

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE GLUCAGON-LIKE PEPTIDE-1
RECEPTOR AGONISTS (GLP-1 RAS)
PRODUCTS LIABILITY LITIGATION

MDL NO. 3094

THIS DOCUMENT RELATES TO ALL
CASES

JUDGE KAREN SPENCER MARSTON

CLIFFORD CARROLL,

Plaintiff,

v.

NOVO NORDISK, INC. and
NOVO NORDISK A/S,

Defendants.

COMPLAINT AND JURY DEMAND

CIVIL ACTION NO.: 2:24-cv-5441

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff files this Complaint pursuant to the Direct Filing Order and is to be bound by the rights, protections and privileges, and obligations of that Direct Filing Order and other Orders of the Court. Further, in accordance with the Direct Filing Order, Plaintiff hereby designates the United States District Court for the District of Kansas as Plaintiff's designated venue ("Original Venue").

Plaintiff makes this selection based upon one (or more) of the following factors:

Plaintiff currently resides in Council Grove, Morris County, Kansas.

Plaintiff purchased and used Defendant(s)' product in Council Grove, Morris County, Kansas.

The Original Venue is a judicial district in which Defendant _____ resides, and all Defendants are residents of the State in which the district is located (28 USC § 1391(b)(1)).

The Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, specifically (28 USC § 1391(b)(2)):

Defendants routinely market Ozempic in this District and conduct business related to Ozempic in this District. Original Venue is further proper as Plaintiff resides in this District, was prescribed

Defendants' product in this District, purchased Defendants' product in this District, and was injured and treated in this District.

x There is no district in which an action may otherwise be brought under 28 USC § 1391, and the Original Venue is a judicial district in which Defendant Novo Nordisk is subject to the Court's personal jurisdiction with respect to this action (28 USC § 1391(b)(3)).

 Other reason (please explain): _____.

JURISDICTION AND VENUE

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

2. This Court has personal jurisdiction over Defendants, consistent with the United States Constitution and Kan. Stat. Ann. § 60-308 as Plaintiff's claims arise out of Defendants' transaction of business and their tortious acts within the State of Kansas, and by virtue of Defendants' substantial, continuous, and systematic contacts with the State of Kansas.

NATURE OF THE CASE

3. Plaintiff CLIFFORD CARROLL ("Plaintiff") by and through his attorneys, files this Complaint against Defendants Novo Nordisk, Inc. and Novo Nordisk A/S (collectively, "Defendants" or "Novo Nordisk Defendants") for their failure to warn Plaintiff about the true risks of its drug, Ozempic, as well as for negligence and deceptive and unfair marketing of the same

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

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

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-1 class of drugs.¹ However, Defendants have downplayed the severity of the gastrointestinal events and digestive events caused by Ozempic, never, for example, warning of the risk of gastroparesis (“paralyzed stomach”) and associated complications.

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, cause nausea, vomiting, abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, vomiting undigested food, undigested food that hardens and remains in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, malnutrition, and a decreased quality of life. There is no cure for gastroparesis.²

PARTIES

9. Plaintiff resides in and is a citizen of Council Grove, Morris County, Kansas.

10. Defendant Novo Nordisk, Inc. is a Delaware corporation with a principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey, 08536.

11. 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.

12. Upon information and belief, Defendants have conducted business in and derived substantial revenue from within the State of Kansas.

13. Defendants designed, researched, manufactured, tested, advertised, promoted,

¹ 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 <https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787> (last visited on 8/1/23).

marketed, sold, and/or distributed Ozempic.

14. All acts and omissions of Defendants, as described herein, were done by its agents, servants, employees, and/or owners acting in the course and scope of their respective agencies, services, employments, and/or ownership.

FACTUAL BACKGROUND

A. FDA's Approval of Ozempic

15. On December 5, 2016, the Novo Nordisk Defendants announced submission of a new drug application (NDA) to the FDA for regulatory approval of once-weekly injectable semaglutide, a new glucagon-like peptide-1 (GLP-1) medication for treatment of type 2 diabetes. In the announcement, Defendants represented that in clinical trials “once-weekly semaglutide had a safe and well tolerated profile with the most common adverse event being nausea.”³

16. On December 5, 2016, Defendant Novo Nordisk Inc. submitted NDA 209637, requesting that the FDA grant it approval to market and sell Ozempic (semaglutide) 0.5 mg or 1 mg injection in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On December 5, 2017, the FDA approved NDA 209637.⁴

17. 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.⁵ On January 16, 2020, the FDA approved sNDA 209637/S-003.⁶

18. On May 28, 2021, Defendant Novo Nordisk Inc. submitted sNDA 209637/S-009,

³ <https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ac7e-48fc6b731183> (last visited on 8/1/23).

⁴ https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf (last visited on 8/1/23).

⁵ <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 8/1/23).

