Exhibit A

Alexander Bylinkin (Attorney ID# 125212014)
MORGAN & MORGAN PHILADELPHIA PLLC
30 Montgomery St., Ste. 410,
Jersey City, NJ 07302
abylinkin@forthepeople.com

Attorneys for Mary Angela Hanson

MARY ANGELA HANSON, **Plaintiff,** **vs.** **NOVO NORDISK A/S,** **NOVO NORDISK INC.,** **ELI LILLY AND COMPANY,** **LILLY USA, LLC,** **JOHN DOES 1-10 (fictitious parties),** **and ABC CORPORATIONS 1-10** **(fictitious designations)** **Defendants.**	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY DOCKET NO.: BER-L- CIVIL ACTION **COMPLAINT; CERT. PURSUANT TO R. 4:5-1; DEMAND FOR JURY TRIAL; AND DESIGN. OF TRIAL COUNSEL**

COMES NOW, Plaintiff, by and through Plaintiff's attorneys, MORGAN & MORGAN PHILADELPHIA PLLC, and files this Original Complaint and demand for Jury Trial, against Defendants NOVO NORDISK A/S and NOVO NORDISK INC. (hereinafter collectively referred to as "the Novo Nordisk Defendants", "Novo Nordisk", or "Novo"), ELI LILLY AND COMPANY and LILLY USA, LLC (hereinafter collectively referred to as "the Eli Lilly Defendants", "Eli Lilly", or "Lilly"), JOHN DOES 1-10 (fictitious parties), and ABC CORPORATIONS 1-10 (fictitious designations) (hereinafter collectively referred to as "Defendants"), and alleges as follows:

INTRODUCTION AND NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiff, who was severely injured as a result of their use of GLP-1 receptor agonists ("GLP-1RAs"), including Ozempic and Mounjaro, prescription medications designed, researched, tested, manufactured, marketed, supplied, promoted, advertised, packaged, labeled, sold and/or distributed by Defendants.

2. Ozempic and Mounjaro belong to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs"). The active ingredient in Ozempic is known as semaglutide. The active ingredient in Mounjaro is known as tirzepatide. Other drugs and active ingredients detailed below also fall within the GLP-1 RA class, based on similarities in their mechanisms of action, physiologic effects, and chemical structure.

3. Medications within the GLP-1RA class of drugs mimic the activities of physiologic GLP-1, a gut hormone that binds to receptors throughout the body and, notably, activates GLP-1 receptors in the pancreas to stimulate the release of insulin and suppress glucagon.[1]

4. GLP-1 RAs are designed to work similarly, to stimulate insulin production and reduce glucose production, but engineered to last longer than naturally-occurring GLP-1, which has a short life and is quickly metabolized by enzymes.

5. GLP-1 RAs are prescribed, for certain patient populations, to control blood sugar in adults with type 2 diabetes, reduce cardiac risk, and/or aid in chronic weight management.

6. Defendants have acknowledged that gastrointestinal events are well known side effects of the GLP-1RA class of drugs.[2] However, Defendants have downplayed the nature,

[1] D. Hinnen, *Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes*, 30(3) DIABETES SPECTR. 202-10 (Aug. 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556578/.
[2] *See, e.g.*, C.T. Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, ROLLING STONE (Jul. 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601.

duration, extent, and seriousness of gastrointestinal events and failed to warn about other adverse events caused by their GLP-1RAs. Defendants have never provided adequate warnings about the risks of, among other things, debilitating cyclical vomiting for days and weeks requiring hospitalization, all other injuries mentioned in this Complaint, and their sequelae.

7. The decision to target the American population for the sale of Defendants' GLP-1RAs was not accidental. Defendants understood the vast financial potential of marketing medications for weight loss in the United States, where obesity rates were on the rise despite the culture's obsession with losing weight and being thin.

8. Defendants set on a course to create and expand the market for weight-loss medication(s) by, among other things, advocating for obesity to be classified as a disease and thereby expanding the market for their drugs, spending hundreds of millions of dollars in an effort to change the medical consensus on how to treat obesity, implementing cutting-edge invasive, unprecedented and multifaceted marketing campaigns that were so effective they engrained these drugs in the pop culture zeitgeist, and spending untold millions in an effort to get weight-loss medications covered under public and private insurance. Defendants engaged in this conduct even before GLP-1 RAs were approved for weight loss, encouraging extensive off-label demand for, and use of, GLP-1 RAs.

