IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

DANA PEACH and GEORGE PEACH,

Plaintiffs, Case No.

JURY TRIAL DEMANDED v.

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

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, Dana Peach and George Peach, by Plaintiff's attorneys, Chaffin Luhana LLP, upon information and belief, at all times hereinafter mentioned, allege as follows:

JURISDICTION AND VENUE

This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, 1. because the amount in controversy as to Plaintiffs exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal

places of business in this state and Plaintiffs reside in another state, which is Pennsylvania.

2. 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, as Defendants routinely design, manufacture or market their products at issue in this District and conduct business in this District related to their products at issue.

NATURE OF THE CASE

- 3. This is an action for damages suffered by Plaintiff, Dana Peach, who was severely injured as a result of Plaintiff's use of Wegovy, an injectable prescription medication that is used for chronic weight management in adults with an initial Body Mass index (BMI) of 30 kg/m2 or greater, or with a BMI of 27 kg/m2 or greater and at least one weight-related comorbid condition.
- 4. The active ingredient in Wegovy is known as semaglutide. Semaglutide works by stimulating insulin production and reducing glucose production in the liver helping to lower blood sugar levels.
- 5. Semaglutide belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

- 6. Defendants acknowledge that gastrointestinal events are well known side effects of the GLP-1RA class of drugs. ¹ However, Defendants have downplayed the severity of the gastrointestinal events caused by their GLP-1RAs, never, for example, warning of the risk of gastroparesis ("paralyzed stomach") and its sequalae.
- 7. 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 cause nausea, vomiting (including vomiting of undigested food), abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, undigested food hardening and remaining 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.²

¹ See, e.g., 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-paralysisweight-loss-side-effects-1234794601 (visited on 9/26/23).

² Gastroparesis, Mayo Clinic (June 11, 2022), available at https://www.mayoclinic.org/diseasesconditions/gastroparesis/symptoms-causes/syc-20355787 (visited on 9/26/23).

PARTY PLAINTIFFS

- 8. Plaintiffs, Dana Peach and George Peach, are citizens of the United States, and residents of the State of Pennsylvania.
- 9. Plaintiffs Dana Peach and George Peach were lawfully married at all times relevant herein.
 - 10. Plaintiff Dana Peach is currently 61 years old.
- 11. Plaintiff Dana Peach used Wegovy from February of 2022 to March of 2022.
- 12. Plaintiff's physician(s) ("prescribing physician(s)") prescribed the Wegovy that was used by Plaintiff.
- 13. As a result of using Wegovy, Plaintiff was caused to suffer from gastroparesis and its sequelae, and as a result sustained severe and permanent personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.
- 14. As a result of using Wegovy, Plaintiff was caused to suffer from gastroparesis and its sequelae, which resulted in, for example, abdominal pain, nausea, vomiting, constipation, frequent diarrhea and decreased bowel function.

PARTY DEFENDANTS

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

- 16. Upon information and belief, Defendant Novo Nordisk Inc. is wholly owned by Defendant Novo Nordisk US Commercial Holdings, Inc.
- 17. 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.
- 18. Upon information and belief, Defendant Novo Nordisk US Commercial Holdings Inc. is wholly owned by Defendant Novo Nordisk US Holdings Inc.
- 19. 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.
- 20. Upon information and belief, Defendant Novo Nordisk US Holdings Inc. is wholly owned by Defendant Novo Nordisk A/S.
- 21. 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.
- 22. 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.
- 23. Novo Nordisk Research Center Seattle, Inc. is a Delaware corporation with a principal place of business at 530 Fairview Ave. N., Seattle, Washington.

- 24. 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.
- 25. Novo Ventures (US) Inc. is a Massachusetts corporation with its principal place of business at 501 2nd Street Suite 300, San Francisco, CA 94107.
- 26. Novo Nordisk Pharmaceutical Industries LP is a Delaware corporation with a principal place of business at 3611 and 3612 Powhatan Road, Clayton, North Carolina.
- 27. Defendant Novo Nordisk Pharmaceutical Industries LP is the labeler for Wegovy, and Defendants Novo Nordisk A/S and Novo Nordisk Inc. are also identified on Wegovy's label.³
- 28. Defendants Novo Nordisk Inc., Novo Nordisk US Commercial Holdings Inc., Novo Nordisk US Holdings Inc., Novo Nordisk A/S, Novo Nordisk North America Operations A/S, Novo Nordisk Research Center Seattle, Inc., Novo Holdings Equity US Inc., Novo Ventures (US) Inc., and Novo Nordisk Pharmaceutical Industries LP are referred to collectively herein as "Novo Nordisk."
- 29. Novo Nordisk also designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Wegovy. Alternatively, Novo

³ Wegovy prescribing information, available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ee06186f-2aa3-4990-a760-757579d8f77b (visited on 06/26/2024).

Nordisk has acquired the entity/entities who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Wegovy and is, thus, the successor to such entity/entities.

FACTUAL BACKGROUND

A. FDA's Approval of Wegovy

30.On December 4, 2020, Defendant Novo Nordisk, Inc. submitted NDA 215256, requesting that the FDA grant it approval to market and sell Wegovy (semaglutide) injections in the United States as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m2 or greater (obesity), or with a BMI of 27 kg/m2 or greater (overweight) and at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia. On June 4, 2021, the FDA approved NDA 215256. ⁴

31. On June 29, 2022, Defendant Novo Nordisk, Inc. submitted sNDA 215256/S-005, requesting that the FDA grant it approval to add the following indication to the Prescribing Information and Medication Guide for Wegovy (semaglutide) injections in the United States: "as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in pediatric patients

⁴ FDA Approval Letter for NDA 215256 (Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/215256Orig1s0001 tr.pdf (visited on 4/17/2024).

aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity)." On December 23, 2022, the FDA approved sNDA 215256/S—005.⁵

