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
KAREN STACEY, *Plaintiff,* v. ELI LILLY AND COMPANY, *Defendant.*	COMPLAINT AND JURY DEMAND CIVIL ACTION NO.: _____

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 Southern District of Alabama as Plaintiff's designated venue ("Original Venue"). Plaintiff makes this selection based upon one (or more) of the following factors (check the appropriate box(es)):

X Plaintiff currently resides in Flomaton, AL (City/State).

X Plaintiff purchased and used Defendant(s)' products in Flomaton, AL (City/State).

__ The Original Venue is a judicial district in which Defendant Eli Lilly and Company resides, and Defendant is a resident of the State in which the district is located (28 USC § 1391(b)(1)).

X 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)): Southern District of Alabama.

__ 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 Eli Lilly and Company is subject to the Court's personal jurisdiction with respect to this action (28 USC § 1391(b)(3)).

__ Other reason (please explain): _____.

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiff, KAREN STACEY, who was severely injured as a result of Plaintiff's use of Mounjaro, an injectable prescription medication that is used to control blood sugar in adults with type 2 diabetes and promote weight loss.

2. Mounjaro is also known as tirzepatide. Mounjaro works by targeting the body's receptors for GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1).

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

4. Defendant acknowledges that gastrointestinal events are well known side effects of the GLP-1RAs class of drugs.[1] However, Defendant has downplayed the severity of the gastrointestinal events caused by Mounjaro, never, for example, warning of the risk of gastroparesis ("paralyzed stomach") and its sequalae including cyclical vomiting and associated complications that go beyond the warnings contemplated on the label.[2]

5. Gastroparesis is a condition that affects normal muscle movement in the stomach. Ordinarily, strong muscular contractions propel food through the digestive tract. However, in a person suffering from gastroparesis, the stomach's motility is slowed down or does not work at all, preventing the stomach from emptying properly. Gastroparesis can interfere with normal digestion and cause nausea, vomiting (including vomiting of undigested food), abdominal pain, abdominal

[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 (last visited on 9/26/23).

[2] Mounjaro's label mentions gastroparesis without warning of the risk; rather, it states that Mounjaro "has not been studied" in patients with gastroparesis or other severe gastrointestinal disease, "and is therefore not recommended in these patients[,]" and it lists gastroparesis among other medical conditions for patients to discuss with their healthcare providers, https://dailymed.nlm.nih.gov/dailymed/druglnfo.cfm?setid=d2d7da 5d-ad07-4228-955f cf7e355c8cc0 (last visited on 8/24/23).

bloating, severe dehydration, a feeling of fullness after eating just a few bites, undigested food hardening and remaining in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, malnutrition, a decreased quality of life, and death. There is no cure for gastroparesis.[3]

PARTY PLAINTIFF

6. Plaintiff, KAREN STACEY, is a citizen of the United States, and is a resident of the State of Alabama.

7. Plaintiff is 46 years old.

8. Plaintiff used Mounjaro from August 2022 to April 2023.

9. Plaintiff's physician(s) ("prescribing physician(s)") prescribed the Mounjaro that was used by Plaintiff.

10. Upon information and belief, as a result of using Mounjaro, Plaintiff was caused to suffer from gastrointestinal injuries sustained severe personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

11. Upon information and belief, as a result of using Mounjaro, Plaintiff was caused to suffer from gastrointestinal injuries, which resulted in, for example, constant nausea, extreme constipation, malnutrition, and severe vomiting requiring emergency medical treatment.

PARTY DEFENDANT

12. Defendant Eli Lilly and Company ("Eli Lilly" or "Defendant") is an Indiana corporation with a principal place of business at 893 S. Delaware St., Indianapolis, Indiana.

13. Eli Lilly designed, researched, manufactured, tested, labeled, advertised, promoted,

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

marketed, sold, and/or distributed Mounjaro and is identified on its label.[4]

FACTUAL BACKGROUND

A. FDA's Approval of Mounjaro

14. On September 14, 2021, Eli Lilly submitted NDA 215866 Mounjaro (tirzepatide) injection as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On May 13, 2022, the FDA approved NDA 215866.[5]

15. On May 13, 2022, Eli Lilly announced the FDA's approval of NDA 215866 Mounjaro (tirzepatide) injection as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. In the press release, Eli Lilly disclosed a safety summary and provided a link to the Medication Guide and Prescribing Information, but gastroparesis and its sequela like cyclical vomiting were not identified as a risk.

