UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARISSA WRUBEL,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

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CASE NO. 7:24-cv-726

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW, Plaintiff, Marissa Wrubel (hereinafter referred to as "Plaintiff"), by and through undersigned counsel, hereby sues Defendant, Eli Lilly and Company (hereinafter referred to as "Defendant"), and in support of her Complaint alleges the following:

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332, because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has a principal places of business in states other than the state in which Plaintiff resides, which is the State of New York.

2. This Court has personal jurisdiction over the Defendant, consistent with the United States Constitution and N.Y.C.P.L.R. 302 (New York's "long arm" statute), as Plaintiff's claims arise out of Defendant's transaction of business and the tortious acts within the State of New York, and by virtue of Defendant's substantial, continuous, and systematic contacts with the State of New York unrelated to Plaintiff's claims.

NATURE OF THE CASE

3. This is an action for damages suffered by Plaintiff as a result of using Mounjaro, an injectable prescription medication that is used to control blood sugar.

4. 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).

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

6. Defendant acknowledges that gastrointestinal events are well known side effects of the GLP-1RA class of drugs.[1] Yet, Defendant has downplayed the severity of the gastrointestinal events caused by its GLP-1RAs, including, for example, failing to warn of the risk of gastroparesis, and intestinal obstructions.[2]

7. Gastroparesis is a condition that affects normal muscle movement in the stomach. Ordinarily, strong muscular contractions propel food through the digestive tract. However, in a person suffering from gastroparesis, the stomach's mobility is slowed down or does not work at all, preventing the stomach from emptying properly. Gastroparesis can interfere with normal digestion and cause nausea, vomiting (including vomiting of undigested food), abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, undigested food hardening and remaining in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, malnutrition, and a decreased quality of life. There is no cure for gastroparesis.[3]

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[1]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).

[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/drugInfo.cfm?setid=d2d7da5d-ad07-4228-955f-cf7e355c8cc0 (last visited on 8/24/23).

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

8. An intestinal obstruction is a partial or complete blockage of the bowel in which the contents of the intestine cannot pass through it.[4] Symptoms of an intestinal obstruction generally include abdominal swelling, fullness, pain, and cramping, as well as constipation, diarrhea, and vomiting. *Id*.

PARTY PLAINTIFF

9. Plaintiff is a citizen of the United States, and is a resident of the State of New York.

10. Plaintiff is 28 years old.

11. In August 2022, Plaintiff's physician (hereinafter referred to as "Prescribing Physician") prescribed her with Mounjaro.

12. Plaintiff used Mounjaro from August 2022 to December 2022.

13. As a result of using Defendant's Mounjaro, Plaintiff was caused to suffer from severe and permanent personal injuries, including a high-grade large bowel obstruction, adhesions to the small intestines, toxic megacolon, and severe sepsis, resulting in the emergency resection of significant portions of both her large and small intestines, as well as a total colectomy and the implementation of a colostomy bag. Plaintiff has also suffered additional complications, including severe vomiting, acute stomach pain, gastrointestinal burning, abdominal bloating, hospitalization for stomach issues on several occasions including visits to the emergency room, and the requirement of additional medications to alleviate her severe nausea and vomiting. To date, Plaintiff continues to suffer from nausea, constipation, and other digestive issues, such as an inability to process foods.

14. Plaintiff's injuries were caused by Defendant's Mounjaro.

PARTY DEFENDANTS

15. Defendant is an Indiana corporation with a principal place of business at 893 South

[4]*Intestinal Obstruction*, Mount Sinai (May 4, 2022), available at https://www.mountsinai.org/health-library/diseases-conditions/intestinal-obstruction.

Delaware Street, Indianapolis, Indiana.

16. Defendant designed, researched, manufactured, tested, labeled, advertised, promoted, marketed, sold, and/or distributed Mounjaro and is identified on its label.