- 32. On September 23, 2022, Defendant Novo Nordisk, Inc. submitted sNDA 215256/S-007, requesting that the FDA grant it approval to update the Prescribing Information and Medication Guide for Wegovy (semaglutide) injections in the United States to include Wegovy (semaglutide) 1.7 mg subcutaneous weekly as an additional maintenance dose for use as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m2 or greater (obesity), or with a BMI of 27 kg/m2 or greater (overweight) and at least one weight-related comorbid condition. On July 21, 2023, the FDA approved sNDA 215256/S—007.6
- 33. On September 8, 2023, Defendant Novo Nordisk, Inc. submitted sNDA 215256/S-011, requesting that the FDA grant it approval to add the following indication to the Prescribing Information and Medication Guide for Wegovy (semaglutide) injections in the United States: "Wegovy is indicated in combination

⁵ FDA Supplement Approval Letter for NDA 215256/S-005 (Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/215256Orig1s0051 <a href="https://www.accessdata.gov/drugsatfda_docs/appletter/2022/215256Or

⁶ FDA Supplement Approval Letter for NDA 215256/S-007 (Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/215256Orig1s0071 tr.pdf (visited on 4/17/2024).

with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight." On March 8, 2024, the FDA approved sNDA 215256/S—011.⁷

B. Novo Nordisk's Marketing and Promotion of Wegovy

34. On December 5, 2017, Novo Nordisk 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-1RAs 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."

⁷ FDA Supplement Approval Letter for NDA 215256/S-011 (Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/215256Orig1s0111 <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/2152

⁸ Novo Nordisk Receives FDA Approval of OZEMPIC® (semaglutide) Injection For the Treatment of Adults with Type 2 Diabetes, Cision PR Newswire (December 05,

⁹), available at https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approvalof-ozempic-semaglutide-injection-for-the-treatment-of-adults-with-type-2diabetes-300567052.html (visited on 9/26/23).

- Ozempic in the United States and touted the medication as a "new treatment option[]" that "addresses the concerns and needs of people with diabetes[.]" Novo Nordisk offered an "Instant Savings Card to reduce co-pays to as low as \$25 per prescription fill for up to two years."
- 36. Novo Nordisk promoted the safety 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.
- 37. On July 30, 2018, Novo Nordisk launched its first television ad for Ozempic, to the tune of the 1970s hit pop song "Magic" by Pilot, wherein Novo Nordisk advertised that "adults lost on average up to 12 pounds" when taking Ozempic, even though it is not indicated for weight loss.¹¹
- 38. 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

¹⁰ Novo Nordisk Launches Ozempic® and Fiasp®, Expanding Treatment Options for Adults with Diabetes, Cision PR Newswire (February 05, 2018), available at https://www.prnewswire.com/news-releases/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment-options-for-adults-with-diabetes-300592808.html (visited on 06/26/2024).

¹¹ Ozempic TV Spot, 'Oh!', iSpot.tv (July 30, 2018), available at https://www.ispot.tv/ad/d6Xz/ozempic-oh (visited on 06/26/2024).

the press release, Novo Nordisk represented Ozempic as having "proven safety" and advertised that "plus it can help many patients lose some weight."¹²

- 39. Since 2018, Novo Nordisk has spent more than \$884,000,000 on television ads in the United States to promote its semaglutide drugs (Ozempic, Wegovy and Rybelsus) with the majority of the spending allocated specifically to advertising Ozempic.¹³
- 40. In 2022, Novo Nordisk spent \$180.2 million on Ozempic ads, including 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 Ozempic, Novo Nordisk forecasts sales growth of 13% to 19% for 2023.¹⁴
- 41. On July 6, 2023, it was reported that Novo Nordisk had spent \$11 million in 2022 on food and travel for doctors "as part of its push to promote Ozempic and

¹² 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-mg-providing-increased-glycemic-control-for-adults-with-type-2-diabetes-301512209.html (visited on 06/26/2024).

¹³ Ritzau, *Novo Nordisk runs TV ads in US for multimillion-dollar sum*, MedWatch (April 26, 2023), available at https://medwatch.com/News/Pharma Biotech/article15680727.ece (visited on 9/26/23).

¹⁴ Adams B, Fierce Pharma, *The top 10 pharma drug ad spenders for 2022*, https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-adspenders-2022 (visited on 9/26/23).

other weight loss-inducing diabetes drugs." ¹⁵ The spending bought more than 457,000 meals for almost 12,000 doctors while also flying doctors to places like London, Paris, Orlando, and Honolulu. ¹⁶

42. In an article published on July 21, 2023, the President and CEO of the Alliance of Community Health Plans described Novo Nordisk's spending on meals for doctors as "outrageous" and suggested that the millions Novo Nordisk spent marketing its drugs to prescribers would be better used furthering research about potential side effects and long-term effectiveness. The author cited research published in the spring of 2023 showing an increased risk of intestinal obstruction as a result of using GLP-1RA drugs.¹⁷

¹⁵ Nicolas Florko, *Novo Nordisk bought prescribers over 450,000 meals and snacks to promote drugs like Ozempic*, National Center for Health Research (July 5, 2023), available at https://www.center4research.org/novo-nordisk-gave-doctors-450000meals-ozempic/ (visited on 9/26/23).

¹⁶ Nicolas Florko, *Novo Nordisk bought prescribers over 450,000 meals and snacks to promote drugs like Ozempic*, National Center for Health Research (July 5, 2023), available at https://www.center4research.org/novo-nordisk-gave-doctors-450000meals-ozempic/ (visited on 9/26/23).

¹⁷ Erin Prater, Ozempic manufacturer Novo Nordisk spent \$11 million last year 'wining and dining' doctors. Experts slam the move as a breach of doctor-patient trust, Fortune Well (July 21, 2023), available at https://fortune.com/well/2023/07/21/ozempic-novo-nordisk-meals-travelprescribing-doctors/ (visited on 9/26/23); see also Erin Prater, Weight-loss drugs like Wegovy may put certain people at risk of serious complications, researchers warn, Fortune Well (March 7, 2023), available at https://fortune.com/well/2023/03/07/ozempic-wegovy-elevated-risk-intestinalobstruction-later-type-2-diabetes-weight-loss-drug/ (visited on 10/18/23).

