UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MARY ARREDONDO,

Plaintiff,

v.

NOVO NORDISK, INC.;
NOVO NORDISK US COMMERICAL HOLDINGS INC,;
NOVO NORDISK A/S;
NOVO NORDISK NORTH AMERICA OPERATIONS A/S;
NOVO NORDISK RESEARCH CENTER SEATTLE, INC.; and
NOVO NORDISK PHARMACEUTRIAL INDUSTRIES LP,

Defendants.

Case No. 1:24-cv-1147

COMPLAINT

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, MARY ARREDONDO, by and through undersigned attorneys, hereby bring this cause of action and allege, upon information and belief and based on the investigation to date of counsel, as follows:

JURISDICTION AND VENUE

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

2. This Court has personal jurisdiction over Defendants, consistent with the United States Constitution and 735 Ill. Comp. Stat. Ann. 5/2-209 (Illinois' "long arm" statute), as Plaintiff's claims arise out of Defendants' transaction of business and the tortious acts within the State of Illinois, and by virtue of Defendants' substantial, continuous, and systematic contacts with the State of Illinois unrelated to Plaintiff's claims.

3. Venue is proper under 28 U.S.C. § 1391(b)(2), because a substantial part of the events or omissions giving rise to the claim occurred are situated, or a substantial part of property that is the subject of the action is situated in this district.

NATURE OF THE CASE

4. This is an action for damages suffered by Plaintiff, MARY ARREDONDO, who was severely injured as a result of Plaintiff's use of Ozempic, injectable prescription medications that are used to control blood sugar in patients with type 2 diabetes.

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

6. Ozempic belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

7. 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 sequelae.

[1] *See, e.g.,* CT Jones, ***Ozempic*** *Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell",* Rolling Stone (July 25, 2023), https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601 (last visited on Jan. 30, 2024).

8. 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]

PARTY PLAINTIFF

9. Plaintiff, Mary Arredondo, is a citizen of the United States, and is a resident of Illinois.

10. Plaintiff is 54 years old.

11. Plaintiff began using Ozempic in July 2021.

12. Plaintiff's physician(s) ("prescribing physician(s)") prescribed the Ozempic that was used by Plaintiff.

13. As a result of using Ozempic, Plaintiff was caused to suffer from stomach paralysis and intestinal blockage 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 Ozempic, Plaintiff was caused to suffer from stomach paralysis and intestinal blockage, which resulted in, for example, severe vomiting, diarrhea, dizziness,

[2] Gastroparesis, Mayo Clinic (June 11, 2022), https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787 (last visited on Jan. 30, 2024).

dehydration, stomach pain, requiring additional medications to treat severe vomiting, and multiple emergency room visits due to severe vomiting and stomach pain.

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

PARTY DEFENDANTS

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

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

18. 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.

19. Upon information and belief, Defendant Novo Nordisk US Holdings Inc. is wholly owned by Defendant Novo Nordisk A/S.

20. Defendant Novo Nordisk A/S is a public limited liability company organized under the laws of Denmark with a principal place of business at Novo Allé, DK-2880, Bagsværd, Denmark.

21. Defendant Novo Nordisk North America Operations A/S is a company organized under the laws of Denmark with a principal place of business in Novo Allé, DK-2880 Bagsværd, Denmark.

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

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

24. Defendant Novo Nordisk Pharmaceutical Industries LP is the labeler for Ozempic, and Defendants Novo Nordisk A/S and Novo Nordisk Inc. are also identified on Ozempic's label.[3]

25. 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., and Novo Nordisk Pharmaceutical Industries LP are referred to collectively herein as "Novo Nordisk." Novo Nordisk designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic. Alternatively, Novo Nordisk has acquired the entity/entities who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Ozempic and is, thus, the successor to such entity/entities.

FACTUAL BACKGROUND

A. FDA's Approval of Ozempic

26. On December 5, 2016, Novo Nordisk announced submission of a new drug application (NDA) to the FDA for regulatory approval of once-weekly injectable semaglutide, a new glucagon-like peptide-1 (GLP-1) medication for treatment of type 2 diabetes. In the announcement Novo Nordisk represented that in clinical trials "once weekly semaglutide had a safe and well tolerated profile with the most common adverse event being nausea."[4]

27. On December 5, 2016, Defendant Novo Nordisk Inc. submitted NDA 209637, requesting that the FDA grant it approval to market and sell Ozempic (semaglutide) 0.5 mg or

[3] Ozempic prescribing information, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=adec4fd2-6858-4c99-91d4-531f5f2a2d79 (last visited on Jan. 30, 2024).
[4] Novo Nordisk, *Novo Nordisk files for regulatory approval of once-weekly semaglutide in the US and EU for the treatment of type 2 diabetes* (Dec. 5, 2016), https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183 (last visited on Jan. 30, 2024).