9. By undertaking that effort, Defendants also were systematically and intentionally targeting users of other diabetes medications. Defendants' promise of weight loss wrongfully enticed users of other diabetes medications to switch to a GLP-1 RA, although they never would have done so if not for the off-label promotion of those drugs.

10. Defendants also sought to make the GLP-1 RAs more accessible by, among other things, marketing through telemedicine where the criteria for qualifying for the drugs, *e.g.*, Body Mass Index ("BMI"), are more easily manipulated.

11. Defendants' efforts to conceal (or minimize) the risks associated with taking their drugs were intended to create the impression that these were "miracle drugs" to help users lose weight. However, Defendants never disclosed that many people who take these drugs stop taking them because of the drastic side effects (thereby never achieving weight loss or any health benefit allegedly associated with the drug(s)); the drugs do not result in meaningful weight loss for up to 15% of people;[3] the average weight loss for someone taking the drugs is a modest 10.09% of the person's

body weight;[4] and a person will need to stay on these drugs for the rest of their lives to maintain the weight loss.[5] What is worse, Defendants kept this information hidden while actively degrading trust in the prevailing view that lifestyle changes like proper nutrition and exercise were the keys to health and can accomplish long-lasting weight loss and management for most people.

12. The efforts to engrain GLP-1 RAs such as Ozempic in the public conscious, to manipulate the medical community's views on obesity treatment, and to make the drugs more accessible acted as a launching pad for the explosive growth of the GLP-1 RAs, both for people with diabetes, and for people seeking to lose weight, whether they were using the drug as

[3] Erica Carbajal, *Up to 15% of patients on weight loss drugs may be 'non-responders'*, BECKER'S HOSPITAL REV. (Apr. 1, 2024) available at https://www.beckershospitalreview.com/glp-1s/upto-15-of-patients-on-weight-loss-drugs-non-responders.html.
[4] Gao, et al., *Efficacy and safety of semaglutide on weight loss in obese or overweight patients without diabetes: A systematic review and meta-analysis of randomized controlled trials*, FRONTIERS IN PHARMACOLOGY 1 (2022).
[5] Wilding, et al., *Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension*, 24 DIABETES OBES METAB. 1553, 1562 ("[T]reatment withdrawal led to most of the weight loss being regained within 1 year, …, reinforcing the need for continued treatment to maintain weight loss ….").

prescribed or off-label. Plaintiff would not have taken GLP-1 RAs if Plaintiff had been provided a full and clear warning of the true risks of taking these drugs.

13. Defendants' efforts to expand and grow the market both for treatment of diabetes and weight-loss, whether off-label or not, worked. The U.S. GLP-1 RA market is expected to exceed $100 Billion by 2030 with total U.S. users comprising about 9% of the population.[6] This growth is a tremendous boon to Defendants but comes at a significant cost. Financially, it is expected that Defendants' lobbying efforts will pay off, and GLP-1 RAs may get added to prescription drug coverage under Medicare Part D in the coming years. Some analysts project that this will add $13.6 to $26.8 Billion to Medicare Part D expenses even if only 10% of people with obesity use them, causing a significant shift in premiums and coverage in other areas.[7]

14. The outsized growth of the market for GLP-1 RAs also means that the patient base has expanded to include many patients who would be better served choosing alternate treatment paths. Defendants' marketing campaigns have altered the public understanding of weight loss treatment, creating the impression that GLP-1 RAs are not just one tool among many available to doctors, but are instead "miracle drugs." But, these patients, like Plaintiff, were lured into a false sense of hope that GLP-1 RAs would guarantee results and be efficacious and safe. Plaintiff and other users injected themselves with GLP-1 RAs believing that they were doing something to promote their health when, in fact, it had the opposite effect.

15. As a result of the foregoing, Plaintiff has suffered and was diagnosed with various forms of injury which were directly and proximately caused by regular and prolonged use of GLP-

[6] J.P. Morgan Research, *The increase in appetite for obesity drugs* (Nov. 29, 2023), available at https://www.jpmorgan.com/insights/global-research/current-events/obesity-drugs#sectionheader#0.
[7] Vanderbilt University Medical Center, *Cost of covering antiobesity drugs could be billions to Medicare despite, a new analysis finds* (Mar. 15, 2023), available at https://www.vumc.org/health-policy/medicare-antiobesity-medications-nejm.