B. Eli Lilly's Marketing and Promotion of Mounjaro

16. On May 13, 2022, Eli Lilly announced approval of Mounjaro, proclaiming "Mounjaro's safety … in a broad range of adults with type 2 diabetes."[6]

17. At all relevant times, Eli Lilly was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Mounjaro.

18. On October 6, 2022, Eli Lilly announced that the FDA had "granted Fast Track

[4] Mounjaro prescribing information, available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d2d7da5d-ad07-4228-955f-cf7e355c8cc0 (last visited on 8/24/23).

[5] FDA Approval Letter for NDA 215866 (Mounjaro) available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/215866Orig1s000ltr.pdf (last visited on 8/24/23).

[6] *FDA approves Lilly's Mounjaro™ (tirzepatide) injection, the first and only GIP and GLP-1 receptor agonist for the treatment of adults with type 2 diabetes*, Cision PR Newswire (May 13, 2022) available at https://www.prnewswire.com/news-releases/fda-approves-lillys-mounjaro-tirzepatide-injection-the-first-and-only-gip-and-glp-1-receptor-agonist-for-the-treatment-of-adults-with-type-2-diabetes-301547339.html (last visited on 8/24/23).

designation for the investigation of tirzepatide" to treat obese or overweight adults.[7]

19. According to a recent publication, in fall 2022, analysts at UBS projected that Mounjaro could reach peak sales of $25 billion, asserting Eli Lilly's position in the multibillion dollar obesity market.[8]

20. In March 2023, it was reported that Eli Lilly kicked off a full-scale consumer campaign for Mounjaro after launching a digital campaign in January, including a 75-second TV spot supporting Mounjaro aired on FOX on February 12, the same day as Super Bowl LVII.[9]

21. 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 "steamrollered 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.[10]

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[7] *Lilly Receives U.S. FDA Fast Track designation for tirzepatide for the treatment of adults with obesity, or overweight with weight-related comorbidities* (October 6, 2022) available at https://investor.lilly.com/news-releases/news-release-details/lilly-receives-us-fda-fast-track-designation-tirzepatide (last visited on 8/24/23).

[8] Munger L, BioSpace, *Eli Lilly and Novo Nordisk Face Off in Lucrative Obesity Market* (May 30, 2023) available at https://www.biospace.com/article/eli-lilly-and-novo-nordisk-face-off-in-lucrative-obesity-market (last visited on 8/24/23).

[9] O'Brien J, Medical Marketing and Media, *Eli Lilly kicks off consumer campaign for diabetes drug Mounjaro* (March 9, 2023) available at https://www.mmm-online.com/home/channel/campaigns/eli-lilly-kicks-off-consumer-campaign-for-diabetes-drug-mounjaro/ (last visited on 8/24/23).

[10] Blum D, *The Diabetes Drug That Could Overshadow Ozempic,* The New York Times (published April 11, 2023, updated June 24, 2023) available at https://www.nytimes.com/2023/04/11/well/live/ozempic-mounjaro-weight-loss-diabetes.html (last visited on 8/24/23).

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

22. As previously noted, Mounjaro (tirzepatide) belongs to a class of drugs called GLP-1RAs.

23. Medications within the GLP-1RA class of drugs mimic the physiological activities of 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.[11]

24. Because the risk of gastroparesis and its sequelae like cyclical vomiting is common to the entire class of drugs, any published literature regarding the association between gastroparesis and its sequelae like cyclical vomiting and any GLP-1RA (such as exenatide, liraglutide, albiglutide, dulaglutide, lixisenatide, and semaglutide) should have put Defendant on notice of the need to warn patients and prescribing physicians of the risk of gastroparesis and its sequelae like cyclical vomiting associated with this class of drugs.

25. In addition to pancreatic effects, the published medical literature shows that GLP-1RAs slow gastric emptying. As early as 2010, a study published in The Journal of Clinical Endocrinology & Metabolism indicated this effect.[12]

26. Defendant knew or should have known of this risk of gastroparesis and its sequelae like cyclical vomiting from the clinical trials, medical literature, and case reports.

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

[11] 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).

[12] 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 28, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery (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.[13]

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

29. 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."[14]

30. 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-1 RA discontinuation in the past 6 months, with 'Made me feel sick' as the most frequently reported

[13] Marso SP et al., *Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes*, N. Eng. J. Med. 375:1834-1844 (November 10, 2016), available at https://www.nejm.org/doi/10.1056/NEJMoa1607141 (last visited on 10/19/23).

[14] 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 9/26/23).

reason (64.4%), followed by 'Made me throw up' (45.4%)."[15] As explained above, these are symptoms of gastroparesis and its sequelae like cyclical vomiting go beyond the warnings contemplated by the drug's labeling.