1 mg injection in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On December 5, 2017, the FDA approved NDA 209637.[5]

28. On March 20, 2019, Defendant Novo Nordisk Inc. submitted supplemental new drug application (sNDA) 209637/S-003 for Ozempic (semaglutide) 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.[6] On January 16, 2020, the FDA approved sNDA 209637/S-003.[7]

29. On May 28, 2021, Defendant Novo Nordisk Inc. submitted sNDA 209637/S-009, requesting approval for a higher 2 mg dose of Ozempic (semaglutide) injection. On March 28, 2022, the FDA approved sNDA 209637/S-009.[8]

B. Novo Nordisk's Marketing and Promotion of Ozempic

30. 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 Ql 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-lRAs 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

[5] FDA Approval Letter for NDA 209637 (Ozempic), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf (last visited Jan. 30, 2024).
[6] PR Newswire, *Novo Nordisk files for US FDA approval of oral semaglutide for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes* (Mar. 20, 2019), https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html (last visited on Jan. 30, 2024).
[7] FDA Supplement Approval Letter for NDA 209637/S-003 (Ozempic), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf (last visited Jan. 30, 2024).
[8] FDA Supplement Approval Letter for NDA 209637/S-009 (Ozempic), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209637Orig1s009ltr.pdf (last visited Jan. 20, 2024).

Nordisk is working with appropriate health insurance providers to establish innovative contracting solutions.[9]

31. On February 5, 2018, Novo Nordisk announced that it had started selling Ozempic in the United States and touted the medication as a "new treatment option[,]" that "addresses the concerns and needs of people with diabetes[.]" Novo Nordisk offered an "Instant Savings Card to reduce co-pays to as low as $25 per prescription fill for up to two years."[10]

32. 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.

33. 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]

34. On March 28, 2022, Novo Nordisk announced the FDA's approval of sNDA 209637/S-009 for a higher 2 mg dose of Ozempic (semaglutide) injection. In the press release, Novo Nordisk represented Ozempic as having "proven safety" and advertised that "plus it can help many patients lose some weight."[12]

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[9] *Novo Nordisk Receives FDA Approval of OZEMPIC® (semaglutide) Injection For the Treatment of Adults with Type 2 Diabetes*, Cision PR Newswire (December 05, 2017), https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-ozempic-semaglutide-injection-for-the-treatment-of-adults-with-type-2-diabetes-300567052.html (last visited on Feb. 1, 2024).

[10] *Novo Nordisk Launches Ozempic® and Fiasp®, Expanding Treatment Options for Adults with Diabetes*, Cision PR Newswire (February 05, 2018), https://www.prnewswire.com/news-releases/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment-options-for-adults-with-diabetes-300592808.html (last visited on Feb. 1, 2024).

[11] *Ozempic TVSpot*, 'Oh!', iSpot.tv (July 30, 2018), https://www.ispot.tv/ad/d6Xz/ozempic-oh (visited on Feb. 1, 2024).

[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), 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 (last visited on Feb. 1, 2024).

35. 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]

36. 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]

37. 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 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]

38. 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]

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[13] Ritzau, *Novo Nordisk runs TV ads in US for multimillion-dollar sum*, MedWatch (April 26, 2023), https://medwatch.com/News/Pharma___Biotech/article15680727.ece (last visited on Feb. 1, 2024).
[14] Ben Adams, *The top 10 pharma drug ad spenders for 2022*, Fierce Pharma (May 1, 2023), https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022 (last visited on Feb. 1, 2024).
[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), https://www.center4research.org/novo-nordisk-gave-doctors-450000-meals-ozempic/ (last visited on Feb. 1, 2024).
[16] *Id*.
[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), https://fortune.com/well/2023/07/21/ozempic-novo-nordisk-meals-travel-prescribing-doctors/ (last visited on Feb. 1, 2024); *See also* Erin Prater, *Weight-loss drugs like Ozempic and Wegovy may put certain people at risk of serious*

39. 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]

40. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,[20] and currently has over 1.3 billion views.[21]

41. On June 15, 2023, NBC News published a report about the "thousands of weight-loss ads on social media for the drugs Ozempic and 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 products, despite claiming in May that it would stop running ads due to a shortage of the drug.[22]

42. 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]

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

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complications, researchers warn, Fortune Well (March 7, 2023), https://fortune.com/well/2023/03/07/ozempic-wegovy-elevated-risk-intestinal-obstruction-later-type-2-diabetes-weight-loss-drug/ (last visited on Feb. 1, 2024).