1 RAs. Plaintiff's injuries include, but are not limited to cyclical vomiting for days and weeks requiring hospitalization and its sequelae, including debilitating nausea, debilitating vomiting, debilitating abdominal pain, extreme constipation, and emotional distress, among other injuries.

PLAINTIFF

16. Plaintiff, MARY ANGELA HANSON, is a citizen of the United States, and is a resident of the State of Kentucky.

17. Plaintiff is 56 years old.

18. Plaintiff used Mounjaro in approximately March 2024.

19. Plaintiff used Ozempic from approximately March 2024 to March 2025.

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

21. As a result of using Mounjaro and Ozempic, Plaintiff was caused to suffer from cyclical vomiting for days and weeks requiring hospitalization, and is sequelae, which resulted in, for example, debilitating nausea, debilitating vomiting, debilitating diarrhea, debilitating abdominal pain, extreme constipation, and emotional distress.

22. As a result of using Mounjaro and Ozempic, Plaintiff was caused to suffer from the injuries identified above, and their sequelae and, as a result, sustained severe personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

DEFENDANTS

23. Defendant Novo Nordisk Inc. is and at all relevant times has been a Delaware corporation with a principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey.

24. Defendant Novo Nordisk A/S is and at all relevant times has been a public limited liability company organized under the laws of Denmark with a principal place of business in Bagsværd, Denmark.

25. Defendants Novo Nordisk Inc. and Novo Nordisk A/S are referred to collectively herein as "the Novo Nordisk Defendants", "Novo Nordisk", or "Novo."

26. Each of the Novo Nordisk Defendants was the agent and employee of Novo Nordisk and the other Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with Novo Nordisk and the other Defendants' actual and implied permission, consent, authorization and approval.

27. In collaboration amongst themselves, as part of their business, and at all relevant times, the Novo Nordisk Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed GLP-1 RAs, including Ozempic. Alternatively, Novo has acquired the entity or entities who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed GLP-1 RAs, including Ozempic, and is, thus, the successor to such entity or entities.

28. Defendant Eli Lilly and Company is and at all relevant times has been an Indiana corporation with a principal place of business at 893 S. Delaware St., Indianapolis, Indiana.

29. Defendant Lilly USA, LLC is and at all relevant times has been an Indiana LLC with a principal place of business at 893 S. Delaware St., Indianapolis, Indiana.

30. Defendants Eli Lilly and Company and Lilly USA, LLC are referred to collectively herein as "the Eli Lilly Defendants" or "Eli Lilly" or "Lilly."

31. Each of the Eli Lilly Defendants was the agent and employee of the other Eli Lilly Defendants and, in doing the things alleged, was acting within the course and scope of such agency

and employment and with the other Eli Lilly Defendants' actual and implied permission, consent, authorization and approval.

32. In collaboration amongst themselves, as part of their business, and at all relevant times, the Eli Lilly Defendants designed, researched, manufactured, tested, labeled, advertised, promoted, marketed, sold, and/or distributed GLP-1 RAs, including Mounjaro.

33. At all times material hereto, Defendants JOHN DOES 1-10 (FICTITIOUS PARTIES), were and/or are fictitiously named individuals, the identity, addresses and culpable conduct of said defendants being presently unknown. Plaintiff reserves the right to amend this Complaint upon obtaining knowledge of the identity, addresses and culpable conduct of the defendants represented herein as JOHN DOES 1-10.

34. At all times material hereto, Defendants ABC CORPORATIONS 1-10 (FICTITIOUS PARTIES), were and/or are fictitiously named partnerships, associations and/or corporations, which exist or are subject to jurisdiction under the laws of the State of New Jersey, the identity, addresses and culpable conduct of said defendants being presently unknown. Plaintiff reserves the right to amend this Complaint upon obtaining knowledge of the identity, addresses and culpable conduct of the defendants represented herein as ABC CORPORATIONS 1-10.

35. At all relevant times, each Defendant conducted business and derived substantial revenue from its marketing, advertising, distributing, and selling of GLP-1 RAs within New Jersey and Plaintiff's state of residence, Kentucky.