- 43. As a result of Novo Nordisk's 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. ¹⁸ In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year. ¹⁹
- 44. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,²⁰ and currently has over 1.3 billion views.²¹
- 45. On June 15, 2023, NBC News published a report about the "thousands of weight-loss ads on social media for the drugs Wegovy." While many of those ads were found to be from online pharmacies, medical spas, and diet clinics, as of June of 2023, Novo Nordisk was still running online social-media ads for its semaglutide

¹⁸ Choi A, Vu H, *Ozempic prescriptions can be easy to get online. Its popularity for weight loss is hurting those who need it most*, CNN (March 17, 2023), available at https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/ (visited on 9/26/23).

¹⁹ Gilbert D, *Insurers clamping down on doctors who prescribe Ozempic for weight loss*, The Washington Post (June 12, 2023), available at https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempicwegovy-insurance/ (visited on 9/26/23).

²⁰ Blum D, *What is Ozempic and Why Is It Getting So Much Attention?*, The New York Times (published Nov. 22, 2022, updated July 24, 2023), available at https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html (visited on 9/26/23).

²¹ https://www.tiktok.com/tag/ozempic (visited on 11/14/23).

products, despite claiming in May that it would stop running ads due to a shortage of the drug.²²

- 46. 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." ²³
- 47. GLP-1RA drugs, including Wegovy, have also been promoted by influencers on social media and other online platforms. This form of advertising often does not adequately convey the risks and potential side effects of these medications.²⁴

²² Ingram D, *More than 4,000 ads for Ozempic-style drugs found running on Instagram and Facebook*, NBC News (June 15, 2023), available at https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagramwegovy-semaglutide-rcna88602 (visited on 9/26/23).

²³ Bain P, *Ozempic was 2023's Buzziest Drug*, AdAge (July 10, 2023), available at https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brandsmost-popular-marketing-2023/2500571 (visited on 9/26/23).

²⁴ Peter Loftus & Sara Ashley O'Brien, *Influencers Love Ozempic—but They Aren't* Telling You About the Risks, Wall Street Journal (published online April 19, 2024), available at https://www.wsj.com/health/pharma/ozempic-weight-loss-drugsideeffects-social-media-influencers-66f73ac0 (visited 4/22/2024). See also Alex Bitter and Sindhu Sundar, Ozempic is now a Hollywood punchline. See how doctors and clinics are using TikTok to sell trendy weight-loss injections, Business Insider, (published online March 13, 2023), available https://www.businessinsider.com/semaglutide-weight-loss-videos-floodtiktokinstagram-discuss-ozempic-wegovy-2023-2 (visited 4/22/2024); Shane O'Neill, New marketing push by Ozempic and others sparks body-positive backlash, The Washington Post (published online 14. at https://www.washingtonpost.com/style/ofavailable 2024), interest/2024/02/14/ozempic-bodypositivity-influencers-weight-loss-drugs/ (visited 4/22/2024); Melissa Davey, TGA investigates influencers after diabetes drug Ozempic promoted as weight-loss treatment, The Guardian (published online January 5, 2023), available at https://www.theguardian.com/australianews/2023/jan/06/tga-investigatesinfluencers-after-diabetes-drug-ozempicpromoted-as-weight-loss-treatment (visited 4/22/2024).

48. At all relevant times, Novo Nordisk was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Wegovy.

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

- 49. As previously noted, Wegovy (semaglutide) belongs to a class of drugs called GLP-1 receptor agonists ("GLP1RAs").
- 50. 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
- 51. 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.

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).

- 52. 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
- 53. Defendants knew or should have known of this risk of gastroparesis from the clinical trials, medical literature, and case reports.
- 54. 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 serious gastrointestinal adverse events such as abdominal pain (upper and lower), intestinal obstruction, change of bowel habits, vomiting, and diarrhea.²⁷
- 55. 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

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 06/26/2024); American Society of Anesthesiologists, Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests (June 28, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery (visited on 06/26/2024).

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).

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 months in the trial.

- 56. 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
- 57. 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

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).

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.

In a September 2020 article funded and reviewed by Novo Nordisk, 58. 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 GLP1RAs." The study further identified as one "key clinical take-home point" that

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/

"patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs." 30

59. 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%. Semaglutide appears to be associated with more frequent vomiting and nausea as compared to other GLP-1RAs. The study

³⁰ 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).

acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"31

- 63. 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 gastroparesis versus medication-induced gastroparesis is critical.³²
- 64. 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,

³¹ 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).

³² 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).

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."³³

- 65. 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.³⁴
- 66. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events." 35

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 Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).

- 67. An October 2022 study analyzed 5,442 GLP-1RA adverse gastrointestinal events. 32% were serious, including 40 deaths, 53 life-threatening conditions, and 772 hospitalizations. The primary events were nausea and vomiting. There were also adverse events for impaired gastric emptying.³⁶
- 68. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.³⁷
- 69. In February 2023, a longitudinal study of GLP-1RA (dulaglutide) reported adverse events for nausea and vomiting.³⁸
- 70. 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."³⁹
- 71. 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

³⁶ 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).

³⁷ Mirsha, *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).

³⁸ 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).

³⁹ 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).

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.⁴⁰

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.⁴¹ 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.

⁴⁰ 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-shouldstop-before-elective-surgery (visited on 9/26/23).

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).

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.⁴²

D. Defendants Failed to Warn of the Risks of Gastroparesis from Wegovy

- 74. The Prescribing Information for Wegovy (the "label") discloses "Warnings and Precautions" and "Adverse Reactions" but does not adequately warn of the risk gastroparesis and its sequalae.⁴³
- 75. The Wegovy label lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Wegovy patients, but they do not include these adverse reactions in its "Warnings and Precautions" section, nor do

⁴² 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 PooledAnalysis of Two Randomized Trials, Diabetes Ther (2020)(https://doi.org/10.1007%2Fs13300-020-00869-z); Almustanyir, Gastroparesis With the Liraglutide: Initiation ACase Report, Cureus (Nov. 28, 2020) (https://doi.org/10.7759/cureus.11735); Ishihara, Gastroparesis Suspected 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).