FACTUAL BACKGROUND

A. FDA's Approval of Mounjaro

17. On September 14, 2021, Defendant 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]

18. On May 13, 2022, Defendant 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, Defendant disclosed a safety summary and provided a link to the Medication Guide and Prescribing Information, but gastroparesis and intestinal obstructions were not identified as risks.

B. Defendant's Marketing and Promotion of Mounjaro

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

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

21. On October 6, 2022, Defendant announced that the FDA had "granted Fast Track

[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]

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

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

24. On April 11, 2023, the New York Times reported that Mounjaro was "gaining attention, with many people using it off-label to lose weight."[10] 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." *Id.* Although Defendant denied promoting or encouraging "the off-label use of any of our medicines[,]" it was obvious to Defendant and others in the industry that Mounjaro was following Ozempic's rising popularity for its weight loss effects. *Id.* Furthermore, the same article also noted Defendant's October announcement regarding the FDA's fast-track designation for its review of tirzepatide. *Id.*

C. The Medical Literature and Clinical Trials Gave Defendant Notice of Gastrointestinal

[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).

Issues Being Causally Associated with GLP-1RAs.

25. As stated above, Mounjaro (tirzepatide) belong to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

26. 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.[11]

27. Defendant knew or should have known of this risk of gastrointestinal issues such as gastroparesis and bowel obstructions from the clinical trials, medical literature, and case reports.

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

29. A 2016 trial funded by Novo Nordisk measuring semaglutide and cardiovascular outcomes in patients with type 2 diabetes found more gastrointestinal disorders in the semaglutide group than in the placebo group, including 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.[12]

30. The published medical literature also shows that GLP-1 slows gastric emptying.

[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/ (visited on 9/26/23).
[12]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).

As early as 2010, a study published in The Journal of Clinical Endocrinology & Metabolism indicated this effect.[13]

31. 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 the second subject being diagnosed with gastroparesis after approximately two months in the trial.

32. 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."[14] 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." *Id*.

33. 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

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

[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 (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 intestinal obstructions.

34. 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."[16] 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." *Id*.

35. In a September 2020 article, scientists affiliated with Novo Nordisk reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes.[17] More patients permanently discontinued taking oral semaglutide (11.6%) than placebo (6.5%) due to adverse events. *Id*. 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). *Id*. Injectable semaglutide had a discontinuation rate of 11.5-14.5% (versus 5.7-7.6% with placebo) over a two-year period. *Id*. 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." *Id*. For patients with other comorbidities, the study warned that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs." *Id*. The study

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

[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:sup2, 37-47, available at https://doi.org/10.1080/00325481.2020.1800286 (visited on 9/26/23).

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." *Id.*

36. A July 2021 article 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.[18] 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). *Id*. Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for gastrointestinal related adverse events, with some trials experiencing 100% discontinuation due to gastrointestinal related adverse events. *Id.* The mean value of gastrointestinal related adverse events that led to discontinuation averaged 57.75%. *Id*. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]" *Id.*

37. 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[.]"[19] In diabetics, making this determination can be particularly "tricky" because both diabetes and GLP-1RAs can cause delayed gastric emptying. *Id*. As such, "the timeline of drug initiation and symptom onset becomes of the upmost importance." *Id*. The authors reviewed two case reports

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

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

(discussed below) and concluded that history taking and making an accurate diagnosis of diabetic gastroparesis versus medication-induced gastroparesis is critical. *Id*.

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

38. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[20]

39. An October 2022 study analyzed 5,442 GLP-1RA adverse gastrointestinal events.

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

32% were serious, including 40 deaths, 53 life-threatening conditions, and 772 hospitalizations.[21] The primary events were nausea and vomiting. *Id.* There were also adverse events for impaired gastric emptying. *Id.*

40. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[22]

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.[23]

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."[24]

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 food into the airways and lungs during general anesthesia and deep sedation."[25] The ASA also warned that the risk is higher where patients on these medications have experienced nausea and vomiting. *Id.*

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[21]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).