JURISDICTION AND VENUE

36. This Court has jurisdiction over the subject matter of this action under the N.J. CONSTIT. art. VI, § 3, para. 2.

37. The causes of action alleged in this Complaint arise out of or relate to the Defendants' activities in and contacts with New Jersey.

38. This Court possesses specific personal jurisdiction over each Defendant by virtue of each Defendant's contacts with New Jersey which gave rise to Plaintiff's injuries. Each Defendant purposefully availed itself of activities within and directed toward New Jersey, making it reasonable for each Defendant to anticipate being haled into court in New Jersey. Such activities include, but are not limited to, acts relating to marketing, promotion, distribution, and sales of GLP-1RAs in New Jersey. Such acts led to Plaintiff's use of Mounjaro and Ozempic, which caused Plaintiff's injuries.

39. This Court possesses general personal jurisdiction over the Novo Nordisk Defendants by virtue of Novo Nordisk Inc.'s citizenship and principal place of business in New Jersey, and because Novo Nordisk Inc. is an agent and alter ego of Novo Nordisk A/S. Both entities maintain and carry on systematic and continuous contacts and regularly transact business in New Jersey. Substantial activities relating to the design, development, marketing, labeling, warnings, promotion, distribution, and sales of Ozempic were performed by Novo Nordisk Inc., a corporation with its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey.

40. Although Novo Nordisk A/S and the Eli Lilly Defendants are nonresidents of New Jersey, this Court has personal jurisdiction over these Defendants pursuant to, and consistent with, New Jersey's long-arm jurisprudence and the requirements of Due Process. *See, e.g., Zahl v. Eastland*, 465 N.J. Super. 79, 92, 239 A.3d 1063, 1071 (App. Div. 2020) ("Our courts have adopted an approach to exercise jurisdiction over nonresident defendants to the uttermost limits permitted by the United States Constitution." (cleaned up)). Each Defendant had sufficient minimum

contacts with New Jersey such that maintenance of the suit does not offend traditional notions of fair play and substantial justice.

41. This lawsuit is not subject to removal based on the existence of a federal question. Plaintiff asserts common law and/or statutory claims under state law. These claims do not arise under the Constitution, laws, or treaties of the United States. 28 U.S.C. § 1447(c).

42. This lawsuit is not subject to removal because Novo Nordisk Inc. is a forum defendant.

43. Additionally, even if removal is effectuated in contravention of 28 U.S.C. § 1441(b)(2), there is no subject matter jurisdiction within federal court because there is not complete diversity.

44. Plaintiff seeks relief that is within the jurisdiction of this Court.

FACTUAL ALLEGATIONS

A. Introduction to GLP-1 and GLP-1 RA Products

45. Researchers first discovered GLP-1 in hamsters in 1983.[8] It is a hormone that helps regulate blood sugar, appetite, and digestion in animals, including humans; and is produced naturally in the brain and intestinal wall of humans.

46. In 1993, researchers discovered that a peptide from the venom of gila monsters activated GLP-1 receptors.[9] Gila monsters can go for months without eating but maintain stable blood sugar levels because they make very high levels of a glucagon peptide called exendin-4. Thus, the gila monster served as the inspiration for the GLP-1 RA class of drugs.

[8] Bell, et al., *Hamster preproglucagon contains the sequence of glucagon and two related peptides*, 302 NATURE 716 (1983).
[9] Thorens, et al., *Cloning and functional expression of the human islet glp-1 receptor*, 42 DIABETES 1678 (1993).

47. Following the discovery that exendin-4 is similar in structure to GLP-1, a synthetic version of exendin-4 was developed to treat diabetes. This became the first GLP-1 drug, known as Byetta, with the active ingredient exenatide, which came to market in 2005. Byetta was initially brought to market as a collaboration between Eli Lilly and Amylin.[10] Whereas naturally-occurring GLP-1 has a short half-life of just a few minutes, Byetta's half-life was noted to be 2.4 hours.[11]

48. Simultaneously with the development of exenatide, Novo was developing another GLP-1 drug called liraglutide. In the early 1990s, Novo researchers discovered that when they injected liraglutide into rats, it caused them to stop eating almost entirely.[12] Liraglutide came to market in 2010, marketed initially as Victoza and later as Saxenda. Liraglutide has a half-life of 13-15 hours.[13]