⁶ https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf (last visited on 8/1/23).

requesting approval for a higher 2 mg dose of Ozempic (semaglutide) injection. On March 28, 2022, the FDA approved sNDA 209637/S-009.⁷

19. On March 28, 2022, the Novo Nordisk Defendants announced the FDA’s approval of sNDA 209637/S-009 for a higher 2 mg dose of Ozempic (semaglutide) injection. In the press release, Defendants represented Ozempic as having “proven safety and efficacy” and advertised that “plus it can help many patients lose some weight.”⁸ As with its prior press releases, Defendants disclosed Important Safety Information and a provided link to the Medication Guide and Prescribing Information, but severe gastrointestinal events including gastroparesis were not identified as risks.

B. Defendants’ Marketing and Promotion of Ozempic

20. On December 5, 2017, the Novo Nordisk Defendants announced the FDA’s approval of Ozempic (semaglutide) 0.5 mg or 1 mg injection in a press release stating that: “Novo Nordisk expects to launch OZEMPIC[®] in the U.S. in Q1 2018, with a goal of ensuring broad insurance coverage and patient access to the product. OZEMPIC[®] will be priced at parity to current market-leading weekly GLP-1 receptor agonists and will be offered with a savings card program to reduce co-pays for eligible commercially-insured patients. Additionally, as part of the access strategy, Novo Nordisk is working with appropriate health insurance providers to establish innovative contracting solutions.”⁹

21. On February 5, 2018, the Novo Nordisk Defendants announced that they had started selling Ozempic in the United States and touted the medication as a “new treatment option[.]” that “addresses the concerns and needs of people with diabetes[.]” The Novo Nordisk Defendants offered

⁷ https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/209637Orig1s009ltr.pdf (last visited on 8/1/23).

⁸ <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 8/1/23).

⁹ <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 8/1/23).

an “Instant Savings Card to reduce co-pays to as low as \$25 per prescription fill for up to two years.”¹⁰

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

23. On July 30, 2018, the Novo Nordisk Defendants launched their first television ad for Ozempic to the tune of the 1970s hit pop song “Magic” by Pilot wherein the Novo Nordisk Defendants advertised that “adults lost on average up to 12 pounds” when taking Ozempic, even though it is not a weight loss drug.¹¹

24. Over the next five years, the Novo Nordisk Defendants spent \$884,000,000 on running television ads in the United States to promote its semaglutide drugs (Ozempic, Wegovy and Rybelsus) with the majority of the spending allocated specifically to advertising Ozempic.¹²

25. On July 6, 2023, it was reported that the Novo Nordisk Defendants had spent \$11,000,000 on food and travel for doctors as part of the Novo Nordisk Defendants’ efforts to promote Ozempic.¹³

26. As a result of the Novo Nordisk Defendants’ advertising and promotion efforts, Ozempic has been widely used throughout the United States. The number of prescriptions filled reached an all-time high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.¹⁴ In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.¹⁵

27. On TikTok, the hashtag #Ozempic had 273 million views as of November 22,

¹⁰ <https://www.prnewswire.com/news-releases/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment-options-for-adults-with-diabetes-300592808.html> (last visited on 8/1/23).

¹¹ <https://www.ispot.tv/ad/d6Xz/ozempic-oh> (last visited on 8/1/23).

¹² https://medwatch.com/News/Pharma_____Biotech/article15680727.ece (last visited on 8/1/23).

¹³ <https://finance.yahoo.com/video/novo-nordisk-spent-11-million-155418308.html> (last visited on 8/1/23).

¹⁴ <https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/> (last visited on 8/1/23).

¹⁵ <https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance/> (last visited on 8/1/23).

2022,¹⁶ and currently has over 1.2 billion views.¹⁷

28. In 2023, a news report was published about the “thousands of weight-loss ads on social media for the drugs Ozempic and Wegovy.” And while many of those ads were found to be from online pharmacies, as of June 2023, the Novo Nordisk Defendants were still running online social-media ads for its semaglutide products despite claiming in May that it would stop running adds due to a shortage of the drug.¹⁸

29. 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.”¹⁹

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

31. On April 11, 2023, the New York Times reported that Mounjaro was “gaining attention, with many people using it off-label to lose weight.” The article described research which “found that Mounjaro may be even more powerful” than Ozempic, which it reported had recently “steamrolled through TikTok, talk shows and tabloids as people raved about using it off-label to lose weight.” Although Eli Lilly denied promoting or encouraging “the off-label use of any of our medicines[,]” it was obvious to Eli Lilly and others in the industry that Mounjaro was following Ozempic’s rising popularity for its weight loss effects. Furthermore, the same article also noted Eli Lilly’s October announcement regarding the FDA’s fast-track designation for its review of tirzepatide.²⁰

¹⁶ <https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html> (last visited on 8/1/23).

¹⁷ <https://www.tiktok.com/tag/ozempic> (last visited on 8/1/23).

¹⁸ <https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602> (last visited on 8/1/23).

¹⁹ <https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571> (last visited on 8/1/23).