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

32. 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 liraglutide, dulaglutide, semaglutide, lixisenatide, or exenatide 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."[16]

33. In a September 2020 scientific 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 2.1 year period. The authors acknowledged the potential for severe gastrointestinal events, warning that "[f]or

[15] 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 29, 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5630073/

[16] 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/ (last visited on 9/26/23).

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."[17]

34. A July 2021 scientific article funded and reviewed by Novo Nordisk considered 23 randomized control trials conducted across the United States, Japan, and China and concluded that "gastrointestinal disturbances" were "well-known" side effects associated with semaglutide use. When compared with placebos, the subcutaneous (injection) form of the drug induced nausea in up to 20% of patients (versus up to 8% on the placebo group), vomiting in up to 11.5% of patients (versus up to 3% in the placebo group) and diarrhea in up to 11.3% of patients (versus up to 6% in the placebo group). Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for gastrointestinal related adverse events accounting for 58.75% of the patients with adverse events leading to trial product discontinuation. Semaglutide appeared to be associated with more frequent vomiting and nausea as compared to the other GLP-1Ras that were studied. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"[18]

35. An October 2021 scientific article in the Journal of Investigative Medicine ("JIM") concluded that because gastroparesis can be associated with several medications, "[i]t is crucial to

[17] 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(S2): 37-47, available at https://doi.org/10.1080/00325481.2020.1800286 (last visited on 9/26/23).

[18] 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).

identify the causative drugs as discontinuation of the drug can result in resolution of the symptoms[.]" In diabetics, making this determination can be particularly "tricky" because both diabetes and GLP-1RAs can cause delayed gastric emptying. As such, "the timeline of drug initiation and symptom onset becomes of the upmost importance." The authors reviewed two case reports (discussed below) and concluded that history taking and making an accurate diagnosis of diabetic gastroparesis versus medication-induced gastroparesis is critical.[19]

36. Case Report #1 in JIM involved a 52-year-old female with long-standing history (10 years) of well-controlled, type 2 diabetes who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis symptoms. The patient had a 7-month history of post-prandial epigastric pain, accompanied by fullness, bloating, and nausea. A gastric emptying study showed a 24% retention of isotope in the patient's stomach at four hours, indicative of delayed gastric emptying. The patient discontinued semaglutide and her symptoms resolved after six weeks. The case report authors concluded that "thorough history taking revealed the cause [of gastroparesis] to be medication induced."[20]

37. Case Report #2 in JIM involved a 57-year-old female with a long-standing history (16 years) of 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.[21]

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[19] 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/ (last visited on 9/26/23).
[20] *Id.*
[21] *Id.*

38. A June 2022 study reported GLP-1RA tirzepatide adverse events of vomiting and nausea, with gastrointestinal events being the most common adverse event.[22]

39. An October 2022 study analyzed 5,442 GLP-1RA gastrointestinal adverse events. 32% were serious, including 40 deaths, 53 life-threatening conditions, and 772 hospitalizations. The primary events were nausea and vomiting. There were also adverse events for impaired gastric emptying.[23]

40. A January 2023 meta-analysis of GLP-1RA tirzepatide adverse events reported high rates of nausea and vomiting.[24]

41. 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.[25]

42. 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."[26]

43. 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

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[22] Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).
[23] Shu Y et al., *Gastrointestinal adverse events associated with semaglutide: A pharmacovigilance study based on FDA adverse event reporting system*, Front. Public Health (Oct. 19, 2022). (https://doi.org/10.3389%2Ffpubh.2022.996179).
[24] Mishra R et al., *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).
[25] Chin R et al., *Safety and effectiveness of dulaglutide 0.75 mg in Japanese patients with type 2 diabetes in real-world clinical practice: 36 month post-marketing observational study*, J Diabetes Investig (Feb. 2023) (https://doi.org/10.1111%2Fjdi.13932).
[26] Klein SR et al., *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).

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.[27]

44. News sources have identified the potential for serious side effects in users of Ozempic, including gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year, leading to hospitalization.[28] For example, NBC News reported in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable, and one user said that five weeks into taking the medication she found herself unable to move off the bathroom floor because she had "vomited so much that [she] didn't have the energy to get up."[29] CNN reported in July that one Ozempic user diagnosed with gastroparesis vomits so frequently that she had to take a leave of absence from her teaching job.[30]

45. A July 25, 2023, article in Rolling Stone magazine - "Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell'" - highlighted three patients who suffered severe gastrointestinal related events, including gastroparesis, as a result of their use of

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[27] *American Society of Anesthesiologists, Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 28, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery (last visited on 9/26/23).