49. Various active ingredients fall within the GLP-1 RA class of drugs, including semaglutide (marketed by Novo as Ozempic, Wegovy, and Rybelsus), liraglutide (marketed by Novo as Saxenda, Victoza, and in combination with insulin as Xultophy 100/3.6), tirzepatide (marketed by Lilly as Mounjaro and Zepbound), dulaglutide (marketed by Lilly as Trulicity), exenatide (marketed by various companies as Byetta, Bydureon, and Bydureon BCise), albiglutide (marketed by GlaxoSmithKline as Tanzeum), and lixisenatide (marketed by Sanofi as Adlyxin and in combination with insulin as Soliqua 100/33). The U.S. Food & Drug Administration ("FDA") recognizes GLP-1 RAs as a class of drugs based on similarities in their mechanisms of action,

[10] News Release: Amylin and Lilly Announce FDA Approval of BYETTA(TM) (Exenatide Injection) (Apr. 29, 2005), *available at* https://investor.lilly.com/news-releases/news-releasedetails/amylin-and-lilly-announce-fda-approval-byettatm-exenatide (last visited Nov. 8, 2023) (describing the drug as a "collaboration" between Amylin and Lilly).
[11] Cai, et al., *Long-acting preparations of exenatide,* DRUG DES. DEVEL. THER. (Sept. 2013).
[12] Gina Kolata, *We Know Where New Weight Loss Drugs Came From, but Not Why They Work*, NEW YORK TIMES (Aug. 17, 2023), available at https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.
[13] Rubino, et al., *Effect of Weekly Subcutaneous Semaglutide vs Daily Liraglutide on Body Weight in Adults with Overweight or Obesity without Diabetes: The STEP 8 Randomized Clinical Trial,* JAMA (Jan. 2022).

physiologic effects, and chemical structure.[14] Defendants likewise recognize that their GLP-1 RAs are members of the same class.[15]

50. Medications within the GLP-1 RA class of drugs mimic the activities of physiologic GLP-1 in numerous ways,[16] including attaching to GLP-1 receptors, sending various signals in the body, triggering a sensation of satiety (or perception of fullness, thereby curbing users' appetites and decreasing intake of calories and nutrients),[17] acting on the pancreas to stimulate the release of insulin, suppressing the release of glucagon, and slowing or inhibiting gastric emptying and intestinal motility.[18]

51. In contrast to naturally-occurring GLP-1, which has a short life and is quickly metabolized by enzymes, GLP-1 RAs are engineered to last longer, as previously noted. The chemical structure of GLP-1 RAs includes a fatty chain that inhibits such quick dissolution. GLP-1 RAs such as semaglutide have a long half-life of well over 100 hours, causing the drugs to stay in the body for a month or more after the last dose.

---

[14] *See* FDA Ozempic Summary Review, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000SumR.pdf at 8 (including liraglutide, dulaglutide, and semaglutide in the GLP-1 RA class) (last visited Jan. 2, 2025); *see also* FDA Mounjaro Clinical Review, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215866Orig1s000MedR.pdf at 52 (results of tirzepatide toxicology studies in animals were typical of the GLP-1 RA pharmacologic class) (last visited Jan. 2, 2025); *see also* https://www.fda.gov/industry/structuredproductlabeling-resources/pharmacologic-class (last visited Dec. 28, 2023).

[15] SURMOUNT-1 Clinical Trial Protocol at 45, available at https://cdn.clinicaltrials.gov/largedocs/22/NCT04184622/Prot_000.pdf ("General safety characteristics of all studied doses of tirzepatide were similar to those of the GLP-1R agonist class…"); STEP-1 Clinical Trial Protocol at 15, accessible at https://cdn.clinicaltrials.gov/large-docs/35/NCT03548935/Prot_002.pdf ("[T]he tolerability and safety profile [of semaglutide] was overall consistent with… the GLP-1 RA class in general.").

[16] Cleveland Clinic, *GLP-1 Agonists* (Jul. 3, 2023), available at https://my.clevelandclinic.org/health/treatments/13901-glp-1-agonists.

[17] *See* Bloemendaal, et al., *Effects of glucagon-like peptide 1 on appetite and body weight: focus on the CNS,* J. ENDOCRINOLOGY (Apr. 2014).