²⁰ <https://www.nytimes.com/2023/04/11/well/live/ozempic-mounjaro-weight-loss-diabetes.html> (last visited on 8/1/23).

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

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

33. 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.²¹

34. Because the risks of gastroparesis and its sequelae is common to the entire class of drugs, any published literature regarding the association between gastroparesis and its sequelae 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 risks of gastroparesis and its sequelae associated with these drugs.

35. In addition to pancreatic effects, the published medical literature shows that GLP-1 slows gastric emptying and intestinal motility. As early as 2010, a study published in *The Journal of Clinical Endocrinology & Metabolism* concluded that GLP-1 slows gastric emptying.²²

36. Defendants knew or should have known of the risks of gastroparesis and its sequelae from the clinical trials, medical literature, and case reports.

37. A 2016 trial funded by Novo Nordisk measuring semaglutide and cardiovascular

²¹ 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/> (last visited on 9/26/23).

²² 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> (last visited on 9/26/23); American Society of Anesthesiologists, Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests (June 29, 2023), available at <https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery> (last visited on 9/26/23).

outcomes in patients with type 2 diabetes found more gastrointestinal disorders in the 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.²³

38. 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.

39. 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.”²⁴

40. Another study in 2017 reviewed the survey results from 10,987 patients and 851 physicians and found that “GI-related issues were the top two patient-reported reasons for GLP-1RA discontinuation in the past 6 months, with ‘Made me feel sick’ as the most frequently reported reason (64.4%), followed by ‘Made me throw up’ (45.4%).”²⁵ As explained above, these are symptoms of gastroparesis.

41. A 2019 study of the GLP-1RA drug dulaglutide identified adverse events for

²³ 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).

²⁴ 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> (last visited on 10/25/23).

²⁵ 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/>

impaired gastric emptying.

42. 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.”²⁶

43. In a September 2020 article funded and reviewed by Novo Nordisk, scientists affiliated with Novo Nordisk reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes. More patients permanently discontinued taking oral semaglutide (11.6%) than placebo (6.5%) due to adverse events. The most common adverse events associated with semaglutide were nausea (2.9% with semaglutide versus 0.5% with placebo), vomiting (1.5% with semaglutide versus 0.3% with placebo), and diarrhea (1.4% with semaglutide versus 0.4% with placebo). Injectable semaglutide had a discontinuation rate of 11.5-14.5% (versus 5.7-7.6% with placebo) over a two-year period. The authors acknowledged the potential for severe gastrointestinal events, warning that “[f]or patients reporting severe adverse gastrointestinal reactions, it is advised to monitor renal function when initiating or escalating doses of oral semaglutide.” For patients with other comorbidities, the study warned that “patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs.” The study further identified as one “key clinical take-home point” that “patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs.”²⁷

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

²⁷ 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).

44. A July 2021 article funded and reviewed by Novo Nordisk considered 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 GI-related adverse events, with some trials experiencing 100% discontinuation due to GI-related adverse events. The mean value of GR-related adverse events that led to discontinuation averaged 57.75%. The study acknowledges that while nausea and vomiting are unwanted side effects, “they may be partly responsible for aspects of the drug’s efficacy[.]”²⁸

45. 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 utmost 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.²⁹

46. 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

²⁸ 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/> (last visited on 9/26/23).

²⁹ 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)

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 his symptoms resolved after six weeks. The case report authors concluded that "thorough history taking revealed the cause [of gastroparesis] to be medication induced."³⁰

47. 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.³¹

48. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."³²

49. An October 2022 study analyzed 5,442 GLP-1RA adverse gastrointestinal events. Thirty-two percent 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.³³

50. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported

³⁰ 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).

³¹ 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).

³² Jastreboff, Tirzepatide Once Weekly for the Treatment of Obesity, N Engl J Med, at 214 (June 4, 2022) (<https://doi.org/10.1056/nejmoa2206038>).

³³ 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>).

high rates of nausea and vomiting.³⁴

51. 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.³⁵

52. 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.”³⁶

53. On June 29, 2023, the American Society of Anesthesiologists (“ASA”) warned that patients taking semaglutide and other GLP-1RAs should stop the medication at least a week before elective surgery because these medications “delay gastric (stomach) emptying” and “the delay in stomach emptying could be associated with an increased risk of regurgitation and aspiration of food into the airways and lungs during general anesthesia and deep sedation.” The ASA also warned that the risk is higher where patients on these medications have experienced nausea and vomiting.³⁷

54. News sources have identified the potential for serious side effects in users of Ozempic leading to hospitalization.³⁸ For example, NBC News reported in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable, and one user said

³⁴ Jastreboff, Tirzepatide Once Weekly for the Treatment of Obesity, *N Engl J Med*, at 214 (June 4, 2022) (<https://doi.org/10.1056/nejmoa2206038>).

³⁵ 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>).

³⁶ 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>).

³⁷ American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at <https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery> (last visited on 9/26/23).