[18] Annette Choi and Han Vu, *Ozempic prescriptions can be easy to get online. Its popularity for weight loss is hurting those who need it most* (March 17, 2023), https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/ (last visited on Feb. 1, 2024).

[19] Daniel Gilbert, *Insurers clamping down on doctors who prescribe Ozempic for weight loss*, The Washington Post (June 12, 2023), https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance/ (last visited on Feb. 1, 2024).

[20] Dani Blum, *What Is Ozempic and Why Is It Getting So Much Attention?*, The New York Times (Nov. 22, 2022), https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html (last visited on Feb. 1, 2024).

[21] https://www.tiktok.com/tag/ozempic (last visited on Feb. 1, 2024).

[22] David Ingram, *More than 4,000 ads for Ozempic-style drugs found running on Instagram and Facebook*, NBC News (June 15, 2023), https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602 (last visited on Feb. 1, 2024).

[23] Phoebe Bain, *Ozempic was 2023's Buzziest Drug*, Ad Age (July 10, 2023), https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571 (last visited on Feb. 1, 2024).

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

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

45. 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.[24]

46. 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.

47. 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.[25]

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

49. A 2016 trial funded by Novo Nordisk measuring semaglutide and cardiovascular outcomes in patients with type 2 diabetes found more gastrointestinal disorders in the

[24] Deborah Hinnen, *Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes*, 30(3) Diabetes Spectr., 202-210 (Aug. 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556578/ (last visited on Feb. 2, 2024).
[25] Adam M. Deane et al., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects*, Attenuating Postprandial Glycemia, 95(1) J Clinical Endo Metabolism, 225-221 (Jan. 1, 2010), https://academic.oup.com/jcem/article/95/1/215/2835243 (last visited on Feb. 2, 2024); American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests*, American Society of Anesthesiologists (June 29, 2023), 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 (last visited on Feb. 2, 2024).

semaglutide group than in the placebo group, including a severe adverse event report of impaired gastric emptying with semaglutide 0.5 mg together with other serious gastrointestinal adverse events such as abdominal pain (upper and lower), intestinal obstruction, change of bowel habits, vomiting, and diarrhea.[26]

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

51. 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."[27]

52. Another study in 2017 reviewed the survey results from 10,987 patients and 851 physicians and found that "GI-related issues were the top two patient-reported reasons for GLP-1RA discontinuation in the past 6 months, with 'Made me feel sick' as the most frequently

[26] Steven P. Marso, M.D., et al., *Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes*, N. Eng. J. Med. 375:1834-1844 (Nov. 10, 2016), https://www.nejm.org/doi/10.1056/NEJMoa1607141 (last visited on Feb. 2, 2024).

[27] Y. Nakatoni 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 (Oct. 2017), https://www.sciencedirect.com/science/article/pii/S1262363617301076 (last visited on Feb. 2, 2024).

reported reason (64.4%), followed by 'Made me throw up' (45.4%)."[28] As explained above, these are symptoms of gastroparesis.

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

54. In August of 2020, medical literature advised that some "patients do not know they have diabetic gastroparesis until they are put on a glucagon-like peptide 1 (GLP-1) receptor agonist such as ... semaglutide ... to manage their blood glucose." The article went on to explain that "[t]his class of drugs can exacerbate the symptoms of diabetic gastroparesis.... Thus, GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis."[29]

55. In a September 2020 article funded and reviewed by Novo Nordisk, scientists affiliated with Novo Nordisk reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes. More patients permanently discontinued taking oral semaglutide (11.6%) than placebo (6.5%) due to adverse events. The most common adverse events associated with semaglutide were nausea (2.9% with semaglutide versus 0.5% with placebo), vomiting (1 .5% with semaglutide versus 0.3% with placebo), and diarrhea (1.4% with semaglutide versus 0.4% with placebo). Injectable semaglutide had a discontinuation rate of 11.5-14.5% (versus 5.7-7.6% with placebo) over a two-year period. The authors acknowledged the potential for severe gastrointestinal events, warning that "[f]or patients reporting severe adverse gastrointestinal reactions, it is advised to

[28] Mirko V Sikirica 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 (Sept. 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5630073/ (last visited on Feb. 2, 2024).
[29] Clipper F. Young et al., *Diabetic Gastroparesis: A Review*, 33(3) Diabetes Spect., 290-297 (Aug. 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/ (last visited on Feb. 2, 2024).

monitor renal function when initiating or escalating doses of oral semaglutide." For patients with other comorbidities, the study warned that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-lRAs." The study further identified as one "key clinical take-home point" that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-lRAs."[30]

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

[30] Ofri Mosenzon et al., *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, https://www.tandfonline.com/doi/full/10.1080/00325481.2020.1800286 (last visited on Feb. 2, 2024).
[31] Mark M. Smits and Daniel H. Van Raalte, *Safety of Semaglutide*, Front. Endocrinol. (July 7, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8294388/ (last visited on Feb. 2, 2024).