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

52. Most GLP-1 RAs are approved to treat type 2 diabetes,[19] but some (Wegovy, Saxenda, and Zepbound) are approved to treat obesity or to reduce cardiovascular risks.

53. Most GLP-1 RAs are administered by injection, with the exception of Rybelsus, which is in tablet form.[20]

54. Most of the GLP-1 RAs at issue in this case are weekly injectable drugs, except that liraglutide (the active ingredient in Saxenda and Victoza) is a daily injectable drug.[21]

55. Most GLP-1 RAs are dosed between 0.25 and 2 milligrams per week, except that the maximum dose for Wegovy is 2.4 milligrams per week, and the maximum dose for Mounjaro is 15 milligrams per week.

B. Introduction to Plaintiff's Injuries

56. GLP-1 RAs can cause a myriad of injuries, including cyclical vomiting and its sequalae.

57. These injuries can be debilitating and go so far as to result in death. The FDA's adverse events database lists nearly 500 deaths related to semaglutide (Novo's GLP-1 RA) in the United States.[22] Recent reports indicate that a British nurse, Susan McGowan, aged 58, passed away from "multiple organ failure, septic shock … pancreatitis … and "the use of prescribed

[19] Unlike patients with type 1 diabetes, who cannot produce insulin, patients with type 2 diabetes cannot use insulin properly. *Compare* Cleveland Clinic, *Type 1 Diabetes* (Mar. 9, 2022), available at https://my.clevelandclinic.org/health/diseases/21500-type-1-diabetes, *with* Cleveland Clinic, *Type 2 Diabetes* (Nov. 8, 2023), available at https://my.clevelandclinic.org/health/diseases/21501-type-2-diabetes.

[20] Cleveland Clinic, *GLP-1 Agonists* (Jul. 3, 2023), available at https://my.clevelandclinic.org/health/treatments/13901-glp-1-agonists.

[21] *Id.*

[22] Meg Tirrell, *Compounded semaglutide associated with at least 10 deaths, Novo Nordisk CEO warns*, CNN (Nov. 10, 2024), available at https://www.cnn.com/2024/11/06/health/compounded-semaglutide-deaths-novo-nordisk-ceo/index.html.

tirzepatide" (Lilly's GLP-1 RA).[23] In the United Kingdom, there have been at least 23 deaths linked to semaglutide since 2019.[24]

1. Gastrointestinal Injuries

58. Gastrointestinal adverse events are well known side effects of the GLP-1 RA class of drugs, as Defendants have acknowledged,[25] but Defendants have downplayed the chronic nature, duration and severity of gastrointestinal injuries caused by their GLP-1 RAs. Many users have experienced debilitating, long-lasting effects, such as vomiting week after week (*i.e.*, unremitting or cyclical vomiting), and for many users, even after being hospitalized and discharged, the effects of life-altering treatment, such as replacement of their colon with a colostomy bag,[26] persist. In addition, many users have experienced adverse events for which Defendants failed to provide any warning.

59. These gastrointestinal injuries caused by GLP-1 RAs can lead to life threatening and long-term consequences, including hospitalization, esophageal tearing, ischemia and necrosis in the digestive tract, bowel perforation, sepsis, bowel resection, colostomy, perioperative aspiration, dehydration, micronutrient deficiency, disability, and death.

a. Other Gastrointestinal Injuries

60. While many injured by Defendants' GLP- 1 RAs are formally diagnosed with gastroparesis, many others experience serious injuries caused by the delays of gastric emptying,

[23] C. MacPhee and J. Cheyne, *Nurse's death linked to approved weight-loss drug*, BBC (Nov. 7, 2024), available at https://www.bbc.com/news/articles/cz6jg6nw2zeo.
[24] *Id.*
[25] C.T. Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, ROLLING STONE (Jul. 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601.
[26] A colostomy bag collects stool. It is attached to the body through a surgical procedure called a colostomy that changes the way that stool exits the body. When medical reasons (such as a removal of part of the bowel) require the colon to be bypassed, surgeons make a new opening in the abdominal wall for stool to come out.

including debilitating cyclical vomiting that can last days or weeks after cessation of GLP-1 RAs, gastroenteritis,[27] esophageal tear, and intestinal obstruction associated with GLP-1 RAs.[28]

61. At least 20% of individuals on GLP-1 RAs experience gastrointestinal adverse effects; predominantly nausea, vomiting, and altered bowel function.[29]