[28] Min P, *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); Nelson EL, *These Are the 5 Most Common Ozempic Side Effects, According to Doctors*, Best Life (April 3, 2023), available at https://bestlifeonline.com/ozempic-side-effects-news/ (visited on 9/26/23); Shultz C, *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 25, 2023), available at https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomach-paralysis/ (last visited on 9/26/23).

[29] 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/healthnews/ozempic-wegovy-diabetes-weight-loss-side-effects-rcna66493 (last visited on 9/26/23).

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

GLP-1RAs. Patient 1 (female, age 37) reported incidents of vomiting multiple times per day and being unable to eat. The patient's physician diagnosed her with severe gastroparesis and concluded that her problems were caused and/or exacerbated by her use of a GLP-1RA medication. Patient 2 (female) used Ozempic for one year and reported incidents of vomiting, including multiple times per day. The patient's physician diagnosed her with severe gastroparesis related to her Ozempic use. Patient 3 (female, age 42) experienced severe nausea both during and after she discontinued use of a GLP-1RA. In a statement to Rolling Stone, Novo Nordisk acknowledged that "[t]he most common adverse reactions, as with all GLP-1 RAs, are gastrointestinal related." Novo Nordisk further stated that while "GLP-1 RAs are known to cause a delay in gastric emptying, … [s]ymptoms of delayed gastric emptying, nausea and vomiting are listed as side effects." Novo Nordisk did not claim to have warned consumers about gastroparesis, or other severe gastrointestinal issues.[31]

46. On July 25, 2023, CNN Health reported that patients taking Ozempic have been diagnosed "with severe gastroparesis, or stomach paralysis, which their doctors think may have resulted from or been exacerbated by the medication they were taking, Ozempic." Another patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.[32]

47. On July 26, 2023, a New York hospital published an article to its online health blog section "What You Need to Know About Gastroparesis" entitled "Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines." It was reported that a growing number of

[31] Jones CT, *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).
[32] Goodman B, *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).

gastroparesis cases had been seen in people taking GLP-1RAs. The article noted that the weight loss drugs can delay or decrease the contraction of muscles that mix and propel contents in the gastrointestinal tract leading to delayed gastric emptying. One concern raised was that patients and doctors often assume the symptoms of gastroparesis are reflux or other gastrointestinal conditions, meaning it may take a long time for someone to be diagnosed correctly.[33]

48. 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.[34] The study found that patients prescribed GLP-1RAs were at 4.22 times higher risk of bowel obstruction and at 3.67 times higher risk of gastroparesis.

49. The medical literature listed above is not a comprehensive list, and several other case reports have indicated that GLP-1RAs can cause gastroparesis, impaired gastric emptying and its sequalae including cyclical vomiting.[35]

50. Defendant knew or should have known of the causal association between the use

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[33] *Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines*, Montefiore Health Blog article (released July 26, 2023), available at https://www.montefiorenyack.org/health-blog/what-you-need-know-about-gastroparesis (last visited on 9/26/2023).

[34] Sodhi M 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).

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

of GLP-1RAs and the risk of developing gastroparesis and its sequelae like cyclical vomiting, but they ignored the causal association. Defendant's 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.

51. On information and belief, Defendant not only knew or should have known that its GLP-1RAs cause delayed gastric emptying, resulting in risks of gastroparesis, but they may have sought out the delayed gastric emptying effect due to its association with weight loss. For example, a recent study published in 2023 notes that "it has been previously proposed that longacting GLP-1RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying,]" and the study authors suggested "further exploration of peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake."[36]

D. Defendant Failed to Warn of the Risk of Gastroparesis from Mounjaro

52. The Prescribing Information for Mounjaro discloses "Warnings and Precautions" and "Adverse Reactions" but does not adequately warn of the risk of gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year.[37]

53. The Mounjaro label lists nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain as common adverse reactions, but it does not indicate a severity of symptoms. Even though the label warns about the risk of severe gastrointestinal

[36] Jensterle M et al., *Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity*, 25(4) Diabetes Obes. Metab. 975-984 (April 2023), available at https://dompubs.onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944 (last visited on 9/26/23).
[37] *Mounjaro prescribing information*, available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d2d7da5d-ad07-4228-955f-cf7e355c8cc0 (last visited on 8/24/23).

disease, gastroparesis is not specifically mentioned.

54. None of Defendant's additional advertising or promotional materials warned prescription providers or the general public of the risks of gastroparesis and its sequelae like cyclical vomiting.

55. Defendant knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by the drug's label. Defendant's actual and constructive knowledge derived from its clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced in this Complaint.