⁴³ See Prescribing Information for Ozempic, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209637s012lbl.pdf; Prescribing information for Wegovy, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215256s003lbl.pdf.

they warn that these adverse reactions may be symptoms of more severe conditions, including gastroparesis. In fact, gastroparesis is not mentioned at all in the label.

- 76. Novo Nordisk's main promotional website for Wegovy (Wegovy.com) also includes information about the benefit of Wegovy for weight loss and cardiovascular health, as well as "Important Safety Information" however, Novo Nordisk does not disclose the risk of gastroparesis within the "Important Safety Information" section of the Wegovy promotional website.⁴⁴
- 77. None of Defendants' additional advertising or promotional materials warned prescription providers or the general public of the risks of gastroparesis and its sequelae.
- 78. It has been recognized in the media that in the aftermath of the marketing frenzy created by Novo Nordisk that the full risks of these drugs are not understood or readily available to the average patient—and perhaps the average provider. From the date Novo Nordisk received FDA approval to market Wegoyv and Ozempic until the present time, Novo Nordisk made, distributed, marketed, and/or sold Wegovy and Ozempic without adequate warning to Plaintiff's prescribing physician(s) and/or Plaintiff that Ozempic was causally associated with and/or could cause gastroparesis.
- 79. Defendants knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing gastroparesis. Defendants'

⁴⁴ See Wegovy.com (visited on 4/22/2024).

actual and constructive knowledge derived from their clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced in this Complaint.

- 80. Upon information and belief, Defendants ignored the causal association between the use of GLP-1RAs and the risk of developing gastroparesis.
- 81. Novo Nordisk's failure to disclose information that they possessed regarding the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae rendered the warnings for Wegovy inadequate.
- 82. On information and belief, as a result of Novo Nordisk's inadequate warnings, the medical community at large, and Plaintiff's prescribing physician in particular, were not aware that Wegovy can cause gastroparesis nor were they aware that "common adverse reactions" listed on the label might be sequelae of gastroparesis.
- 83. On information and belief, had Novo Nordisk adequately warned Plaintiff's prescribing physician that Wegovy is causally associated with gastroparesis, then the physician's prescribing decision would have changed by not prescribing Wegovy, or by monitoring Plaintiff's health for symptoms of gastroparesis and discontinuing Wegovy when the symptoms first started.
- 84. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from gastroparesis which resulted in 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 abovenamed health consequences.

FIRST CAUSE OF ACTION (NEGLIGENT FAILURE TO WARN-AGAINST ALL DEFENDANTS)

- 85. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 86. Under Pennsylvania law, Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Wegovy into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as gastroparesis.
- 87. At all times mentioned herein, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Wegovy that was used by Plaintiff.
- 88. We govy was expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which they was produced, manufactured, sold, distributed, and marketed by Defendants.

- 89. At all relevant times, and at the times Wegovy left Defendants' control, Defendants knew or should have known that Wegovy was unreasonably dangerous because they did not adequately warn of the risk of gastroparesis, especially when used in the form and manner as provided by Defendants.
- 90. Despite the fact that Defendants knew or should have known that Wegovy caused unreasonably dangerous injuries, Defendants continued to market, distribute, and/or sell Wegovy to consumers, including Plaintiff, without adequate warnings.
- 91. Despite the fact that Defendants knew or should have known that Wegovy caused unreasonably dangerous injuries, Defendants continued to market Wegovy to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.
- 92. 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.
- 93. At all relevant times, given their increased safety risks, Ozempic and Wegovy was not fit for the ordinary purpose for which they were intended.
- 94. At all relevant times, given their increased safety risks, Wegovy did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

- 95. At all relevant times, Plaintiff was using Wegovy for the purposes and in a manner normally intended.
- 96. The Wegovy designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings or instructions, as Defendants knew or should have known that the products created a risk of serious and dangerous injuries, including gastroparesis, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendants failed to adequately warn of said risk.
- 97. The Wegovy designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was 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 gastroparesis, as well as other severe and permanent health consequences from Wegovy, they failed to provide adequate warnings to users and/or prescribers of the product, and continued to improperly advertise, market and/or promote their products, Wegovy.
- 98. The labels for Wegovy was inadequate because they failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Wegovy, including the increased risk of gastroparesis.

- 99. The labels for Wegovy was inadequate because they failed to warn and/or adequately warn that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis.
- 100. The labels for Wegovy was inadequate because they failed to warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Wegovy.
- 101. The labels for Wegovy was inadequate because they 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.
- 102. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Wegovy, including the increased risk of gastroparesis.
- 103. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis.
- 104. Plaintiff had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and her reliance upon Defendants' warnings was reasonable.

- 105. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and their reliance upon Defendants' warnings was reasonable.
- 106. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risks of gastroparesis causally associated with Wegovy, then the prescribing physician would not have prescribed Wegovy and/or would have provided Plaintiff with adequate warnings regarding the dangers of Wegovy so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy.
- 107. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, the prescribing physician would not have prescribed Wegovy and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Wegovy so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy.
- 108. Had Plaintiff been warned of the increased risks of gastroparesis, which are causally associated with Wegovy, Plaintiff would not have used Wegovy and/or suffered from gastroparesis.
- 109. Had Plaintiff been warned that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, Plaintiff would not have used Wegovy and/or suffered gastroparesis.

- 110. Had Plaintiff been warned of the increased risks of gastroparesis causally associated with Wegovy, Plaintiff would have informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Wegovy.
- 111. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Wegovy due to the risks of gastroparesis, or the lack of adequate testing for safety risks, then Plaintiff's prescribing physician(s) would not have prescribed Wegovy.
- 112. By reason of the foregoing, Defendants have become liable to Plaintiff for the designing, marketing, promoting, distribution and/or selling of unreasonably dangerous products, Ozempic, and Wegovy.
- 113. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore liable for the injuries sustained by Plaintiff.
- 114. Defendants' inadequate warnings for Wegovy was acts that amount to willful, wanton, and/or reckless conduct by Defendants.
- 115. Said inadequate warnings for Defendants' drugs Wegovy was a substantial factor in causing Plaintiff's injuries.
- 116. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including gastroparesis, which resulted in other

severe and personal injuries which are permanent and lasting in nature, including 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.