62. Gastroenteritis refers to inflammation of the stomach and intestines. While viral gastroenteritis is also known as stomach flu, gastroenteritis may also be caused by ingesting medications. Its symptoms include debilitating vomiting, nausea, diarrhea, stomach cramps, muscle aches, headaches, and fever. Notably, vomiting and diarrhea can cause dehydration, which is the main complication of gastroenteritis, and which can lead to death.[30]

63. Patients on GLP-1 RAs can experience vomiting so severely they suffer a torn esophagus.[31]

C. GLP-1 RAs Are Ineffective in Many Patients Due to High Discontinuation Rates, Minimal to No Weight Loss for Some Patients, and Rebound Weight Gain

64. Many patients find GLP-1 RAs ineffective because they discontinue use of the drugs.

65. In May 2024, Blue Cross Blue Shield published an "Issue brief" that examined whether "patients prescribed [GLP-1 RAs] for weight loss are dropping out of treatment too

---

[27] J. Gotfried, *Drug-Related Gastroenteritis and Chemical-Related Gastroenteritis*, MERCK MANUAL (Jun. 2023), available at https://www.merckmanuals.com/home/digestive-disorders/gastroenteritis/drug-related-gastroenteritis-and-chemical-related-gastroenteritis.

[28] Gudin, et al., *Incretin-based drugs and intestinal obstruction: a pharmacovigilance study*, 75(6) THERAPIES 641-47 (Nov.-Dec. 2020).

[29] Jalleh, et al., *Gastrointestinal effects of GLP-1 receptor agonists: mechanisms, management, and future directions* (pub. online Jul. 31, 2024), available at https://doi.org/10.1016/S2468- 1253(24)00188-2.

[30] Mayo Clinic, *Viral gastroenteritis (stomach flu)*, available at https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847; *see also* J. Gotfried, *Drug-Related Gastroenteritis and Chemical-Related Gastroenteritis*, MERCK MANUAL (Jun. 2023), available at https://www.merckmanuals.com/home/digestive-disorders/gastroenteritis/drug-related-gastroenteritis-and-chemical-related-gastroenteritis.

[31] L. Pennock, *Illinois woman who vomited so violently after using Ozempic that she tore her ESOPHAGUS joins huge legal fight against maker of blockbuster weight loss drug - as Novo Nordisk braces for up to 10,000 lawsuits*, DailyMail.com (Feb. 18, 2024), available at https://www.dailymail.co.uk/health/article-13087635/woman-torn-esophagus-ozempic-lawsuit-novo-nordisk.html.

quickly to attain the health benefits of these drugs." The company reviewed the behavior of nearly 170,000 GLP-1 RA users covered by Blue Cross Blue Shield and concluded that 30% of GLP-1 RA patients discontinued treatment within 4 weeks, that 58% of GLP-1 RA patients discontinued treatment within 180 days, and that patients who discontinue shortly after starting GLP-1 RA therapy are unlikely to see any health benefits.[32] As a result, Blue Cross Blue Shield of Michigan, the largest health insurer in the state, announced a plan to greatly restrict coverage for GLP-1 RA prescriptions, citing concerns about efficacy and safety.[33]

66. In June 2024, a real-world study of 4,066 insured GLP-1 RA weight-loss patients concluded that only 1 in 3 patients remained on GLP-1 RAs at one year, which "is substantially lower than what has been reported in clinical trials." The authors also concluded that the high discontinuation rates for GLP-1 RAs "create GLP-1 obesity treatment effectiveness concerns" because the value of the treatment "is not likely to be realized if [the GLP-1 RA] is discontinued during the first year and weight loss is not achieved or maintained."[34]

67. Published in March 2021, a study funded by Novo acknowledged that weight loss for semaglutide users is likely to plateau between weeks 60 and 68 and that patients who discontinued use of semaglutide "gradually regained weight."[35]