56. Upon information and belief, Defendant ignored the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by the drug's labeling.

57. Defendant's failure to disclose information that it possessed regarding the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae like cyclical vomiting, rendered the warnings for Mounjaro inadequate.

58. On information and belief, as a result of Defendant's inadequate warnings, the medical community at large, and Plaintiff's prescribing physician in particular, were not aware that Mounjaro can cause gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by the drug's labeling, nor were they aware that "common adverse reactions" listed on the label might be sequelae of these problems.

59. On information and belief, had Defendant adequately warned Plaintiff's prescribing physician that Mounjaro is causally associated with gastrointestinal injuries and its sequelae, then the physician's prescribing decision would have changed by not prescribing Mounjaro, or by

monitoring Plaintiff's health for symptoms of gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by the drug's labeling and discontinuing Mounjaro when the symptoms first started.

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

FIRST CAUSE OF ACTION (INADEQUATE WARNING)

61. 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.

62. Alabama 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.

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

64. Mounjaro was expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendant.

65. At all relevant times, and at the times Mounjaro left Defendant's control, Defendant knew or should have known that Mounjaro was unreasonably dangerous because they did not

adequately warn of the risk of gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by the drug's labeling, especially when used in the form and manner as provided by Defendant.

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

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

68. Defendant 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.

69. At all relevant times, given its increased safety risks, Mounjaro was not fit for the ordinary purpose for which it was intended.

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

71. Defendant had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Mounjaro into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as cyclical vomiting that goes beyond the warnings contemplated by the drug's labeling.

72. At all relevant times, Plaintiff was using Mounjaro for the purposes and in a manner normally intended—namely, weight loss.

73. The Mounjaro designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendant was defective due to inadequate warnings or instructions, as Defendant knew or should have known that the product created a risk of serious and dangerous injuries, gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by the drug's labeling, as well as other severe and personal injuries, and Defendant failed to adequately warn of said risk.

74. The Mounjaro designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendant knew or should have known of the risks of serious side effects, including gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by the drug's labeling, as well as other severe and permanent health consequences from Mounjaro, 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, Mounjaro.

75. The label for Mounjaro was inadequate because it did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Mounjaro, including the increased risk of gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year that go beyond the warnings contemplated by the drug's labeling.

76. The label for Mounjaro was inadequate because it did not warn and/or adequately warn that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year that go beyond the warnings contemplated by the drug's labeling.

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

78. The label for Mounjaro 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.

79. Communications made by Defendant to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendant failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Mounjaro, including the increased risk of gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by the drug's labeling.

80. Communications made by Defendant to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendant failed to warn and/or adequately warn that Mounjaro had not been sufficiently and/or adequately tested for safety risks, gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by the drug's labeling.

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

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

83. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risks of gastroparesis and its sequelae like cyclical vomiting, which are causally associated with Mounjaro, then the prescribing physician would not have prescribed Mounjaro

and/or would have provided Plaintiff with adequate warnings regarding the dangers of Mounjaro so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

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

85. If Plaintiff had been warned of the increased risks of gastroparesis and its sequelae like cyclical vomiting, which are causally associated with Mounjaro, then Plaintiff would not have used Mounjaro and/or suffered from cyclical vomiting and other gastrointestinal issues.

86. If Plaintiff had been warned that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae like cyclical vomiting, then Plaintiff would not have used Mounjaro and/or suffered from cyclical vomiting and other gastrointestinal issues.

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

88. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Mounjaro due to the risks of gastroparesis and its sequelae like cyclical vomiting, or the lack of adequate testing for safety risks, then Plaintiff's prescribing physician(s) would not have prescribed Mounjaro.

89. By reason of the foregoing, Defendant has become liable to Plaintiff for the

designing, marketing, promoting, distribution and/or selling of an unreasonably dangerous product, Mounjaro.

90. Defendant 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 Defendant is therefore liable for the injuries sustained by Plaintiff.

91. Defendant's inadequate warnings for Mounjaro were acts that amount to willful, wanton, and/or reckless conduct by Defendant.

92. Said inadequate warnings for Defendant's drug Mounjaro was a substantial factor in causing Plaintiff's injuries.

93. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including cyclical vomiting, 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.

94. 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.

95. Pleading further and subject to the foregoing and without waiving same, Plaintiff would show that Defendant owed Plaintiff's prescribing physician(s) and/or Plaintiff a duty to adequately warn of the extent and the nature of the risks posed by their medications. Plaintiff would

further show that because Defendant improperly withheld and/or concealed and/or hid information regarding the extent and the nature of the risks posed by their medications from Plaintiff's prescribing physician(s) and/or Plaintiff, Plaintiff was unable to learn about the cause of Plaintiff's injuries until after March 2023, when Plaintiff learned that Mounjaro may cause gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by Mounjaro's label. Accordingly, Defendant fraudulently concealed the existence of Plaintiff's claims.