³⁸ Penny Min, *Ozempic May Cause Potential Hospitalizations*, *healthnews* (June 26, 2023), available at <https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/> (last visited on 9/26/23); Elizabeth Laura Nelson, *These Are the 5 Most Common Ozempic Side Effects, According to Doctors*, *Best Life* (April 3, 2023), available at <https://bestlifeonline.com/ozempic-side-effects-news/> (last visited on 9/26/23); Cara Shultz, *Ozempic and Wegovy May Cause Stomach Paralysis in Some Patients*, *People* (July 26, 2023), available at <https://people.com/ozempic-wegovy-weight-loss-stomach-paralysis-7565833> (last visited on 9/26/23); CBS News Philadelphia, *Popular weight loss drugs Ozempic and Wegovy may cause stomach paralysis, doctors warn* (July 23, 2023), available at <https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomach-paralysis/> (last visited on 9/26/23).

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.”³⁹

55. A July 25, 2023 article in Rolling Stone magazine—“Ozempic Users Report Stomach Paralysis from Weight Loss Drug: ‘So Much Hell’”—discussed the severe gastrointestinal effects of GLP-1RAs. 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 and its sequelae, or other severe gastrointestinal issues.⁴⁰

56. On July 25, 2023, CNN Health reported that patients taking GLP-1RAs are experiencing severe gastrointestinal reactions. One patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.⁴¹

57. On July 26, 2023, a New York hospital published an article to its online health blog section noting that GLP-1RAs 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 doctors often misdiagnose the patients’ symptoms, meaning it may take a long time for someone to be diagnosed correctly.⁴²

³⁹ Bendix A, Lovelace B Jr., *What it’s like to take the blockbuster drugs Ozempic and Wegovy, from severe side effects to losing 50 pounds*, NBC News (Jan. 29, 2023), available at <https://www.nbcnews.com/health/health-news/ozempic-wegovy-diabetes-weight-loss-side-effects-rca66493> (last visited on 9/26/23).

⁴⁰ CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: ‘So Much Hell’*, Rolling Stone (July 25, 2023), available at <https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601> (last visited on 9/26/23).

⁴¹ Brenca Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN Health (July 25, 2023), available at <https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis> (last visited on 9/26/23).

⁴² *Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines*, Montefiore Health Blog

58. 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. The study found that patients prescribed GLP-1RAs were at 4.22 times higher risk of intestinal obstruction and 3.67 times higher risk of gastroparesis.⁴³

59. 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.

60. On information and belief, Defendants not only knew or should have known that their GLP-1RAs cause delayed gastric emptying and inhibit intestinal motility, resulting in risks of gastroparesis and its sequelae, 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,]”⁴⁴

article (released July 26, 2023), available at <https://www.montefiorenyack.org/health-blog/what-you-need-know-about-gastroparesis> (last visited on 9/26/2023).

⁴³ 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).

⁴⁴ Jensterle M et al., *Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity*, 25(4) Diabetes Obes. Metab. 975-984 (April 2023), available at <https://dom-pubs.onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944> (last visited on 9/26/23).

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

61. 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 sequelae.⁴⁵

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

63. 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.

64. Similarly, Novo Nordisk’s main promotional website for Ozempic (22zempic.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 the website.⁴⁶

65. In January 2020, Novo Nordisk removed the “Instructions” portion from Section 17

⁴⁵ <https://www.novo-pi.com/ozempic.pdf>

⁴⁶ See Ozempic.com (last visited on 10/16/23).

“Patient Counseling Information” of the Ozempic label, which had instructed prescribers to “[a]dvice 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.

66. 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 gastroparesis and its sequelae.

67. 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 Plaintiff’s prescribing physician(s) and/or Plaintiff that Ozempic was causally associated with and/or could cause gastroparesis and its sequelae.

68. Upon information and belief, 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.

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

70. 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.

71. 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.

E. Plaintiff's Medical History and Experiences.

72. Plaintiff was born on January 12, 1962.

73. Plaintiff began using Ozempic in the fall of 2022 for its intended use to treat type 2 diabetes.

74. Plaintiff's physician prescribed the Ozempic that was used by Plaintiff.

75. In 2022, after Plaintiff had been using Ozempic, he began suffering from persistent and severe abdominal pain and vomiting.

76. In late 2022, Plaintiff visited Olathe Medical Center complaining of persistent and severe abdominal pain and vomiting and was diagnosed with gastroparesis after undergoing a gastric emptying test.

77. After his gastroparesis diagnosis, Plaintiff discontinued his use of Ozempic.

78. As a result of using Defendants' Ozempic, Plaintiff was caused to suffer from severe gastrointestinal events, including severe abdominal pain, vomiting and gastroparesis. As a result, Plaintiff has sustained severe and potentially permanent personal injuries, pain, suffering, and emotional distress and incurred medical expenses.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

79. 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.

80. Defendants, directly or indirectly, caused Ozempic to be sold, distributed, packaged,

labeled, marketed, promoted, and used by Plaintiff. At all relevant times, Defendants registered, researched, distributed, marketed, overpromoted, and sold Ozempic within the State of Kansas and throughout the United States.