117. 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.

SECOND CAUSE OF ACTION (STRICT PRODUCT LIABILITY FAILURE TO WARN- AGAINST ALL DEFENDANTS)

- 118. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 119. Under Pennsylvania law, Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Wegovy into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as gastroparesis.
- 120. At all times mentioned herein, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Wegovy that was used by Plaintiff.

- 121. We govy was expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed, and marketed by Defendants.
- 122. At all relevant times, and at the times Wegovy left Defendants' control, Defendants knew or should have known that Wegovy was unreasonably dangerous because they did not adequately warn of the risk of gastroparesis, especially when used in the form and manner as provided by Defendants.
- 123. Despite the fact that Defendants knew or should have known that Wegovy caused unreasonably dangerous injuries, Defendants continued to market, distribute, and/or sell Wegovy to consumers, including Plaintiff, without adequate warnings.
- 124. Despite the fact that Defendants knew or should have known that Wegovy caused unreasonably dangerous injuries, Defendants continued to market Wegovy to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.
- 125. 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.
- 126. At all relevant times, given their increased safety risks, Wegovy was not fit for the ordinary purpose for which they were intended.

- 127. At all relevant times, given their increased safety risks, Wegovy did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.
- 128. At all relevant times, Plaintiff was using Wegovy for the purposes and in a manner normally intended.
- 129. The Wegovy designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings or instructions, as Defendants knew or should have known that the product created a risk of serious and dangerous injuries, including gastroparesis, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendants failed to adequately warn of said risk.
- 130. The Wegovy designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was 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 gastroparesis, as well as other severe and permanent health consequences from Wegovy, they failed to provide adequate warnings to users and/or prescribers of the products, and continued to improperly advertise, market and/or promote their products, Wegovy.
- 131. The labels for Wegovy was inadequate because they failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Wegovy, including the increased risk of gastroparesis.

- 132. The labels for Wegovy was inadequate because they failed to warn and/or adequately warn that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis.
- 133. The labels for Wegovy was inadequate because they failed to warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Wegovy.
- 134. The labels for Wegovy was inadequate because they 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.
- 135. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Wegovy, including the increased risk of gastroparesis.
- 136. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis.
- 137. Plaintiff had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and her reliance upon Defendants' warnings was reasonable.

- 138. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and their reliance upon Defendants' warnings was reasonable.
- 139. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risks of gastroparesis causally associated with Wegovy, then the prescribing physician would not have prescribed Wegovy and/or would have provided Plaintiff with adequate warnings regarding the dangers of Wegovy so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy.
- 140. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, the prescribing physician would not have prescribed Wegovy and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Wegovy so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy.
- 141. Had Plaintiff been warned of the increased risks of gastroparesis, which are causally associated with Wegovy, Plaintiff would not have used Wegovy and/or suffered from gastroparesis.
- 142. Had Plaintiff been warned that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, Plaintiff would not have used Wegovy and/or suffered bowel obstruction, ischemic colitis, malnutrition, and their sequelae.

- 143. Had Plaintiff been warned of the increased risks of gastroparesis causally associated with Wegovy, Plaintiff would have informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Wegovy.
- 144. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Wegovy due to the risks of gastroparesis, or the lack of adequate testing for safety risks, then Plaintiff's prescribing physician(s) would not have prescribed Wegovy.
- 145. By reason of the foregoing, Defendants have become liable to Plaintiff for the designing, marketing, promoting, distribution and/or selling of unreasonably dangerous products, Wegovy.
- 146. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore liable for the injuries sustained by Plaintiff.
- 147. Defendants' inadequate warnings for Wegovy was acts that amount to willful, wanton, and/or reckless conduct by Defendants.
- 148. Said inadequate warnings for Defendants' drugs Wegovy was a substantial factor in causing Plaintiff's injuries.
- 149. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including gastroparesis, which resulted in other

severe and personal injuries which are permanent and lasting in nature, including 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.

150. 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.

THIRD CAUSE OF ACTION (NEGLIGENCE – DESIGN DEFECT – AGAINST ALL DEFENDANTS)

- 151. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 152. Defendants are liable to Plaintiff for the injuries and damages sustained due to Defendants' negligent design and/or formulation of Wegovy.
- 153. At all relevant times to this lawsuit, Defendants owed a duty to consumers, including Plaintiff and Plaintiff's health care providers, to assess, manage, and communicate the risks, dangers and adverse effects of Wegovy. Defendants' duties included, but were not limited to, carefully and properly designing, testing, studying, and manufacturing Wegovy.

- 154. Defendants negligently and carelessly breached the above-described duties to Plaintiff by, among other acts and omissions:
 - (a) Failing to use ordinary care in designing, testing, and manufacturing Wegovy;
 - (b) Failing to design Wegovy as to properly minimize the adverse effects to the gastrointestinal system;
 - (c)Failing to counteract in the design of Wegovy the known adverse effects on the gastrointestinal system;
 - (d)Designing Wegovy in such a way that the benefits were greatly outweighed by the risks of gastroparesis, intestinal obstructions, bowel ischemia, malnutrition, hospitalization, and death;
 - (e)Designing Wegovy without taking into consideration the proper dosage that could avoid gastroparesis, intestinal obstructions, bowel ischemia, malnutrition, hospitalization, and death;
 - (f) Introducing Wegovy to the marketplace, and continuing to market them, despite actual or constructive knowledge that these drugs were too harmful to be used by anyone.
- 155. Furthermore, Wegovy was defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

- 156. At all reasonable times, given their lack of efficacy and increased safety risks, Wegovy did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff and/or her medical providers.
- 157. We govy was defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers and/or distributors, they were unreasonably dangerous, more dangerous than an ordinary consumer would expect, so dangerous that they should not be used, and more dangerous than other medications, treatments, or interventions which could be used as a substitute for treatment of Type 2 Diabetes or for chronic weight management.
- 158. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of Wegovy at all times relevant, Defendants designed and brought these products to market, and continued to market these drugs, when there were safer alternatives available.
- 159. As a result of Defendants' negligent and reckless design, Plaintiff was caused to suffer serious and dangerous injuries, including bowel obstruction, bowel ischemia, and malnutrition, which resulted in other severe and personal injuries which are permanent and lasting in nature, including 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.