SECOND CAUSE OF ACTION (BREACH OF EXPRESS WARRANTY)

96. 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.

97. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or has acquired the Defendant who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Mounjaro, which was used by Plaintiff as hereinabove described.

98. At all relevant times, Defendant expressly warranted to Plaintiff and Plaintiff's prescribing physician(s) that Mounjaro was safe as a weight loss drug.

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

100. As a result of Defendant's express warranties, Plaintiff's prescribing physician was induced to prescribe Mounjaro to Plaintiff, and Plaintiff was induced to use Mounjaro.

101. At all relevant times, Defendant reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Mounjaro based upon their express

warranties.

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

103. At all relevant times, Defendant knew or should have known that Mounjaro was unreasonably dangerous because of its increased risk of gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year that go beyond the warnings contemplated by Mounjaro's label, especially when the drug was used in the form and manner as provided by Defendant.

104. At all relevant times, Defendant knew or should have known that Mounjaro had not been sufficiently and/or adequately tested for safety.

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

106. The unreasonably dangerous characteristics of Mounjaro were 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.

107. At the time Mounjaro left Defendant's control, Mounjaro did not conform to Defendant's express warranties because Mounjaro was not safe to use as weight loss aid, in that it was causally associated with increased risks of gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year that go beyond the warnings contemplated by Mounjaro's label.

108. The express warranties made by Defendant regarding the safety of Mounjaro were

made with the intent to induce Plaintiff to use the product and/or Plaintiff's prescribing physician(s) to prescribe the product.

109. Defendant knew and/or should have known that by making the express warranties to Plaintiff and/or Plaintiff's prescribing physician(s), it would be the natural tendency of Plaintiff to use Mounjaro and/or the natural tendency of Plaintiff's prescribing physician(s) to prescribe Mounjaro.

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

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

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

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

114. Accordingly, Defendant is liable as a result of their breach of express warranties to Plaintiff.

115. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including cyclical vomiting that goes beyond the warnings contemplated by Mounjaro's label, as well as other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

116. 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 Defendant's Mounjaro drug.

117. 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.

118. Pleading further and subject to the foregoing and without waiving same, Plaintiff would show that Defendant owed Plaintiff's prescribing physician(s) and/or Plaintiff a duty to adequately warn of the extent and the nature of the risks posed by their medications. Plaintiff would further show that because Defendant improperly withheld and/or concealed and/or hid information regarding the extent and the nature of the risks posed by their medications from Plaintiff's prescribing physician(s) and/or Plaintiff, Plaintiff was unable to learn about the cause of Plaintiff's injuries until after March 2023, when Plaintiff learned that Mounjaro may cause gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by Mounjaro's label. Accordingly, Defendant fraudulently concealed the existence of Plaintiff's claims.

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

119. 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.

120. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Mounjaro drug used by Plaintiff.

121. Mounjaro 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 Defendant.

122. At all relevant times, Defendant impliedly warranted to Plaintiff, Plaintiff's prescribing physician(s), and the medical community that Mounjaro was of merchantable quality and safe and fit for its ordinary purpose.

123. At all relevant times, Defendant knew or should have known that Mounjaro was unreasonably dangerous because of its increased risk of gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year that go beyond the warnings contemplated by Mounjaro's label, especially when the drug was used in the form and manner as provided by Defendant.

124. At all relevant times, Defendant knew or should have known that Mounjaro had not been sufficiently and/or adequately tested for safety.

125. At the time Mounjaro left Defendant's control, Mounjaro did not confirm to Defendant's implied warranty and was unfit for its ordinary purpose because Defendant failed to provide adequate warnings of the drug's causal association with increased risk of gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year that go beyond the warnings contemplated by Mounjaro's label.

126. At all relevant times, Defendant reasonably anticipated and expected that prescribing physician(s), such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Mounjaro for use by their patients to improve glycemic control in adults with type 2 diabetes, reduce cardiovascular risk, and/or to promote weight loss.

127. At all relevant times, Defendant reasonably anticipated and expected that

individuals, such as Plaintiff, would use and/or consume Mounjaro for its ordinary purpose.

128. Despite the fact that Defendant knew or should have known that Mounjaro causes unreasonably dangerous injuries, such as gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year that go beyond the warnings contemplated by Mounjaro's label, Defendant continued to market, distribute, and/or sell Mounjaro to consumers, including Plaintiff, without adequate warnings.