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

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

83. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known that the use of Ozempic could cause Plaintiff's injuries and, thus, created a dangerous and unreasonable risk of injury to Plaintiff and other users of this product for which Defendants did not warn.

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

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

86. In disregard of its duties, Defendants committed one or more of the following

negligent acts or omissions:

- a. Manufacturing, producing, overpromoting, marketing, formulating, creating, developing, designing, selling, and distributing Ozempic without thorough and adequate pre- and post-market testing of the product;
- b. Manufacturing, producing, overpromoting, marketing, advertising, formulating, creating, developing, and distributing Ozempic and, upon information and belief, while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Ozempic;
- c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Ozempic was safe for its intended use;
- d. Upon information and belief, failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendant knew and had reason to know that Ozempic was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;
- e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that Ozempic's risk of harm was unreasonable and that there were safer and effective alternative products available to Plaintiff and other consumers;
- f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use Ozempic;
- g. Advertising, marketing, and recommending the use of Ozempic while concealing and failing to disclose or warn of the dangers known by Defendant to be connected with and inherent in the use of Ozempic;

- h. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of Ozempic so as to avoid the risk of serious harm associated with the use of Ozempic. Failing to design and manufacture Ozempic so as to ensure the drug was at least as safe and effective as other similar products;
- i. Failing to ensure that Ozempic was accompanied by proper and accurate warnings about the risk of severe gastrointestinal problems including gastroparesis and its sequelae;
- j. Failing to ensure that Ozempic was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Ozempic and that use of Ozempic created a high risk of severe injuries; and
- k. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Ozempic.

87. A reasonable manufacturer, designer, distributor, promotor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

88. As a direct and proximate result of Defendants' negligent testing, monitoring, and pharmacovigilance of Ozempic, Defendants introduced a drug into this State that they knew or should have known would cause serious and severe complications in people, including Plaintiff, such as gastroparesis, an incurable condition, and Plaintiff has been injured catastrophically and sustained severe and permanent pain, suffering, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

89. The aforementioned negligence and wrongs done by Defendants were aggravated by the kind of grossly negligent conduct and disregard for the rights of others, the public, and Plaintiff, for which the law allows the imposition of exemplary or punitive damages, in that Defendants' conduct

involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants proceeded with a reckless disregard to the rights, safety, or welfare of others, including Plaintiff.

90. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Kansas law.

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

SECOND CAUSE OF ACTION
(NEGLIGENT FAILURE TO WARN)

92. 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.

93. Kansas tort 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.

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

95. 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.

96. 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 they were produced, manufactured, sold, distributed, and marketed by the Defendants.

97. At all relevant times, and at the times Ozempic left the Defendants' control, Defendants knew or should have known that Ozempic was and is unreasonably dangerous because Defendants did not adequately warn of the risks of severe gastrointestinal events and digestive events, especially when used in the form and manner as provided by Defendants.

98. 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.

99. 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.

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

101. At all relevant times, given its 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.

102. At all relevant times, given the increased safety risks, Ozempic did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

103. 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 severe gastrointestinal

events, including gastroparesis.

104. 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.

105. The Ozempic product designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the product created a risk of serious and dangerous injuries, including severe gastrointestinal events (e.g., gastroparesis) and digestive events, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risks.

106. 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 severe gastrointestinal events (e.g., gastroparesis) and severe digestive events, 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 its product, Ozempic.

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

108. The label for Ozempic was inadequate because it did not warn and/or adequately warn that Ozempic had not been sufficiently and/or adequately tested for safety risks, including the increased risk of gastroparesis and its sequelae.

109. The label for Ozempic was inadequate because it did not warn and/or adequately

warn of all possible adverse side effects concerning the failure and/or malfunction of Ozempic.

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

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

112. Communications made by Defendants to Plaintiff and his prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn that Ozempic had not been sufficiently and/or adequately tested for safety risks, including the increased risk of gastroparesis and its sequelae.

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

114. 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.

115. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of severe gastrointestinal events (e.g., gastroparesis and gastroenteritis) associated with Ozempic, they 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 his use of Ozempic.

116. 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 severe

gastrointestinal events (e.g., gastroparesis and gastroenteritis), they 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 his use of Ozempic.

117. Had Plaintiff been warned of the increased risk of gastroparesis and its sequelae, and other severe gastrointestinal symptoms, which are causally associated with Ozempic, he would not have used Ozempic and would not have suffered from gastroparesis and its sequelae.

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

119. Had Plaintiff been warned of the increased risk of gastroparesis and its sequelae, and other severe gastrointestinal symptoms, which are causally associated with Ozempic, he would have informed his prescribing physicians that he did not want to take Ozempic.

120. Upon information and belief, if Plaintiff had informed his prescribing physician(s) that he did not want to take Ozempic, his prescribing physician(s) would not have prescribed Ozempic.