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

[23]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).

[24]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).

[25]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 (visited on 9/26/23).

44. News sources have identified the potential for serious side effects in users of Ozempic, including gastroparesis, leading to hospitalization.[26] 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."[27] 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.[28]

45. 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."[29] It was reported that a growing number of gastroparesis cases had been seen in people taking GLP-1RAs. *Id*. 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. *Id*. 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. *Id*.

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

[27]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-rcna66493 (visited on 9/26/23).

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

[29]*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).

46. 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.[30] The study found that patients prescribed GLP-1RAs were at 4.22 times higher risk of intestinal obstruction and at 3.67 times higher risk of gastroparesis. *Id*.

47. Defendant knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing severe gastrointestinal issues such as gastroparesis and intestinal obstructions.

48. Defendant's actual and constructive knowledge derived from clinical studies, case reports, and medical literature, including the medical literature and case reports referenced herein.

49. Defendant not only knew or should have known that its GLP-1RAs causes severe gastrointestinal issues such as gastroparesis and intestinal obstructions, but in fact, may have sought out the delayed gastric emptying effect because of its association with weight loss. For example, a recent study published in 2023 notes that "it has been previously proposed that long-acting GLP-1RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying,]" and the study authors suggested "further exploration of peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake."[31]

D. Defendant Failed to Warn of the Risk of Known Gastrointestinal Issues from

[30]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).
[31]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 (visited on 9/26/23).

Mounjaro

50. The Prescribing Information for Mounjaro (the "Mounjaro Label") discloses "Warnings and Precautions" and "Adverse Reactions" but does not adequately warn of the risk of gastrointestinal issues such as gastroparesis and intestinal obstructions.

51. 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 Disease, gastroparesis and intestinal obstructions are not specifically mentioned. Nor did any of Defendant's additional advertising or promotional materials warn prescription providers or the general public of these risks either.

52. Defendant knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing gastrointestinal issues such as gastroparesis and intestinal obstructions. Defendant's actual and constructive knowledge derived from clinical studies, case reports, and medical literature, including the medical literature and case reports referenced herein.

53. Upon information and belief, Defendant ignored the causal association between the use of GLP-1RAs and the risk of developing gastrointestinal issues such as gastroparesis and intestinal obstructions.

54. Defendant's failure to disclose information that they possessed regarding the causal association between the use of GLP-1RAs and the risk of developing gastrointestinal issues such as gastroparesis and intestinal obstructions rendered the warnings for Mounjaro inadequate.

55. Upon 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 intestinal obstructions, nor were they aware that

"common adverse reactions" listed on the labels might be sequelae of same.

56. Upon information and belief, had Defendant adequately warned Plaintiff's Prescribing Physician that Mounjaro is causally associated with gastroparesis, intestinal obstructions and their sequelae, then the Prescribing Physician's decision would have changed by not prescribing Mounjaro and/or by monitoring Plaintiff's health for symptoms of same and discontinuing Mounjaro when the symptoms first started.

57. As a result of the foregoing acts and omissions, Plaintiff has and continues to suffer from severe gastrointestinal issues including intestinal obstructions, which resulted in severe and personal injuries that 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.

COUNT I
(Negligent Failure to Warn)

58. Plaintiff incorporates by reference Paragraphs 1 through 57 as if fully set forth herein.

59. Under New York law, 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 products would not cause users to suffer unreasonable, dangerous injuries, such as gastroparesis, intestinal obstructions and their sequelae.

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

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

62. 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, intestinal obstructions and their sequelae, especially when used in the form and manner as provided by Defendant.

63. 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.

64. 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, without adequate warnings.

65. 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.

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

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

68. At all relevant times, Plaintiff was using Mounjaro for the purposes and in a manner normally intended.

69. 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, including gastroparesis, intestinal obstructions and their sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendant failed to adequately warn of said risk.