57. 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-IRAs 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]

58. Case Report #1 in JIM involved a 52-year-old female with long-standing (10 years) well-controlled, type 2 diabetes who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis symptoms. The patient was referred with a 7-month history of post-prandial epigastric pain, accompanied by fullness, bloating, and nausea. A gastric emptying study showed a 24% retention of isotope in the patient's stomach at four hours, indicative of delayed gastric emptying. The patient discontinued semaglutide and her symptoms resolved after six weeks. The case report authors concluded that "thorough history taking revealed the cause [of gastroparesis] to be medication induced."[33]

59. 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

[32] M Ammar Kalas, Gian Marco Galura, and Richard W. McCallum, *Medication-Induced Gastroparesis: A Case Report*, J Investig. Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (last visited on Feb. 2, 2024).
[33] *Id*.

four hours, indicating delayed gastric emptying. After discontinuing dulaglutide, the patient experienced a gradual resolution of symptoms over a four-week period.[34]

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

61. 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]

62. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[37]

63. In February 2023, a longitudinal study of GLP-1RA (dulaglutide) reported adverse events for nausea and vomiting, and one adverse event of impaired gastric emptying.[38]

64. 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]

65. 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

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[34] *Id.*
[35] Ania M. Jastreboff et al., *Tirzepatride Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022), https://www.nejm.org/doi/10.1056/NEJMoa2206038 (last visited on Feb. 2, 2024).
[36] Yamin Shu et al., *Gastrointestinal adverse events associated with semaglutide: A pharmacovigilance study based on FDA adverse event reporting system*, Front. Public Health (Oct. 20, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9631444/ (last visited on Feb. 2, 2024).
[37] Rahul Mishra et al., *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9915969/ (last visited on Feb. 2, 2024).
[38] Rina Chin et al., *Safety and effectiveness of dulaglutide 0.75 mg in Japanese patients with type 2 diabetes in real-world clinical practice: 36 month post-marketing observational study*, J Diabetes Investig (Nov. 11, 2022), https://pubmed.ncbi.nlm.nih.gov/36367417/ (last visited on Feb. 2, 2024).
[39] Sandra R. Klein and Ion A Hobai, *Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report*, Can J. Anesth (Mar. 28, 2023), https://pubmed.ncbi.nlm.nih.gov/36977934/ (last visited on Feb. 2, 2024).

before elective surgery because these medications "delay gastric (stomach) emptying" and "the delay in stomach emptying could be associated with an increased risk of regurgitation and aspiration of food into the airways and lungs during general anesthesia and deep sedation." The ASA also warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[40]

66. News sources have identified the potential for serious side effects in users of Ozempic, including gastroparesis, leading to hospitalization.[41] For example, NBC News reported in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable, and one user said that five weeks into taking the medication she found herself unable to move off the bathroom floor because she had "vomited so much that [she] didn't have the energy to get up."[42] CNN reported in July that one Ozempic user diagnosed with gastroparesis vomits so frequently that she had to take a leave of absence from her teaching job.[43]

67. A July 25, 2023, article in Rolling Stone magazine-"Ozempic Users Report Stomach Paralysis from WeightLoss Drug: 'So Much Hell'"-highlighted three patients who

[40] American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), 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 (last visited on Feb. 2, 2024).

[41] Penny Min, *Ozempic May Cause Potential Hospitalizations*, Healthnews (June 26, 2023), https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/ (last visited on Feb. 2, 2024); Elizabeth Laura Nelson, *These Are the 5 Most Common Ozempic Side Effects, According to Doctors, Best Life* (April 3, 2023), https://bestlifeonline.com/ozempic-side-effects-news/ (last visited on Feb. 2, 2024); Cara Lynn Shultz, *Ozempic and Wegovy May Cause Stomach Paralysis in Some Patients*, People (July 26, 2023), https://people.com/ozempic-wegovy-weight-loss-stomach-paralysis-7565833 (last visited on Feb. 2, 2024); CBS News Philadelphia, Popular weight loss drugs Ozempic and Wegovy may cause stomach paralysis, doctors warn (July 25, 2023), https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomach-paralysis/ (last visited on Feb. 2, 2024).