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

122. 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 the Plaintiff in particular, and Defendants are therefore liable for the injuries sustained by the Plaintiff in accordance with state law.

123. Defendants' inadequate warnings of Ozempic were acts that amount to willful,

wanton, and/or reckless conduct by Defendants.

124. Defendants' inadequate warnings of Ozempic were a substantial factor in causing Plaintiff's injuries.

125. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for surgical intervention, lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

126. 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 he will require future medical and/or hospital care, attention, and services.

THIRD CAUSE OF ACTION
(NEGLIGENCE – DESIGN DEFECT)

127. 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.

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

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

130. Defendants negligently and carelessly breached the above-described duties to

Plaintiff by, among other acts and omissions, negligently and carelessly:

- a. Failing to use ordinary care in designing, testing, and manufacturing Ozempic;
- b. Failing to design Ozempic as to properly minimize the adverse effects to the gastrointestinal and immune system;
- c. Failing to counteract in the design the known adverse effects on the gastrointestinal and immune system;
- d. Designing a product where the benefits were greatly outweighed by the risks malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, intraoperative aspiration, Wernicke's encephalopathy, and death;
- e. Designing a product without taking into consideration the proper dosage that could avoid malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, intraoperative aspiration, Wernicke's encephalopathy, and death; and
- f. Ozempic was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

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

132. Ozempic was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, more dangerous

than an ordinary consumer would expect, and more dangerous than other similar drugs.

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

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

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

FOURTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION AND MARKETING)

136. 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.

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

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

139. The information distributed by Defendants to the public, the medical community,

Plaintiff and his healthcare providers, including advertising campaigns, labeling materials, print advertisements, commercial media, and marketing was false and misleading and contained omissions and concealment of truth about the dangers of Ozempic.

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

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

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

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

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

145. Defendants made the misrepresentations alleged herein with the intent to induce consumers, like Plaintiff, to take their diabetes treatment product.

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

147. As a direct and proximate result of the foregoing negligent misrepresentations and marketing and conduct with capacity to deceive and/or intention to deceive, Plaintiff suffered serious and ongoing injuries.

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

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

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

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

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

153. Defendants failed to exercise ordinary care in making representations concerning Ozempic while they were involved in the manufacture, design, sale, testing, quality assurance, quality

control, promotion, marketing, labeling, and distribution in interstate commerce, because Defendants negligently misrepresented Ozempic's high risk of unreasonable and dangerous adverse side effects.

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

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

FIFTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

156. 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.

157. 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 Ozempic as hereinabove described that was used by Plaintiff.

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

159. At all relevant times, Defendants expressly warranted to Plaintiff and his 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.

160. 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.

161. The aforementioned express warranties were made to Plaintiff and Plaintiff's

prescribing physician(s) by way of Ozempic's labels, websites, advertisements, promotional materials, and through other statements.

162. As a result of Defendants' express warranties to his prescribing physician(s), they were induced to prescribe Ozempic to Plaintiff, and Plaintiff was induced to use Ozempic.

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

164. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as the Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Ozempic based upon their express warranties.

165. At all relevant times, Defendants knew or should have known that Ozempic was unreasonably dangerous because of the drug's increased risk of severe gastrointestinal events and digestive events, especially when the drugs were used in the form and manner as provided by Defendants.

166. At all relevant times, Defendants knew or should have known that Ozempic was unreasonably dangerous because the drug's safety risks outweighed any efficacy the drug may have.

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

168. The unreasonably dangerous characteristics of Ozempic were and are 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.

169. The unreasonably dangerous characteristics of Ozempic were and are 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.

170. 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 it was associated with an increased risk of severe gastrointestinal events.

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

172. Defendants knew and/or should have known that by making the express warranties to Plaintiff and/or his prescribing physician(s), it would be the natural tendency of Plaintiff to use Ozempic and/or the natural tendency of his prescribing physician(s) to prescribe Ozempic.

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

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

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

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

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

178. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including severe gastrointestinal events, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for surgical intervention, lifelong medical treatment,

monitoring and/or medications, and fear of developing any of the above-named health consequences.

179. 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.

180. 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 he will require future medical and/or hospital care, attention, and services.

SIXTH CAUSE OF ACTION
(STRICT LIABILITY FAILURE TO WARN)

181. 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.

182. At all relevant times, Defendants were responsible for the labeling, packaging, promotion, marketing and sale of the Defendants' Ozempic that was used by Plaintiff.

183. At all relevant times, Defendants were required to warn of Ozempic's potential dangers under the Kansas Products Liability Act. K.S.A § 60-3301 et seq.

184. At all relevant times, Defendants' Ozempic was defective or unreasonably dangerous because it lacked adequate warnings.

185. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Ozempic that Plaintiff used.

186. 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.

187. At all relevant times, and at the times Ozempic left Defendants' control, Defendants

knew or should have known that Ozempic was unreasonably dangerous because it did not adequately warn of the risk of gastroparesis and its sequelae, especially when used in the form and manner as provided by Defendants.

