical and scientific communities that Ozempic had a certain risk benefit profile that has been shown to be completely false.

166. Defendants were in possession of evidence demonstrating that Ozempic caused serious side effects including but not limited to but not limited to the increased risk of gastroparesis and its sequelae. Nevertheless, Defendants continued to market Ozempic by providing false and misleading information with regard to its safety and efficacy to Plaintiff and Plaintiff's treating physicians.

167. Plaintiff and Plaintiff's treating physicians justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations as set out above concerning Ozempic. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered injuries and damages, and is at an increased risk of developing further injuries and damages and has suffered compensatory damages in an amount to be proven at trial.

TEXAS DECEPTIVE TRADE PRACTICES ACT

168. Plaintiff incorporates the foregoing herein by reference as if fully set forth herein and further alleges as follows:

169. By reason of the conduct as alleged herein, Defendants violated the provisions of Chapter 17 of the Texas Business and Commerce Code known and titled the Texas Deceptive Trade Practices Act, by knowingly and intentionally inducing Plaintiff to purchase and use Ozempic through false and/or misleading advertising, representations and statements. The product failed

to perform as represented and advertised, and in fact was unsafe.

170. Defendants violated Sec. 17.12 of the Act by disseminate a statement Defendants know materially misrepresents the character of Ozempic.

171. Defendants violated Sec. 17.46 of the Act by engaging in false, misleading, or deceptive acts or practices in the conduct of the designed, researched, manufacture, testing, advertising, promotion, marketing, selling, and/or distributing of Ozempic in including but not limited to but not limited to the following acts:

a. causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services; Sec. 17.46(2)

b. causing confusion or misunderstanding as to affiliation, connection, or association with, or certification by, another; Sec. 17.46(3)

c. using deceptive representations or designations of geographic origin in connection with goods or services; Sec. 17.46(4)

d. representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which the person does not; Sec. 17.46(5)

e. advertising goods or services with intent not to sell them as advertised; Sec. 17.46(9)

f. misrepresenting the authority of a salesman, representative or agent to negotiate the final terms of a consumer transaction; Sec. 17.46(14)

g. representing that a guaranty or warranty confers or involves rights or remedies which it does not have or involve; Sec. 17.46(20)

h. failing to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed; Sec. 17.46(24)

172. As a direct and proximate result of Defendants' statutory violations, Plaintiff used Ozempic as a means of controlling Plaintiff's weight which Plaintiff would not have used had

the Defendants not issued false and/or misleading advertising, representations and statements to induce the Plaintiff to use Ozempic. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered injuries and damages.

173. Pursuant to Sec. 17.50, Plaintiff seeks to recover economic or mental anguish damages that the following were a producing cause of:

(1) the use or employment by any person of a false, misleading, or deceptive act or practice that is:
   (A) specifically enumerated in a subdivision of Subsection (b) of Section 17.46 of this subchapter; and
   (B) relied on by a consumer to the consumer's detriment;

(2) breach of an express or implied warranty; or

(3) any unconscionable action or course of action by any person.

174. Pursuant to Sec. 17.50(b), Plaintiff will seek economic damages. If the trier of fact finds that the conduct of the defendant was committed knowingly, the consumer may also recover damages for mental anguish, as found by the trier of fact, and the trier of fact may award not more than three times the amount of economic damages; or if the trier of fact finds the conduct was committed intentionally, the consumer may recover damages for mental anguish, as found by the trier of fact, and the trier of fact may award not more than three times the amount of damages for mental anguish and economic damages (Sec. 17.50(b) (1)) and court costs and reasonable and necessary attorneys' fees. (Sec. 17.50(d))

RESPONDEAT SUPERIOR

175. The acts of Defendants' employees were performed while in their employment to further Defendants' business, to accomplish the objective for which the employees were hired, and within the course and scope of that employment and/or within the authority delegated to those employees.

176. Further, Defendants' have all of the responsibilities to its' employees attended to and with the employer/employee relationship and ratified the acts of Defendants' employees who had anything to do with the events made the basis of the lawsuit and are therefore liable for Plaintiff's injuries and damages under respondeat superior.

DEMAND FOR JURY TRIAL

177. Plaintiff hereby demands a jury trial on all claims so triable in this action.

PRAYER

178. Plaintiff prays for relief and judgment against Defendants, jointly and severally, as follows:

a. Compensatory damages/actual damages;

b. Consequential damages;

c. Exemplary damages;

d. Interest on damages (pre- and post-judgment) in accordance with law;

e. Costs of court;

f. Such other and further relief to which Plaintiff is entitled.

Respectfully submitted,

BRENT COON & ASSOCIATES

By:*/s/ Brent W. Coon*

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