[42] Aria Bendix and Berkeley Lovelace Jr., *What it's like to take the blockbuster drugs Ozempic and Wegovy, from severe side effects to losing 50 pounds*, NBC News (Jan. 29, 2023), https://www.nbcnews.com/health/health-news/ozempic-wegovy-diabetes-weight-loss-side-effects-rcna66493 (last visited on Feb. 2, 2024).

[43] Brenda Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN (July 25, 2023), https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis/index.html (last visited on Feb. 2, 2024).

have suffered severe gastrointestinal related events, including gastroparesis, as a result of their use of GLP-1RAs. Patient 1 (female, age 37) reported incidents of vomiting multiple times per day and being unable to eat. The patient's physician diagnosed her with severe gastroparesis and concluded that her problems were caused and/or exacerbated by her use of a GLP-1RA medication. Patient 2 (female) used Ozempic for one year and reported incidents of vomiting, including multiple times per day. The patient's physician diagnosed her with severe gastroparesis related to her Ozempic use. Patient 3 (female, age 42) experienced severe nausea both during and after she discontinued use of a GLP-1RA. In a statement to Rolling Stone, Novo Nordisk acknowledged that "[t]he most common adverse reactions, as with all GLP-1 RAs, are gastrointestinal related." Novo Nordisk further stated that while "GLP-1 RAs are known to cause a delay in gastric emptying, ... [s]ymptoms of delayed gastric emptying, nausea and vomiting are listed as side effects." Novo Nordisk did not claim to have warned consumers about gastroparesis, or other severe gastrointestinal issues.[44]

68. On July 25, 2023, CNN Health reported that patients taking Ozempic have been diagnosed "with severe gastroparesis, or stomach paralysis, which their doctors think may have resulted from or been exacerbated by the medication they were taking, Ozempic." Another patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.[45]

69. On July 26, 2023, a New York hospital published an article to its online health blog section "What You Need to Know About Gastroparesis" entitled "Delayed Stomach Emptying

[44] CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell'*, Rolling Stones (July 25, 2023), https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601/ (last visited on Feb. 2, 2024).

[45] Brenda Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN Health (July 25, 2023), https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis (last visited on Feb. 2, 2024).

Can Be Result of Diabetes or New Weight-Loss Medicines." It was reported that a growing number of gastroparesis cases had been seen in people taking GLP- RAs. The article noted that the weight-loss drugs can delay or decrease the contraction of muscles that mix and propel contents in the gastrointestinal tract leading to delayed gastric emptying. One concern raised was that patients and doctors often assume the symptoms of gastroparesis are reflux or other gastrointestinal conditions, meaning it may take a long time for someone to be diagnosed correctly.[46]

70. 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.[47] 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.

71. 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.[48]

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[46] *Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines*, Montefiore Health Blog article (released July 26, 2023), https://www.montefiorenyack.org/health-blog/what-you-need-know-about-gastroparesis (last visited on Feb. 2, 2024).

[47] Mohit Sodhi, MSc et al., *Risk of Gastrointestinal Adverse Events Associated With Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss*, Jama Network (Oct. 5, 2023), https://jamanetwork.com/journals/jama/fullarticle/2810542 (last visited on Feb. 2, 2024).

[48] Cure, *Exenatide and Rare Adverse Events*, N. Eng. J. Med. (May 1, 2008) (https://doi.org/10.1056/nejmc0707137); Puja Rai et al., *Liraglutide-induced Acute Gastroparesis*, Cureus (Dec. 28, 2018) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6402745/); Guo, *A Post Hoc Pooled Analysis of Two Randomized Trials*, Diabetes Ther (2020) (https://doi.org/10.1007®sl3300-020-00869-z); Sami Almustanyir et al., *Gastroparesis With the Initiation of Liraglutide: A Case Report*, Cureus (Nov. 28, 2020) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7773310/); Yo Ishihara et al., *Suspected Gastroparesis With Concurrent Gastroesophageal Reflux Disease Induced by Low-Dose Liraglutide*, Cureus (Jul. 16, 2022) (https://pubmed.ncbi.nlm.nih.gov/35983392/); Veronica Preda et al., *Gastroparesis with bezoar formation in patients*

72. Defendants knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae, but they ignored the causal association. Defendants' actual and constructive knowledge derived from their clinical studies, case reports, medical literature, including the medical literature and case reports referenced above in this Complaint.