70. 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, intestinal obstructions and their sequelae, 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 the product.

71. The label for Mounjaro was inadequate because it 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, intestinal obstructions and their sequelae.

72. The label for Mounjaro was inadequate because it failed to warn and/or adequately warn that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae.

73. The label for Mounjaro was inadequate because it failed to warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Mounjaro.

74. 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.

75. Communications made by Defendant to Plaintiff and her Prescribing Physician 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, intestinal obstructions and their sequelae.

76. Communications made by Defendant to Plaintiff and her Prescribing Physician were inadequate because Defendant failed to warn and/or adequately warn that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae.

77. 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.

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

79. Upon information and belief, had Plaintiff's Prescribing Physician been warned of the increased risks of gastroparesis, intestinal obstructions and their sequalae causally associated with Mounjaro, then they 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.

80. Upon information and belief, had Plaintiff's Prescribing Physician been warned that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae, 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 as to allow Plaintiff to make an informed decision

regarding Plaintiff's use of Mounjaro.

81. Had Plaintiff been warned of the increased risks of gastroparesis, intestinal obstructions and their sequelae, which are causally associated with Mounjaro, Plaintiff would not have used Mounjaro and/or suffered severe gastrointestinal issues including intestinal obstructions and its sequelae.

82. Had Plaintiff been warned that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae, Plaintiff would not have used Mounjaro and/or suffered severe gastrointestinal issues including intestinal obstructions and its sequelae.

83. Had Plaintiff been warned of the increased risks of gastroparesis, intestinal obstructions and their sequelae causally associated with Mounjaro, Plaintiff would have informed her Prescribing Physician that she did not want to take Mounjaro.

84. Upon information and belief, if Plaintiff had informed her Prescribing Physician that she did not want to take Mounjaro due to the risks of gastroparesis, intestinal obstructions and their sequelae, or the lack of adequate testing for safety risks, then her Prescribing Physician would not have prescribed Mounjaro.

85. 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.

86. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the 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.

87. Defendant's inadequate warning for Mounjaro amounts to willful, wanton, and/or reckless conduct by Defendant.

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

89. As a result of the foregoing acts and omissions, Plaintiff has and continues to suffer from severe gastrointestinal issues including intestinal obstructions 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.

90. 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 further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

COUNT II
(Strict Product Liability Failure to Warn)

91. Plaintiff incorporates by reference Paragraphs 1 through 57 as if fully set forth herein.

92. Under New York law, 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 gastroparesis, intestinal obstructions and their sequelae.

93. At all times mentioned herein, Defendant designed, researched, manufactured,

tested, advertised, promoted, marketed, sold and/or distributed the Mounjaro that was used by Plaintiff.

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

95. 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, intestinal obstructions and their sequelae, especially when used in the form and manner as provided by Defendant.

96. 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.

97. 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, without adequate warnings.

98. 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.

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

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

101. At all relevant times, Plaintiff was using Mounjaro for the purposes and in a manner

normally intended.

102. 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, including gastroparesis, intestinal obstructions and their sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendant failed to adequately warn of said risk.

103. 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, intestinal obstructions and their sequelae, 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 the product.

104. The label for Mounjaro was inadequate because it 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, intestinal obstructions and their sequelae.

105. The label for Mounjaro was inadequate because it failed to warn and/or adequately warn that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae.

106. The label for Mounjaro was inadequate because it failed to warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Mounjaro.

107. 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.

108. Communications made by Defendant to Plaintiff and her Prescribing Physician 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, intestinal obstructions and their sequelae.

109. Communications made by Defendant to Plaintiff and her Prescribing Physician were inadequate because Defendant failed to warn and/or adequately warn that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae.

110. 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.

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

112. Upon information and belief, had Plaintiff's Prescribing Physician been warned of the increased risks of gastroparesis, intestinal obstructions and their sequelae causally associated with Mounjaro, then they 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.