160. As a result of Defendants' negligent and reckless design, 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.

FOURTH CAUSE OF ACTION (BREACH OF EXPRESS WARRANTY-AGAINST ALL DEFENDANTS)

- 161. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 162. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Wegovy, which were used by Plaintiff as hereinabove described.
- 163. At all relevant times, Defendants expressly warranted to Plaintiff and Plaintiff's prescribing physician(s) that Ozempic was safe to treat 2 diabetes, and that Wegovy was safe to reduce cardiovascular risk and promote weight loss, and assured them that these drugs did not carry an increased risk of gastrointestinal complications, including, but not limited to, gastroparesis.

- 164. The aforementioned express warranties were made to Plaintiff and Plaintiff's prescribing physician(s) by way of Wegovy's labels, website, advertisements, promotional materials, and through other statements.
- 165. As a result of Defendants' express warranties, Plaintiff's prescribing physician(s) was induced to prescribe Wegovy to Plaintiff, and Plaintiff was induced to use Wegovy.
- 166. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Wegovy based upon their express warranties.
- 167. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Wegovy based upon their express warranties.
- 168. At all relevant times, Defendants knew or should have known that Wegovy was unreasonably dangerous because of their increased risk of gastroparesis, especially when the drugs were used in the form and manner as provided by Defendants.
- 169. At all relevant times, Defendants knew or should have known that Wegovy had not been sufficiently and/or adequately tested for safety.
- 170. The unreasonably dangerous characteristics of Wegovy was beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drugs' characteristics.

- 171. The unreasonably dangerous characteristics of Wegovy was beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drugs' characteristics.
- 172. At the time Ozempic left Defendants' control, Ozempic did not conform to Defendants' express warranties because Ozempic was not safe to improve glycemic control in adults with type 2 diabetes, reduce cardiovascular risk in patients with type 2 diabetes, or to promote weight loss, in that it was causally associated with increased risks of gastroparesis.
- 173. At the time Wegovy left Defendants' control, Wegovy did not conform to Defendants' express warranties because Wegovy was not safe for chronic weight management in patients with a BMI of 30 kg/m² or greater, or a BMI of 27 kg/m² and at least one weight-related comorbid condition, in that it was causally associated with increased risks of gastroparesis.
- 174. The express warranties made by Defendants regarding the safety of Wegovy was made with the intent to induce Plaintiff to use the product and/or Plaintiff' prescribing physician(s) to prescribe the product.
- 175. Defendants knew and/or should have known that by making the express warranties to Plaintiff and/or Plaintiff's prescribing physician(s), it would be the natural tendency of Plaintiff to use Wegovy and/or the natural tendency of Plaintiff's prescribing physician(s) to prescribe Wegovy.

- 176. Plaintiff and Plaintiff's prescribing physician(s), as well as members of the medical community, relied on the express warranties of Defendants identified herein.
- 177. Had Defendants not made these express warranties, Plaintiff would not have used Wegovy and/or, upon information and belief, Plaintiff's prescribing physician(s) would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Wegovy so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy.
- 178. Had Plaintiff been warned of the increased risk of gastroparesis causally associated with Wegovy, Plaintiff would not have used Wegovy and/or suffered from gastroparesis.
- 179. Had Plaintiff been warned that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, Plaintiff would not have used Wegovy and/or suffered gastroparesis.
- 180. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiff.
- 181. Defendants' breach of express warranty was a substantial factor in causing Plaintiff's injuries.
- 182. Plaintiff's injuries and damages arose from a reasonably anticipated use of the products by Plaintiff.

- 183. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis, as well as other severe and personal injuries which are permanent and lasting in nature, including physical pain, 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 abovenamed health consequences.
- 184. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Wegovy drugs.
- 185. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

FIFTH CAUSE OF ACTION (BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY- AGAINST ALL DEFENDANTS)

- 186. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 187. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Wegovy drugs used by Plaintiff.

- 188. We govy was expected to and did reach the usual consumers, handlers, and persons encountering said products without substantial change in the condition in which it they were produced, manufactured, sold, distributed, and marketed by the Defendants.
- 189. At all relevant times, Defendants impliedly warranted to Plaintiff, Plaintiff's prescribing physician(s), and the medical community that Wegovy was of merchantable quality and safe and fit for their ordinary purpose.
- 190. At all relevant times, Defendants knew or should have known that Wegovy was unreasonably dangerous because of their increased risk of gastroparesis, especially when the drug was used in the form and manner as provided by Defendants.
- 191. At all relevant times, Defendants knew or should have known that Wegovy had not been sufficiently and/or adequately tested for safety.
- 192. At the time Wegovy left Defendants' control, Wegovy did not confirm to Defendants' implied warranty and were unfit for their ordinary purpose because Defendants failed to provide adequate warnings of the drugs' causal association with increased risk of gastroparesis.
- 193. At all relevant times, Defendants reasonably anticipated and expected that prescribing physician(s), such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Ozempic for use by their patients to improve

glycemic control in adults with type 2 diabetes, reduce cardiovascular risk, and/or to promote weight loss.

- 194. At all relevant times, Defendants reasonably anticipated and expected that prescribing physician(s). such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Wegovy for use by their patients for prescribing physician(s), would recommend, prescribe and/or dispense Ozempic for use by their patients for chronic weight management in patients with a BMI of 30 kg/m² or greater, or a BMI of 27 kg/m² and at least one weight-related comorbid condition.
- 195. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Wegovy for their ordinary purpose.
- 196. Despite the fact that Defendants knew or should have known that Wegovy cause unreasonably dangerous injuries, such as gastroparesis, Defendants continued to market, distribute, and/or sell Wegovy to consumers, including Plaintiff, without adequate warnings.
- 197. The unreasonably dangerous characteristics of Wegovy was beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drugs' characteristics.