73. On information and belief, Defendants not only knew or should have known that their GLP-1RAs cause delayed gastric emptying, resulting in risks of gastroparesis, but they may have sought out the delayed gastric emptying effect due to its association with weight loss. For example, a recent study published in 2023 notes that "it has been previously proposed that long-acting GLP-1RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying,]" and the study authors suggested "further exploration of peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake."[49]

D. Defendants Failed to Warn of the Risk of Gastroparesis from Ozempic

74. The Prescribing Information for Ozempic (the "label") discloses "Warnings and Precautions" and "Adverse Reactions" but does not adequately warn of the risk of gastroparesis and its sequalae.[50]

75. The Ozempic label lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Ozempic patients, but it does not include these adverse reactions in its "Warnings and Precautions" section, nor does it warn that these

treated with glucagon-like peptide-1 receptor agonists: potential relevance for bariatric and other gastric surgery, BJS Open (Feb. 1, 2023) (https://academic.oup.com/bjsopen/article/7/1/zrac169/7021142?login=false).

[49] Mojca Jensterle PhD et al., *Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity*, 25(4) Diabetes Obes. Metab. 975-984 (April 2023), https://dom-pubs.onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944 (last visited on Feb. 2, 2024).

[50] *See* https://www.novo-pi.com/ozempic.pdf.

adverse reactions are symptoms of more severe conditions, including gastroparesis. In fact, gastroparesis is not mentioned at all in the label.

76. Instead of properly disclosing gastrointestinal risks, the label discloses delayed gastric emptying in the "Drug Interaction" section and notes that Ozempic "may impact absorption of concomitantly administered oral medications." Similarly, in the "Mechanism of Action" section, the label minimizes gastrointestinal risks by stating that "[t]he mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase." These statements only describe the drug's mechanism of action and do not disclose gastroparesis as a risk of taking Ozempic, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Ozempic.

77. Similarly, Novo Nordisk's main promotional website for Ozempic (ozempic.com) includes a variety of information about the benefits of Ozempic relating to blood sugar, cardiovascular health, and weight loss, as well as "Important Safety Information" - however, Novo Nordisk does not disclose the risk of gastroparesis within the "Important Safety Information" section of their promotional website.[51]

78. None of Defendants' additional advertising or promotional materials warned prescription providers or the general public of the risks of gastroparesis and its sequalae.

79. In January 2020, Novo Nordisk removed the "Instructions" portion from Section 17 "Patient Counseling Information" of the Ozempic label, which had instructed prescribers to "[a]dvise patients that the most common side effects of Ozempic are nausea, vomiting, diarrhea, abdominal pain and constipation." These instructions were present in the 2017 and 2019 labels.

[51] *See* Ozempic.com (last visited on Feb. 2, 2024).

80. The 2017 and 2019 labels for Ozempic also instructed physicians that "vomiting ... decreases over time in the majority of patients." As a result, a physician would not only fail to appreciate vomiting as a symptom of gastroparesis but, even worse, would encourage a patient to continue using Ozempic despite symptoms of gastroparesis.

81. In its section on "Females and Males of Reproductive Potential," the Ozempic label advises female users to discontinue Ozempic at least 2 months before a planned pregnancy due to the long washout period for semaglutide. This demonstrates that Novo Nordisk knew or should have known that symptoms, such as continuous and violent vomiting, can linger long after the drugs are discontinued and shows the need to warn of gastroparesis and its sequelae.

82. From the date Novo Nordisk received FDA approval to market Ozempic until the present time, Novo Nordisk made, distributed, marketed, and/or sold Ozempic without adequate warning to Plaintiffs prescribing physician(s) and/or Plaintiff that Ozempic was causally associated with and/or could cause gastroparesis and its sequelae.

83. Defendants knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae. Defendants' 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.

84. Upon information and belief, Defendants ignored the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae.

85. 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 Ozempic inadequate.

86. On information and belief, as a result of Novo Nordisk's inadequate warnings, the medical community at large, and Plaintiffs prescribing physician in particular, were not aware that Ozempic can cause gastroparesis, nor were they aware that "common adverse reactions" listed on the label might be sequelae of gastroparesis.

87. On information and belief, had Novo Nordisk adequately warned Plaintiffs prescribing physician that Ozempic is causally associated with gastroparesis and its sequelae, then the physician's prescribing decision would have changed by not prescribing Ozempic, or by monitoring Plaintiff's health for symptoms of gastroparesis and discontinuing Ozempic when the symptoms first started.

88. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from gastroparesis and its sequelae, 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 above-named health consequences.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

89. 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.

90. Illinois law imposes a duty on the manufacturer of a product to exercise reasonable care in the design of a product to protect those who may be reasonably expected to be in the foreseeable area of the use of the product, from unreasonable risk of harm.

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

92. At all times mentioned herein, Defendants had a duty to Plaintiff to exercise reasonable care in the design, research, manufacture, testing, advertising, promotion, marketing, selling, and/or distributing of Ozempic.