188. 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.

189. 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.

190. 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.

191. At all relevant times, given their increased safety risks, Ozempic was not fit for the ordinary purposes for which they were intended.

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

193. 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.

194. 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.

195. 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 risks.

196. 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.

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

198. The label for Ozempic was inadequate because it did not warn and/or adequately warn that Ozempic had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae.

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

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

201. 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 Ozempic, including the increased risk of gastroparesis and its sequelae.

202. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) were 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.

203. 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.

204. 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.

205. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risks of gastroparesis and its sequelae, which are causally 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.

206. 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 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.

207. If Plaintiff had been warned of the increased risks of gastroparesis and its sequelae,

which are causally associated with Ozempic, then Plaintiff would not have used Ozempic and/or suffered from gastroparesis and its sequelae.

208. If 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.

209. If Plaintiff had been warned of the increased risks of gastroparesis and its sequelae, which are causally associated with Ozempic, then Plaintiff would have informed Plaintiff's prescribing physician(s) that Plaintiff did not want to use Ozempic.

210. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to use 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.

211. 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.

212. 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.

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

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

215. As a 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.

216. 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.

SEVENTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)

217. 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.

218. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Ozempic drug used by Plaintiff.

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

220. At all relevant times, Defendants impliedly warranted to Plaintiff, Plaintiff's prescribing physician(s), and the medical community that Ozempic was of merchantable quality and safe and fit for their ordinary purposes.

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

222. At all relevant times, Defendants knew or should have known that Ozempic had not

been sufficiently and/or adequately tested for safety. At the time Ozempic left Defendants' control, Ozempic did not conform to Defendants' implied warranty and were unfit for its ordinary purposes because Defendants failed to provide adequate warnings of the drug's causal association with increased risk of gastroparesis and its sequelae.

223. At the time Ozempic left Defendants' control, Ozempic did not conform to Defendants' implied warranty because Ozempic was an unreasonably dangerous product to use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus or to aid weight loss in adults with obesity or who are overweight and also have at least one weight-related comorbid condition, and children ages 12-17 with obesity and have a body weight above 132 pounds, in that they were causally associated with increased risks of gastroparesis and its sequelae.

224. 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.

225. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Ozempic for its ordinary purposes.

226. Despite the fact that Defendants knew or should have known that Ozempic caused unreasonably dangerous injuries, such as gastroparesis and its sequelae, Defendants continued to market, distribute, and/or sell Ozempic to consumers, including Plaintiff, without adequate warnings. 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 drugs' characteristics.

227. The unreasonably dangerous characteristics of Ozempic 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.

228. Plaintiff reasonably relied on Defendants' implied warranty of merchantability relating to Ozempic's safety and efficacy.

229. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Ozempic was of merchantable quality and safe and fit for its intended use.

230. Upon information and belief Plaintiff's prescribing physician(s) relied on Defendants' implied warranty of merchantability and fitness for the ordinary uses and purposes relating to Ozempic.

231. Upon information and belief Plaintiff's prescribing physician(s), reasonably relied upon the skill and judgment of Defendants as to whether Ozempic was of merchantable quality and safe and fit for their intended uses.

232. Had Defendants not made these implied warranties, Plaintiff would not have used Ozempic and/or, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Ozempic, and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic. Defendants herein breached the aforesaid implied warranty of merchantability because the drug Ozempic was not fit for its intended purpose.

233. Defendants' breaches of implied warranty of merchantability was a substantial factor in causing Plaintiff's injuries.

234. As a result of the foregoing breaches, 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 above-named health consequences.

235. 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
(FRAUDULENT CONCEALMENT)

236. 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.

237. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Ozempic, which was used by Plaintiff as hereinabove described.

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

239. 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 drug was used in the form and manner as provided by Defendants.

240. Defendants had a duty to disclose material information about Ozempic to Plaintiff and Plaintiff's prescribing physician(s), namely that Ozempic is causally associated with increased risk of gastroparesis and its sequelae, 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.

241. 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.

242. Although the Ozempic label lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Ozempic patients, it does not mention 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.

243. Defendants' promotional websites for Ozempic similarly do not disclose that Ozempic is causally associated with increased risk of gastroparesis.

244. 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 patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Ozempic for treatment of type 2 Diabetes and/or to promote weight loss.

245. Defendants knew or should have known that Plaintiff's prescribing physician(s) would prescribe and Plaintiff would use Ozempic without the awareness of the risks of serious side effects, including gastroparesis and its sequelae.

246. Defendants knew that Plaintiff and Plaintiff's prescribing physicians (s) had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding Ozempic, as set forth herein.

247. 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 Ozempic.

248. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of gastroparesis causally associated with Ozempic, they would not have prescribed Ozempic and/or would have provided Plaintiff with adequate information regarding the increased

risk of gastroparesis causally associated with Ozempic to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic.

249. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, they 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 to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic.