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

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

131. Plaintiff reasonably relied on Defendant's implied warranty of merchantability relating to Mounjaro's safety and efficacy.

132. Plaintiff reasonably relied upon the skill and judgment of Defendant as to whether Mounjaro was of merchantable quality and safe and fit for its intended use.

133. Upon information and belief Plaintiff's prescribing physician(s) relied on Defendant's implied warranty of merchantability and fitness for the ordinary use and purpose relating to Mounjaro.

134. Upon information and belief Plaintiff's prescribing physician(s), reasonably relied upon the skill and judgment of Defendant as to whether Mounjaro was of merchantable quality and safe and fit for its intended use.

135. Had Defendant not made these implied warranties, Plaintiff would not have used

Mounjaro and/or, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Mounjaro, and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Mounjaro to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

136. Defendant herein breached the aforesaid implied warranty of merchantability because the drug Mounjaro was not fit for its intended purposes.

137. Defendant's breaches of implied warranty of merchantability were a substantial factor in causing Plaintiff's injuries.

138. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including cyclical vomiting that goes beyond the warnings contemplated by Mounjaro's label, 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.

139. 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.

140. Pleading further and subject to the foregoing and without waiving same, Plaintiff would show that Defendant owed Plaintiff's prescribing physician(s) and/or Plaintiff a duty to adequately warn of the extent and the nature of the risks posed by their medications. Plaintiff would further show that because Defendant improperly withheld and/or concealed and/or hid information regarding the extent and the nature of the risks posed by their medications from Plaintiff's

prescribing physician(s) and/or Plaintiff, Plaintiff was unable to learn about the cause of Plaintiff's injuries until after March 2023, when Plaintiff learned that Mounjaro may cause gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by Mounjaro's label. Accordingly, Defendant fraudulently concealed the existence of Plaintiff's claims.

FOURTH CAUSE OF ACTION (FRAUDULENT CONCEALMENT)

141. 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.

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

143. At all relevant times, Defendant knew or should have known that Mounjaro had not been adequately and/or sufficiently tested for safety.

144. At all relevant times, Defendant knew or should have known that Mounjaro was unreasonably dangerous because of the increased risk of gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year that go beyond the warnings contemplated by Mounjaro's label, especially when the drug was used in the form and manner as provided by Defendant.

145. Defendant had a duty to disclose material information about Mounjaro to Plaintiff and Plaintiff's prescribing physician(s), namely that Mounjaro is causally associated with increased risk of gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year that go beyond the warnings contemplated by Mounjaro's label, because Defendant have superior knowledge of the drug and its dangerous side effects, this material information is not

readily available to Plaintiff or Plaintiff's prescribing physician(s) by reasonable inquiry, and Defendant knew or should have known that Plaintiff and Plaintiff's prescribing physician would act on the basis of mistaken knowledge.

146. Nonetheless, Defendant 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.

147. The Mounjaro labels lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Mounjaro patients but with no indication as to severity, and it does not mention gastroparesis as a risk of taking Mounjaro, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Mounjaro.

148. Defendant's promotional website for Mounjaro similarly does not disclose that Mounjaro is causally associated with increased risk of gastroparesis.

149. Defendant's 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 Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Mounjaro to promote weight loss.

150. Defendant knew or should have known that Plaintiff's prescribing physician(s) would prescribe, and Plaintiff would use Mounjaro without the awareness of the risks of serious side effects, including gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by Mounjaro's label.

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

152. 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 Mounjaro.

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

154. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by Mounjaro's label, they would not have prescribed Mounjaro and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Mounjaro to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

155. Plaintiff justifiably relied on Defendant' material misrepresentations, including the omissions contained therein, when making the decision to purchase and/or consume Mounjaro.

156. Had Plaintiff been informed of the increased risks causally associated with Mounjaro, Plaintiff would not have used Mounjaro and/or suffered cyclical vomiting that goes beyond the warnings contemplated by Mounjaro's label.

157. Defendant's fraudulent concealments were a substantial factor in causing Plaintiff's injuries.

158. As a direct and proximate result of the above stated omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including cyclical vomiting that goes

beyond the warnings contemplated by Mounjaro's label, 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.

159. 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.