113. Upon information and belief, had Plaintiff's Prescribing Physician been warned that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae, 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 as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

114. Had Plaintiff been warned of the increased risks of gastroparesis, intestinal obstructions and their sequelae, which are causally associated with Mounjaro, Plaintiff would not have used Mounjaro and/or suffered severe gastrointestinal issues including intestinal obstructions and its sequelae.

115. Had Plaintiff been warned that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae, Plaintiff would not have used Mounjaro and/or suffered severe gastrointestinal issues including intestinal obstructions and its sequelae.

116. Had Plaintiff been warned of the increased risks of gastroparesis, intestinal obstructions and their sequelae causally associated with Mounjaro, Plaintiff would have informed her Prescribing Physician that she did not want to take Mounjaro.

117. Upon information and belief, if Plaintiff had informed her Prescribing Physician that she did not want to take Mounjaro due to the risks of gastroparesis, intestinal obstructions and their sequelae, or the lack of adequate testing for safety risks, then they would not have prescribed her Mounjaro.

118. 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.

119. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the 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.

120. Defendant's inadequate warnings for Mounjaro amounted to willful, wanton, and/or reckless conduct by Defendant.

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

122. As a direct and proximate result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including severe gastrointestinal issues including intestinal obstructions 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.

123. 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 further alleges that she will require future medical and/or hospital care, attention, and services.

COUNT III
(Breach of Express Warranty)

124. Plaintiff incorporates by reference Paragraphs 1 through 57 as if fully set forth herein.

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

126. At all relevant times, Defendant expressly warranted to Plaintiff and her Prescribing

Physician that Mounjaro was safe and effective and assured them that it did not carry increased risks of gastrointestinal complications, including gastroparesis, intestinal obstructions and their sequelae.

127. The aforementioned express warranties were made to Plaintiff and her Prescribing Physician by way of Mounjaro's label, website, advertisements, promotional materials, and through other statements.

128. 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.

129. 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.

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

131. At all relevant times, Defendant knew or should have known that Mounjaro was unreasonably dangerous because of the increased risk of gastroparesis, intestinal obstructions and their sequelae, especially when the drug was used in the form and manner as provided by Defendant.

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

133. 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.

134. The unreasonably dangerous characteristics of Mounjaro were beyond that which

would be contemplated by Plaintiff's Prescribing Physician, with the ordinary knowledge common to prescribing physicians as to the drug's characteristics.

135. At the time Mounjaro left Defendant's control, Mounjaro did not conform to Defendant's express warranties because Mounjaro was not safe and effective, in that the drug was causally associated with increased risks of gastroparesis, intestinal obstructions and their sequelae.

136. The express warranties made by Defendant regarding the safety of Mounjaro were made with the intent to induce Plaintiff to use the products and/or Plaintiff's Prescribing Physician to prescribe the product.

137. Defendant knew and/or should have known that by making the express warranties to Plaintiff and/or Plaintiff's Prescribing Physician, it would be the natural tendency of Plaintiff to use Mounjaro and/or the natural tendency of Plaintiff's Prescribing Physician to prescribe Mounjaro.

138. Plaintiff and her Prescribing Physician, as well as members of the medical community, relied on the express warranties of Defendant identified herein.

139. Had Defendant not made these express warranties, Plaintiff would not have used Mounjaro and/or, upon information and belief, Plaintiff's Prescribing Physician would have altered their prescribing practices 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.

140. Had Plaintiff been warned of the increased risk of gastroparesis, intestinal obstructions and their sequelae causally associated with Mounjaro, Plaintiff would not have used Mounjaro and/or suffered severe gastrointestinal issues including intestinal obstructions and its sequelae.

141. Had Plaintiff been warned that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae, Plaintiff would not have used Mounjaro and/or suffered severe gastrointestinal issues including intestinal obstructions and its sequelae.