250. Plaintiff justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to purchase and/or consume Ozempic.

251. Had Plaintiff been informed of the increased risks causally associated with Ozempic, Plaintiff would not have used Ozempic and/or suffered gastroparesis and its sequelae.

252. Defendants' fraudulent concealments were a substantial factor in causing Plaintiff's injuries.

253. 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 above-named health consequences.

254. 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.

NINTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

255. 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.

256. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Ozempic, which was used by Plaintiff as hereinabove described.

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

258. At all relevant times, Defendants knew or should have known of the serious side effects of Ozempic, including gastroparesis and its sequelae.

259. At all relevant times, Defendants knew or should have known that Ozempic was unreasonably dangerous because of the increased risk of its propensity to cause malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, Wernicke's encephalopathy, and death, especially when the drug was used in the form and manner as provided by Defendants.

260. 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.

261. 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 Ozempic.

262. 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 Ozempic.

263. Defendants were aware or should have been aware that its representations were false or misleading and knew that it was concealing or omitting material information from Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community, and the general public.

264. 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.

265. Upon information and belief, Plaintiff's prescribing physician(s) had no way to determine the truth behind Defendants' false and/or misleading statements, concealments and omissions surrounding Ozempic, 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.

266. Upon information and belief, Plaintiff's prescribing physician(s) justifiably relied on Defendant's material misrepresentations, including the omissions contained therein, when making the decision to dispense, provide, and prescribe Ozempic.

267. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of all safety risks, including gastroparesis and its sequelae, causally associated with Ozempic, they would not have prescribed Ozempic and/or would have provided Plaintiff with adequate information regarding the increased risks causally associated with Ozempic to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic.

268. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic had not been sufficiently and/or adequately tested for safety risks, they 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 to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic.

269. Plaintiff had no way to determine the truth behind Defendants' false and/or misleading statements, concealments and omissions surrounding Ozempic, 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.

270. Plaintiff justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to purchase and/or consume Ozempic.

271. Had Plaintiff been informed of the increased risks causally associated with Ozempic, Plaintiff would not have used Ozempic and/or suffered gastroparesis and its sequelae.

272. Defendants' fraudulent concealments were a substantial factor in causing Plaintiff's injuries.

273. 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, 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 above-named health consequences.

274. As a result of the foregoing acts and omission, 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.

TENTH CAUSE OF ACTION
(VIOLATION OF KANSAS CONSUMER PROTECTION ACT (“CPA”))

275. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

276. Plaintiff is a “consumer” as defined by Kan. Stat. Ann. § 50-624(b).

277. Defendants are “suppliers” under Kan. Stat. Ann. § 50-624(1).

278. The sale of Ozempic described herein to the Plaintiff was a “consumer transaction” within the meaning of Kan. Stat. Ann. § 50- 624(c).

279. The Kansas CPA states “[n]o supplier shall engage in any deceptive act or practice in connection with a consumer transaction.” Kan. Stat. Ann. § 50-626(a). Deceptive acts or practices include: (1) knowingly making representations or with reason to know that “(A) Property or services have sponsorship, approval, accessories, characteristics, ingredients, uses, benefits or quantities that they do not have;” and “(D) property or services are of particular standard, quality, grade, style or model, if they are of another which differs materially from the representation;” “(2) the willful use, in any oral or written representation, of exaggeration, falsehood, innuendo or ambiguity as to a material fact;” and “(3) the willful failure to state a material fact, or the willful concealment, suppression or omission of a material fact.” The Kansas CPA also provides that “[n]o supplier shall engage in any unconscionable act or practice in connection with a consumer transaction.” Kan. Stat. Ann. § 50-627(a).

280. Defendants, while engaged in the conduct and practices identified above, committed one or more violations of state law related to consumer protection law or practices, including, but not limited to, the following:

- a. Representing that Ozempic has approval, characteristics, ingredients, uses,

benefits, or quantities that it does not have;

- b. Representing that Ozempic is of a particular standard, quality or grade; and
- c. Engaging in other fraudulent or deceptive conduct which creates likelihood of confusion or of misunderstanding, as alleged in this Complaint.

281. Defendants deliberately and/or negligently misrepresented the safety of Ozempic and concealed the risks attendant to use of the drug. Through their misrepresentations, Defendants' conduct had the tendency or capacity to deceive and affected the decisions of Plaintiff and his health care providers to purchase, prescribe, and use Ozempic and to exclude the options of not using another drug product for treatment.

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

Plaintiff seeks all monetary and non-monetary relief allowed by law, including economic damages, damages for mental anguish, treble damages for each act committed intentionally or knowingly, court costs, reasonably and necessary attorneys' fees, and any other relief which the court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the 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 the 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 the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff reasonable attorneys' fees;
4. Awarding Plaintiff the costs of these proceedings; and
5. 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: October 10, 2024

RESPECTFULLY SUBMITTED,

/s/ Sarah S. Ruane

Sarah S. Ruane (*Admitted Pro Hac Vice*)

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