160. Pleading further and subject to the foregoing and without waiving same, Plaintiff would show that Defendant owed Plaintiff's prescribing physician(s) and/or Plaintiff a duty to adequately warn of the extent and the nature of the risks posed by their medications. Plaintiff would further show that because Defendant improperly withheld and/or concealed and/or hid information regarding the extent and the nature of the risks posed by their medications from Plaintiff's prescribing physician(s) and/or Plaintiff, Plaintiff was unable to learn about the cause of Plaintiff's injuries until after March 2023, when Plaintiff learned that Mounjaro may cause gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by Mounjaro's label. Accordingly, Defendant fraudulently concealed the existence of Plaintiff's claims.

FIFTH CAUSE OF ACTION (FRAUDULENT MISREPRESENTATION)

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

162. At all relevant times, Defendant designed, researched, manufactured, tested,

advertised, promoted, marketed, sold, and distributed Mounjaro, which was used by Plaintiff as hereinabove described.

163. At all relevant times, Defendant knew or should have known that Mounjaro had not been adequately and/or sufficiently tested for safety.

164. At all relevant times, Defendant knew or should have known of the serious side effects of Mounjaro, including gastroparesis and its sequelae like cyclical vomiting and delayed emptying lasting a year that go beyond the warnings contemplated by Mounjaro's label.

165. At all relevant times, Defendant knew or should have known that Mounjaro 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.

166. Nonetheless, Defendant 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 Mounjaro.

167. Defendant represented affirmatively and by omission on television advertisements and on the label of Mounjaro that Mounjaro was a safe and effective drug for treatment obesity, despite being aware of increased risks of gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by Mounjaro's label causally associated with using Mounjaro.

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

169. Defendant's misrepresentations of material facts were made purposefully,

knowingly, willfully, wantonly, recklessly and/or without regard to its truth, in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Mounjaro to promote weight loss.

170. Upon information and belief Plaintiff's prescribing physician(s) had no way to determine the truth behind Defendant's false and/or misleading statements, concealments and omissions surrounding Mounjaro, and reasonably relied on false and/or misleading facts and information disseminated by Defendant, which included Defendant's omissions of material facts in which Plaintiff's prescribing physician(s) had no way to know were omitted.

171. 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 prescribe Mounjaro to Plaintiff.

172. Upon information and belief, had Plaintiff's prescribing physician(s) been informed of the increased risk of gastroparesis causally associated with Mounjaro, Plaintiff's prescribing physician(s) would not have prescribed Mounjaro and/or would have provided Plaintiff with adequate information regarding safety of Mounjaro to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

173. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by Mounjaro's label, they would not have prescribed Mounjaro and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Mounjaro so that Plaintiff can make an informed decision regarding Plaintiff's use of Mounjaro.

174. Plaintiff had no way to determine the truth behind Defendant's false and/or misleading statements, concealments and omissions surrounding Mounjaro, and reasonably relied on false and/or misleading facts and information disseminated by Defendant, which included Defendant's omissions of material facts in which Plaintiff had no way to know were omitted.

175. Plaintiff justifiably relied on Defendant's material misrepresentations, including the omissions contained therein, when making the decision to accept, purchase and/or consume Mounjaro.

176. Had Plaintiff been told of the increased risk of gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by Mounjaro's label causally associated with Mounjaro, Plaintiff would not have used Mounjaro and/or suffered cyclical vomiting that goes beyond the warnings contemplated by Mounjaro's label.

177. Had Plaintiff been told of the lack of sufficient and/or appropriate testing of Mounjaro for safety risks, including gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by Mounjaro's label, Plaintiff would not have used Mounjaro and/or suffered cyclical vomiting that goes beyond the warnings contemplated by Mounjaro's label.

178. As a direct and proximate result of the above stated false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including cyclical vomiting that goes beyond the warnings contemplated by Mounjaro's label, 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.

179. 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.

180. Pleading further and subject to the foregoing and without waiving same, Plaintiff would show that Defendant owed Plaintiff's prescribing physician(s) and/or Plaintiff a duty to adequately warn of the extent and the nature of the risks posed by their medications. Plaintiff would further show that because Defendant improperly withheld and/or concealed and/or hid information regarding the extent and the nature of the risks posed by their medications from Plaintiff's prescribing physician(s) and/or Plaintiff, Plaintiff was unable to learn about the cause of Plaintiff's injuries until after March 2023, when Plaintiff learned that Mounjaro may cause gastroparesis and its sequelae like cyclical vomiting that go beyond the warnings contemplated by Mounjaro's label. Accordingly, Defendant fraudulently concealed the existence of Plaintiff's claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendant, who demonstrated a complete disregard and reckless indifference for the safety

and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendant and deter future similar conduct;

3. Awarding Plaintiff the costs of these proceedings; and

4. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: September 12, 2024

RESPECTFULLY SUBMITTED,

/s/ Melissa Ephron
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