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

143. Defendant's breach of express warranties was a substantial factor in causing Plaintiff's injuries.

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

145. As a direct and proximate result of the foregoing breach, Plaintiff was caused to suffer serious and dangerous injuries, including severe gastrointestinal issues including intestinal obstructions and its sequelae, 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.

146. 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 Mounjaro.

147. 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 further alleges that she will require future medical and/or hospital care, attention, and services.

COUNT IV
(Breach of Implied Warranty of Merchantability)

148. Plaintiff incorporates by reference Paragraphs 1 through 57 as if fully set forth herein.

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

150. 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.

151. At all relevant times, Defendant impliedly warranted to Plaintiff, Plaintiff's Prescribing Physician, and the medical community that Mounjaro was of merchantable quality and safe and fit for its ordinary purposes.

152. At all relevant times, Defendant knew or should have known that Mounjaro was unreasonably dangerous because of the increased risk of gastroparesis, intestinal obstructions and their sequelae, especially when the drug was used in the form and manner as provided by Defendant.

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

154. At the time Mounjaro left Defendant's control, Mounjaro did not confirm to Defendant's implied warranty and was unfit for its ordinary purposes because Defendant failed to provide adequate warnings of the drug's causal association with increased risk of gastroparesis, intestinal obstructions and their sequelae.

155. At all relevant times, Defendant reasonably anticipated and expected that prescribing physicians, such as Plaintiff's Prescribing Physician, would recommend, prescribe and/or dispense Mounjaro for patients.

156. At all relevant times, Defendant reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Mounjaro for its ordinary purpose.

157. Despite the fact that Defendant knew or should have known that Mounjaro causes unreasonably dangerous injuries, such as gastroparesis, intestinal obstructions and their sequelae, Defendant continued to market, distribute, and/or sell Mounjaro to consumers, including Plaintiff, without adequate warnings.

158. 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.

159. The unreasonably dangerous characteristics of Mounjaro were beyond that which would be contemplated by Plaintiff's Prescribing Physician, with the ordinary knowledge common to prescribing physicians as to the drug's characteristics.

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

161. 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.

162. Upon information and belief, Plaintiff's Prescribing Physician relied on Defendant's implied warranty of merchantability and fitness for the ordinary use and purpose relating to Mounjaro.

163. Upon information and belief, Plaintiff's Prescribing Physician 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.

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

Mounjaro and/or, upon information and belief, Plaintiff's Prescribing Physician 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.

165. Defendant herein breached the aforesaid implied warranty of merchantability because the drug Mounjaro was not fit for the drug's intended purpose.

166. Defendant breach of implied warranty of merchantability was a substantial factor in causing Plaintiff's injuries.

167. As a direct and proximate result of the foregoing breach, Plaintiff was caused to suffer serious and dangerous injuries, including severe gastrointestinal issues including intestinal obstructions 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.

168. 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 further alleges that she will require future medical and/or hospital care, attention, and services.

COUNT V
(Fraudulent Concealment)

169. Plaintiff incorporates by reference Paragraphs 1 through 57 as if fully set forth herein.

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

hereinabove described.

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

172. At all relevant times, Defendant knew or should have known that Mounjaro was unreasonably dangerous because of the increased risk of gastroparesis, intestinal obstructions and their sequelae, especially when the drug was used in the form and manner as provided by Defendant.

173. Defendant had a duty to disclose material information about Mounjaro to Plaintiff and Plaintiff's Prescribing Physician, namely that Mounjaro is causally associated with increased risk of gastroparesis, intestinal obstructions and their sequelae, because Defendant has superior knowledge of the drug and its dangerous side effects, this material information is not readily available to Plaintiff or Plaintiff's Prescribing Physician 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.

174. Nonetheless, Defendant consciously and deliberately withheld and concealed from Plaintiff and her Prescribing Physician, the medical and healthcare community, and the general public this material information.