- 198. The unreasonably dangerous characteristics of Wegovy was beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drugs' characteristics.
- 199. Plaintiff reasonably relied on Defendants' implied warranty of merchantability relating to Wegovy's safety and efficacy.
- 200. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Wegovy was of merchantable quality and safe and fit for their intended use.
- 201. Upon information and belief Plaintiff's prescribing physician(s) relied on Defendants' implied warranty of merchantability and fitness for the ordinary use and purpose relating to Wegovy.
- 202. Upon information and belief Plaintiff's prescribing physician(s), reasonably relied upon the skill and judgment of Defendants as to whether Wegovy was of merchantable quality and safe and fit for their intended use.
- 203. Had Defendants not made these implied warranties, Plaintiff would not have used Wegovy and/or, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Wegovy, and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Wegovy to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy.

- 204. Defendants herein breached the aforesaid implied warranty of merchantability because the drugs Wegovy was not fit for their intended purposes.
- 205. Defendants' breaches of implied warranty of merchantability were a substantial factor in causing Plaintiff's injuries.
- 206. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis, which resulted in 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 abovenamed health consequences.
- 207. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SIXTH CAUSE OF ACTION (FRAUDULENT CONCEALMENT-AGAINST ALL DEFENDANTS)

208. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

- 209. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Wegovy, which were used by Plaintiff as hereinabove described.
- 210. At all relevant times, Defendants knew or should have known that Wegovy had not been adequately and/or sufficiently tested for safety.
- 211. At all relevant times, Defendants knew or should have known that Wegovy was unreasonably dangerous because of the increased risk of gastroparesis, especially when the drug was used in the form and manner as provided by Defendants.
- 212. Defendants had a duty to disclose material information about Wegovy to Plaintiff and Plaintiff's prescribing physician(s), namely that Wegovy is causally associated with increased risk of gastroparesis, because Defendants have superior knowledge of the drugs and their dangerous side effects, this material information is not readily available to Plaintiff or Plaintiff's prescribing physician(s) by reasonable inquiry, and Defendants knew or should have known that Plaintiff and Plaintiff's prescribing physician would act on the basis of mistaken knowledge.
- 213. Nonetheless, Defendants consciously and deliberately withheld and concealed from Plaintiff's prescribing physician(s), Plaintiff, the medical and healthcare community, and the general public this material information.
- 214. Although the Wegovy labels list nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Wegovy patients,

they do not mention bowel obstruction, ischemic colitis, or malnutrition as a risk of taking Ozempic and/or Wegovy.

- 215. Defendants' promotional websites for Wegovy similarly do not disclose that Ozempic is causally associated with increased risk of bowel obstruction, ischemic colitis, and malnutrition.
- 216. Defendants' omissions and concealment of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and adult Type 2 diabetes or prediabetes patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Ozempic for treatment of Type 2 Diabetes.
- 217. Defendants' omissions and concealment of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and adult patients with a BMI of 30 kg/m² or greater, or with a BMI of 27 kg/m² or greater and at least one weight-related comorbid condition, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Wegovy for chronic weight management.

- 218. Defendants knew or should have known that Plaintiff's prescribing physician(s) would prescribe, and Plaintiff would use Wegovy, without the awareness of the risks of serious side effects, including gastroparesis.
- 219. Defendants knew that Plaintiff and Plaintiff's prescribing physicians (s) had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding Wegovy, as set forth herein.
- 220. Upon information and belief, Plaintiffs prescribing physician(s) justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to dispense, provide, and prescribe Wegovy.
- 221. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of gastroparesis and its sequelae causally associated with Wegovy, they would not have prescribed Wegovy and/or would have provided Plaintiff with adequate information regarding the increased risk of gastroparesis and its sequelae causally associated with Wegovy to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy.
- 222. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, they would not have prescribed Wegovy and/or would have provided Plaintiff with adequate warnings regarding the

lack of sufficient and/or adequate testing of Wegovy to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy.

- 223. Plaintiff justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to purchase and/or consume Wegovy.
- 224. Had Plaintiff been informed of the increased risks causally associated with Wegovy, Plaintiff would not have used Wegovy and/or suffered gastroparesis and its sequelae.
- 225. Defendants' fraudulent concealments were a substantial factor in causing Plaintiff's injuries.
- 226. As a direct and proximate result of the above stated omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in 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 abovenamed health consequences.
- 227. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health,

incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SEVENTH CAUSE OF ACTION (FRAUDULENT MISREPRESENTATION-AGAINST ALL DEFENDANTS)

- 228. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 229. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Wegovy, which were used by Plaintiff as hereinabove described.
- 230. At all relevant times, Defendants knew or should have known that Wegovy had not been adequately and/or sufficiently tested for safety.
- 231. At all relevant times, Defendants knew or should have known of the serious side effects of Wegovy, including gastroparesis and its sequelae.
- 232. At all relevant times, Defendants knew or should have known that Ozempic was not safe to improve glycemic control in adults with type 2 diabetes, reduce cardiovascular risk in patients with type 2 diabetes, or promote weight loss, given its increased risk of gastroparesis and its sequelae.
- 233. At all relevant times, Defendants knew or should have known that Wegovy was not safe for chronic weight management in adults with a BMI of 30

kg/m² or greater, or 27 kg/m² or greater and one or more weight-related comorbid conditions, given its increased risk of gastroparesis and its sequelae.

- 234. Nonetheless, Defendants made material misrepresentations to Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Wegovy.
- 235. Defendants represented affirmatively and by omission on television advertisements, social media, and other online advertisements, and on the label of Ozempic that Ozempic was a safe and effective drug for treatment of adults with Type 2 diabetes, despite being aware of increased risks of gastroparesis and its sequelae causally associated with using Ozempic.
- 236. Defendants represented affirmatively and by omission on television advertisements, social media, and other online advertisements, and on the label of Wegovy that Wegovy was a safe and effective drug for chronic weight management in adults with a BMI of 30 kg/m² or greater, or 27 kg/m² or greater and one or more weight-related comorbid conditions, despite being aware of increased risks of gastroparesis and its sequelae causally associated with using Wegovy.
- 237. Defendants were aware or should have been aware that its representations were false or misleading and knew that they were concealing and/or omitting material information from Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community, and the general public.