93. At all times mentioned herein, Defendants had a duty to Plaintiff to exercise reasonable care in the inspection of Ozempic and to locate visible or hidden defects in the product that could lead to harm or injury.

94. At all times mentioned herein, Defendants had a duty to Plaintiff to exercise reasonable care, as Plaintiff was reasonably expected to be in the vicinity of Ozempic's probable use and to be endangered in the event that Ozempic is defective.

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

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

97. At all relevant times, Plaintiff was a foreseeable user or consumer of Ozempic.

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

99. As a direct or proximate result of the foregoing acts and omissions, 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, 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.

100. 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
(INADEQUATE WARNING AGAINST ALL DEFENDANTS)

101. 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.

102. Illinois law imposes a duty on producers, manufacturers, distributors, lessors, and sellers of a product to exercise all reasonable care when producing, manufacturing, distributing, leasing, and selling their products.

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

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

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

106. Despite the fact that Defendants knew or should have known that Ozempic caused unreasonably dangerous injuries, Defendants continued to market, distribute, and/or sell Ozempic to consumers, including Plaintiff, without adequate warnings.

107. Despite the fact that Defendants knew or should have known that Ozempic caused unreasonably dangerous injuries, Defendants continued to market Ozempic to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

108. 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.

109. At all relevant times, given their lack of efficacy and increased safety risks, Ozempic was not fit for the ordinary purpose for which it was intended— namely, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

110. At all relevant times, given their lack of efficacy and increased safety risks, Ozempic did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

111. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Ozempic 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 and its sequelae.

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

113. The Ozempic 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 this product created a risk of serious and dangerous injuries, including gastroparesis and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendants failed to adequately warn of said risk.

114. The Ozempic 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 and its sequelae, as well as other severe and permanent health consequences from Ozempic, they failed to provide adequate warnings to users and/or prescribers of the product, and continued to improperly advertise, market and/or promote their product, Ozempic.

115. The labels for Ozempic were inadequate because they did not warn and/or adequately warn of all possible adverse side effects associated with the use of Ozempic, including gastroparesis and its sequelae.

116. The labels for Ozempic were inadequate because they did not warn and/or adequately warn that Ozempic had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae.

117. The label for Ozempic was inadequate because they did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Ozempic.

118. The label for Ozempic 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.

119. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) was inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic, including the gastroparesis and its sequelae.

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

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

122. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and his/her/their reliance upon Defendants' warnings was reasonable.

123. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of gastroparesis and its sequelae, associated with Ozempic, then the prescribing physician(s) would not have prescribed Ozempic and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic.

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

125. Had Plaintiff had been warned of the increased risk of gastroparesis and its sequelae, which are causally associated with Ozempic, then Plaintiff would not have used Ozempic and/or suffered severe gastrointestinal events.

126. Had Plaintiff had been warned that Ozempic had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, then Plaintiff would not have used Ozempic and/or suffered gastroparesis and its sequelae.

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

128. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Ozempic due to the risks of gastroparesis and

its sequelae, or the lack of adequate testing for safety risks, then Plaintiff's prescribing physician(s) would not have prescribed Ozempic.

129. By reason of the foregoing, Defendants have become liable to Plaintiff for the designing, marketing, promoting, distribution and/or selling of unreasonably dangerous product, Ozempic.

130. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product 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.

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

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

133. As a direct or proximate result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, as well 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.

134. 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
(BREACH OF EXPRESS WARRANTY AGAINST ALL DEFENDANTS)

135. 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.

136. At all times mentioned herein, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Ozempic that was used by Plaintiff.

137. At all relevant times, Defendants expressly warranted to Plaintiff and Plaintiff's prescribing physician(s) that Ozempic was safe to improve glycemic control in adults with type 2 diabetes mellitus, reduce cardiovascular risk, and/or to promote weight loss.

138. At all relevant times, Defendants expressly warranted to Plaintiff and Plaintiff's prescribing physician(s) that Ozempic was effective to use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

139. At all relevant times, Defendants expressly warranted to Plaintiff and his prescribing physician(s) that the effectiveness of Ozempic outweighed any potential dangers and/or risks.

140. The aforementioned express warranties were made to Plaintiff and Plaintiff's prescribing physician(s) by way of Ozempic's label, website, advertisements, promotional materials, and through other statements.

141. As a result of Defendants' express warranties, Plaintiff's prescribing physician was induced to prescribe Ozempic to Plaintiff, and Plaintiff was induced to use Ozempic.

142. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Ozempic based upon their express warranties.

143. 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 Ozempic based upon their express warranties.