175. Although the Mounjaro label lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Mounjaro patients, it does not mention gastroparesis, intestinal obstructions and their sequelae as risks of taking Mounjaro.

176. Defendant's promotional websites for Mounjaro similarly does not disclose that Mounjaro is causally associated with increased risk of gastroparesis, intestinal obstructions and their sequelae.

177. 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, and patients such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Mounjaro.

178. Defendant knew or should have known that Plaintiff's Prescribing Physician would prescribe, and Plaintiff would use Mounjaro without the awareness of the risks of serious side effects, including gastroparesis, intestinal obstructions and their sequelae.

179. Defendant knew that Plaintiff and Plaintiff's Prescribing Physicians had no way to determine the truth behind Defendant's misrepresentations and concealments surrounding Mounjaro, as set forth herein.

180. Upon information and belief, Plaintiff's Prescribing Physician justifiably relied on Defendant's material misrepresentations, including the omissions contained therein, when making the decision to dispense, provide, and prescribe Mounjaro.

181. Upon information and belief, had Plaintiff's Prescribing Physician been warned of the increased risk of gastroparesis, intestinal obstructions and their sequelae 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, intestinal obstructions and their sequelae causally associated with Mounjaro to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

182. Upon information and belief, had Plaintiff's Prescribing Physician been told that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae, 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.

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

184. Had Plaintiff been informed of the increased risks causally associated with Mounjaro, Plaintiff would not have used Mounjaro and/or suffered severe gastrointestinal issues including intestinal obstructions and its sequelae.

185. Defendant's fraudulent concealments was a substantial factor in causing Plaintiff's injuries.

186. As a direct and proximate result of the above stated omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries, including severe gastrointestinal issues including intestinal obstructions 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.

187. 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 further alleges that she will require future medical and/or hospital care, attention, and services.

COUNT VI
(Fraudulent Misrepresentation)

188. Plaintiff incorporates by reference Paragraphs 1 through 57 as if fully set forth herein.

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

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

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

191. At all relevant times, Defendant knew or should have known of the serious side effects of Mounjaro, including gastroparesis, intestinal obstructions and their sequelae.

192. At all relevant times, Defendant knew or should have known that Mounjaro was not a safe and effective drug, given its increased risk of gastroparesis, intestinal obstructions and their sequelae.

193. Nonetheless, Defendant made material misrepresentations to Plaintiff, Plaintiff's Prescribing Physician, the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Mounjaro.

194. Defendant represented affirmatively and by omission on television advertisements and on the label of Mounjaro, that it was safe and effective, despite being aware of the increased risks of gastroparesis, intestinal obstructions and their sequelae causally associated with using Mounjaro.

195. Defendant was aware or should have been aware that their representations was false or misleading and knew that they were concealing and/or omitting material information from Plaintiff, Plaintiff's Prescribing Physician, the medical and healthcare community, and the general public.

196. Defendant's 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, and patients such as Plaintiff, to dispense, provide, prescribe,

accept, purchase, and/or consume Mounjaro.

197. Upon information and belief, Plaintiff's Prescribing Physician 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 had no way to know were omitted.

198. Upon information and belief, Plaintiff's Prescribing Physician justifiably relied on Defendant's material misrepresentations, including the omissions contained therein, when making the decision to prescribe Mounjaro to Plaintiff.

199. Upon information and belief, had Plaintiff's Prescribing Physician been informed of the increased risk of gastroparesis, intestinal obstructions and their sequelae causally associated with Mounjaro, they would not have prescribed Mounjaro and/or would have provided Plaintiff with adequate information regarding the safety of Mounjaro to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

200. Upon information and belief, had Plaintiff's Prescribing Physician been told that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae, 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 could make an informed decision regarding Plaintiff's use of Mounjaro.

201. 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.