- 238. Defendants' misrepresentations of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and adult Type 2 diabetes patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Ozempic for treatment of Type 2 Diabetes.
- 239. Defendants' misrepresentations of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and adult patients with a BMI of 30 kg/m² or greater, or 27 kg/m² or greater and one or more weight-related comorbid conditions, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Wegovy for chronic weight management.
- 240. Upon information and belief that Plaintiff's prescribing physician(s) had no way to determine the truth behind Defendants' false and/or misleading statements, concealments and omissions surrounding Wegovy, and reasonably relied on false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiff's prescribing physician(s) had no way to know were omitted.

- 241. Upon information and belief that Plaintiff's prescribing physician(s) justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to prescribe Wegovy to Plaintiff.
- 242. Upon information and belief, had Plaintiff's prescribing physician(s) been informed of the increased risk of gastroparesis and its sequelae causally associated with Wegovy, Plaintiff's prescribing physician(s) would not have prescribed Wegovy and/or would have provided Plaintiff with adequate information regarding safety of Wegovy to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy.
- 243. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, they would not have prescribed Wegovy and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Wegovy so that Plaintiff can make an informed decision regarding Plaintiff's use of Wegovy.
- 244. Plaintiff had no way to determine the truth behind Defendant's false and/or misleading statements, concealments and omissions surrounding Wegovy, and reasonably relied on false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiff had no way to know were omitted.

- 245. Plaintiff justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to accept, purchase and/or consume Wegovy.
- 246. Had Plaintiff been told of the increased risk of gastroparesis and its sequelae causally associated with Wegovy, Plaintiff would not have used Wegovy and/or suffered gastroparesis and its sequelae.
- 247. Had Plaintiff been told of the lack of sufficient and/or appropriate testing of Wegovy for safety risks, including gastroparesis and its sequelae, Plaintiff would not have used Wegovy and/or suffered gastroparesis and its sequelae.
- 248. As a direct and proximate result of the above stated false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in 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 abovenamed health consequences.
- 249. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

EIGHTH CAUSE OF ACTION (NEGLIGENT MISREPRESENTATION-AGAINST ALL DEFENDANTS)

- 250. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 251. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Wegovy, which were used by Plaintiff as hereinabove described.
- 252. At all relevant times, knew or should have known that Ozempic and Wegovy had not been adequately and/or sufficiently tested for safety.
- 253. At all relevant times, Defendants knew or should have known of the serious side effects of Wegovy, including gastroparesis and its sequelae.
- 254. Defendants had a duty to disclose material information about Wegovy to Plaintiff and Plaintiff's prescribing physician(s), including that Wegovy is causally associated with increased risk of gastroparesis and its sequelae, because Defendants held a special expertise with respect to Wegovy, Plaintiff, as a user of Wegovy, had a special relationship of trust with Defendants, and Defendants knew that their statements regarding the risks causally associated with Wegovy would be relied on by Wegovy users.
- 255. At all relevant times, Defendants knew or should have known of the serious side effects of Wegovy, including gastroparesis and its sequelae.

- 256. Nonetheless, Defendants made material misrepresentations and omissions and/or concealments to Plaintiff, Plaintiff's prescribing physician[s], the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Wegovy.
- 257. Defendants represented affirmatively and by omission on television advertisements, social media and other online advertisements, and on the label of Ozempic that Ozempic was a safe and effective drug for treatment of adults with Type 2 diabetes, despite being aware of the increased risks of gastroparesis and its sequelae causally associated with using Ozempic.
- 258. Defendants represented affirmatively and by omission on television advertisements, social media, and other online advertisements, and on the label of Wegovy that Wegovy was a safe and effective drug for chronic weight management in adults with a BMI of 30 kg/m2 or greater, or 27 kg/m2 or greater and one or more weight-related comorbid conditions, despite being aware of increased risks of gastroparesis and its sequelae causally associated with using Wegovy.
- 259. Defendants were aware or should have been aware that their representations were false or misleading and/or knew that Defendants were concealing and/or omitting material information from Plaintiff, Plaintiff's prescribing physician[s], the medical and healthcare community, and the general public.

- 260. Defendants knew that Plaintiff and Plaintiff's prescribing physicians (s) had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding Wegovy, as set forth herein.
- 261. Upon information and belief that Plaintiff's prescribing physician(s) justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to prescribe Wegovy to Plaintiff.
- 262. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of gastroparesis and its sequelae causally associated with Wegovy, they would not have prescribed Wegovy and/or would have provided Plaintiff with adequate information regarding the safety of Wegovy so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy.
- 263. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Wegovy had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, they would not have prescribed Wegovy and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Wegovy so that Plaintiff can make an informed decision regarding Plaintiff's use of Wegovy.
- 264. Plaintiff reasonably relied on the false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiff had no way to know were omitted.

- 265. Had Plaintiff been told of the increased risk of gastroparesis and its sequelae causally associated with Wegovy, Plaintiff would not have used Wegovy and/or suffered gastroparesis and its sequelae.
- 266. Defendants' misrepresentations and omissions of material facts amount to willful, wanton, and/or reckless conduct.
- 267. As a direct and proximate result of the above stated false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis, which resulted in 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 abovenamed health consequences.
- 268. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

NINTH CAUSE OF ACTION (LOSS OF CONSORTIUM)

269. Plaintiff George Peach re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

- 270. Plaintiff George Peach is, and at all time herein mentioned was, the lawful spouse of Plaintiff Dana Peach.
- 271. As a direct, legal and proximate result of the culpability and fault of the Defendants, be such fault through strict liability or negligence, Plaintiff George Peach suffered the loss of support, service, love, companionship, affection, society, intimate relations, and other elements of consortium, all to his general damage, in an amount in excess of the jurisdictional minimum of this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

- 1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;
- 2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendants, who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
 - 3. Awarding Plaintiff, the costs of these proceedings; and
 - 4. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all issues.

Dated: June 28, 2024.

s/ Roopal P. Luhana
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