144. At all relevant times, Defendants knew or should have known that Ozempic was unreasonably dangerous because of the increased risk of gastroparesis and its sequelae, especially when the drugs were used in the form and manner as provided by Defendants.

145. At all relevant times, Defendants knew or should have known that Ozempic had not been sufficiently and/or adequately tested for safety.

146. The unreasonably dangerous characteristics of Ozempic were beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drug's characteristics.

147. The unreasonably dangerous characteristics of Ozempic were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drug's characteristics.

148. At the time Ozempic left the Defendants' control, Ozempic did not conform to Defendants' express warranties because Ozempic was not safe to use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, in that they were associated with an increased risk of gastroparesis and its sequelae.

149. The express warranties made by Defendants regarding the safety of Ozempic were made with the intent to induce Plaintiff to use the product and/or Plaintiff's prescribing physician(s) to prescribe the product.

150. 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 Ozempic and/or the natural tendency of Plaintiff's prescribing physician(s) to prescribe Ozempic.

151. Plaintiff and Plaintiff's prescribing physician(s), as well as members of the medical community, justifiably relied on the express warranties of Defendants identified herein.

152. Had Defendants not made these express warranties, Plaintiff would not have used Ozempic and/or, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Ozempic.

153. Plaintiff's injuries and damages were directly caused by Defendants' breach of the aforementioned express warranties.

154. Plaintiff's injuries and damages arose from a reasonably anticipated use of the products by Plaintiff.

155. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiff.

156. As a direct or proximate result of the foregoing acts and omissions, 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, 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.

157. 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' Ozempic drug.

158. 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.

FOURTH CAUSE OF ACTION
(ILLINOIS CONSUMER FRAUD ACT)

159. 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.

160. Ozempic is "merchandise," as that term is defined by the Consumer Fraud Act, 815 Ill. Comp. Stat. Ann. 505/1.

161. Defendants are the designer, researcher, manufacturer, tester, advertiser, promoter, marketed, seller, and/or distributer of Ozempic into the stream of commerce.

162. Defendants knew or should have known that the use of Ozempic causes serious and dangerous injuries but failed to warn the public, including Plaintiff and Plaintiff's prescribing physician(s), of the same.

163. In violation of the Consumer Fraud Act, Defendants made untrue, deceptive, or misleading representations of material facts to and knowingly omitted and/or concealed

material facts from Plaintiff in product packaging, labeling, advertising, promotional campaigns and materials, among other ways, regarding the safety and use of Ozempic.

164. Defendants knew of the growing public acceptance of the misinformation and misrepresentations regarding the safety and efficacy of Ozempic but continued to misrepresent material facts and remained silent about the truth.

165. The aforesaid conduct constitutes an unconscionable commercial practice, deception, false pretense, misrepresentations, and/or the knowing concealment, suppression, or omission of material facts with the intent that others, including prescribing physicians and consumers such as Plaintiff, would rely upon such concealment, suppression, or omission in connection with the sale or advertisement of such merchandise or services by Defendants, in violation of the Consumer Fraud Act.

166. Defendants concealed, omitted, or minimized the dangers of Ozempic or provided misinformation about adverse reactions, risks, and potential harms from Ozempic.

167. Defendants' practice of promoting and marketing Ozempic created and reinforced a false impression as to the safety of Ozempic, thereby placing consumers at risk of serious and dangerous effects.

168. Ozempic lacked appropriate warnings, and the packaging and labels used by Defendants were misleading, inaccurate, incomplete, and/or untimely.

169. Defendants' actions in connection with manufacturing, distributing, and marketing of Ozempic as set forth herein evidence a lack of good faith, honesty in fact and observance of fair dealing so as to constitute unconscionable commercial practices, in violation of the Consumer Fraud Act.

170. As a direct or proximate result of the foregoing acts and omissions, 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, 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.

171. 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.

FIFTH CAUSE OF ACTION
(MANUFACTURING DEFECT)

172. 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.

173. At all relevant times, Ozempic contained a manufacturing defect which made it not reasonably safe.

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

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

176. At all relevant times, Plaintiff was a foreseeable user or consumer of Ozempic.

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

178. As a direct or proximate result of the foregoing acts and omissions, 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, 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.

179. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands 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

Plaintiff hereby demands trial by jury as to all issues.

Dated: February 9, 2024

Respectfully submitted,

THE SIMON LAW FIRM, P.C.

/s/ *Anthony G. Simon*

Anthony G. Simon, IL #6209056
THE SIMON LAW FIRM, P.C.
800 Market Street, Suite 1700
St. Louis, Missouri 63139
Tel: (314) 241-2929
Fax: (314) 241-2029
Email: asimon@simonlawpc.com

ATTORNEY FOR PLAINTIFF