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

203. Had Plaintiff been told of the increased risk of gastroparesis, intestinal obstructions and their sequelae causally associated with Mounjaro, Plaintiff would not have used Mounjaro and/or suffered severe gastrointestinal issues including intestinal obstructions and its sequelae.

204. Had Plaintiff been told of the lack of sufficient and/or appropriate testing of Mounjaro for safety risks, including gastroparesis, intestinal obstructions and their sequelae, Plaintiff would not have used Mounjaro and/or suffered severe gastrointestinal issues including intestinal obstructions and its sequelae.

205. 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 gastrointestinal issues including intestinal obstructions 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.

206. 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 further alleges that she will require future medical and/or hospital care, attention, and services.

COUNT VII
(Negligent Misrepresentation)

207. Plaintiff incorporates by reference Paragraphs 1 through 57 as if fully set forth herein.

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

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

210. At all relevant times, Defendant knew or should have known of the serious side effects of Mounjaro, including gastroparesis, intestinal obstructions and their sequelae.

211. Defendant had a duty to disclose material information about Mounjaro to Plaintiff and Plaintiff's Prescribing Physician that Mounjaro is causally associated with increased risk of gastroparesis, intestinal obstructions and their sequelae, because Defendant held a special expertise with respect to Mounjaro, Plaintiff, as a user of Mounjaro, had a special relationship of trust with Defendant, and Defendant knew that their statements regarding the risks causally associated with Mounjaro would be relied on by Mounjaro users.

212. At all relevant times, Defendant knew or should have known of the serious side effects of Mounjaro, including gastroparesis, intestinal obstructions and their sequelae.

213. Nonetheless, Defendant made material misrepresentations and omissions and/or concealments to Plaintiff, Plaintiff's Prescribing Physician, the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Mounjaro.

214. Defendant represented affirmatively and by omission on television advertisements and on the label of Mounjaro that Mounjaro was a safe and effective drug, despite being aware of the increased risks of gastroparesis, intestinal obstructions and their sequelae causally associated

with using Mounjaro.

215. Defendant was aware or should have been aware that their representations were false or misleading and/or knew that they were concealing and/or omitting material information from Plaintiff, Plaintiff's Prescribing Physician, the medical and healthcare community, and the general public.

216. Defendant knew that Plaintiff and Plaintiff's Prescribing Physician had no way to determine the truth behind Defendant's misrepresentations and concealments surrounding Mounjaro, as set forth herein.

217. Upon information and belief, Plaintiff's Prescribing Physician justifiably relied on Defendant's material misrepresentations, including the omissions contained therein, when making the decision to prescribe Mounjaro to Plaintiff.

218. Upon information and belief, had Plaintiff's Prescribing Physician been warned of the increased risk of gastroparesis, intestinal obstructions and their sequelae causally associated with Mounjaro, they would not have prescribed Mounjaro and/or would have provided Plaintiff with adequate information regarding the safety of Mounjaro so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Mounjaro.

219. Upon information and belief, had Plaintiff's Prescribing Physician been told that Mounjaro had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, intestinal obstructions and their sequelae, 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 could make an informed decision regarding Plaintiff's use of Mounjaro.

220. Plaintiff reasonably relied on the 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.

221. Had Plaintiff been told of the increased risk of gastroparesis, intestinal obstructions and their sequelae causally associated with Mounjaro, Plaintiff would not have used Mounjaro and/or suffered severe gastrointestinal issues including intestinal obstructions and its sequelae.

222. Defendant's misrepresentations and omissions of material facts amount to willful, wanton, and/or reckless conduct.

223. 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 severe gastrointestinal issues including intestinal obstructions 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.

224. 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 further alleges that she will require future medical and/or hospital care, attention, and services.

PRAYER FOR RELIEF

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

A. 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;

B. 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;

C. Awarding Plaintiff the costs of these proceedings; and

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

Dated: February 1, 2024

By: */s/ Jeffrey L. Haberman*

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: February 1, 2024

By: */s/ Jeffrey L. Haberman*

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