---

[32] *Real-world trends in glp-1 treatment persistence and prescribing for weight management*, Blue Health Intelligence Issue Brief (2024), available at https://www.bcbs.com/media/pdf/BHI_Issue_Brief_GLP1_Trends.pdf.
[33] Blue Cross Blue Shield of Michigan, *Changes coming for select weight loss drugs for some commercial members* (Jul. 2024), available at https://www.bcbsm.com/content/dam/microsites/corpcomm/provider/the_record/2024/jul/Record_0724h.html.
[34] P. Gleason, *Real-world persistence and adherence to glucagon-like peptide-1 receptor agonists among obese commercially insured adults without diabetes*, J. MANAGED CARE + SPECIALTY PHARM. (Jun. 2024), available at https://www.jmcp.org/doi/10.18553/jmcp.2024.23332.
[35] Rubino, et al., *Effect of Continued Weekly Subcutaneous Semaglutide vs Placebo on Weight Loss Maintenance in Adults with Overweight or Obesity: The STEP 4 Randomized Clinical Trial*, JAMA (Mar. 2021), available at https://jamanetwork.com/journals/jama/fullarticle/10.1001/jama.2021.3224.

68. Another study funded by Novo, which was published in February 2022, concluded that withdrawal of once-weekly semaglutide "led to most of the weight loss being regained within 1 year."[36]

69. A systematic review and network meta-analysis published in January 2024 reported that the effects of GLP-1 RAs on body weight gradually decline during long term use, indicating "potential limitations of GLP-1 RAs for sustained long term weight loss efforts."[37]

70. There is also some percentage of people who do not respond to GLP-1 RAs for weight-loss at all. Research suggests that approximately 14% of patients taking GLP-RAs for weight loss lost less than 5% of their body weight and one-third lost less than 10% of their body weight.[38]

[36] Wilding, et al., *Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension*, DIABETES OBES. METAB. (Feb. 2022), available at https://dompubs.onlinelibrary.wiley.com/doi/10.1111/dom.14725.
[37] Yao, et al., *Comparative effectiveness of GLP-1 receptor agonists on glycaemic control, body weight, and lipid profile for type 2 diabetes: systematic review and network meta-analysis*, BMJ (Jan. 2024), available at http://dx.doi.org/10.1136/bmj-2023-076410.
[38] Carbajal, Erica, *Up to 15% of patients on weight loss drugs may be 'non-responders*, BECKER'S HOSPITAL REV. (April 1, 2024) available at https://www.beckershospitalreview.com/glp-1s/upto-15-of-patients-on-weight-loss-drugs-non-responders.html.

71. In contrast to GLP-1 RAs, studies show that bariatric surgery is highly effective to treat type 2 diabetes and obesity, and to improve mortality for such patients.[39] Not only is bariatric surgery far more effective, it is also safer[40] and more cost-effective[41] than GLP-1 RAs.

72. Likewise, other, well-established, prescription and over-the-counter medications with FDA approval for weight loss are available and offer significantly lower risk profiles than GLP-1 RAs. For example, Orlistat, an over-the-counter medication, was FDA-approved for weight loss in 1999 and has been shown to reduce fat absorption by up to 30%. While associated with some gastrointestinal adverse effects, they are much less severe than those seen with GLP-1 RAs and include fatty stools, fecal urgency, incontinence, and increased defecation.[42] Similarly, a prescription appetite suppressant combining phentermine and topiramate has been approved since 2012 and has been shown effective for long-term weight loss. While contraindicated in pregnancy, other risks are generally non-severe and include dizziness, constipation, dry mouth, and inattention.[43]

---

[39] *See, e.g.*, Courcoulas, et al., *Long-term outcomes of medical management vs bariatric surgery in type 2 diabetes*, 331 JAMA 654 (2024) ("After 7 to 12 years of follow-up, individuals originally randomized to undergo bariatric surgery compared with medical/lifestyle intervention had superior glycemic control with less diabetes medication use and higher rates of diabetes remission."), available at https://pubmed.ncbi.nlm.nih.gov/38411644/; Syn, et al., *Association of metabolic-bariatric surgery with long-term survival in adults with and without diabetes: a one-stage meta-analysis of matched cohort and prospective controlled studies with 174772 participants*, 397 LANCET 1830 (2021) ("Median life expectancy was approximately 9.3 years (95% CI 7.1–11.8) longer for patients with diabetes in the surgery group than in the control group. […] Among adults with obesity, metabolic–bariatric surgery is associated with substantially lower all-cause mortality rates and longer life expectancy than usual obesity management."), available at https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00591- 2/abstract.

[40] *See, e.g.*, Dicker, et al., *Bariatric metabolic surgery vs glucagon-like peptide-1 receptor agonists and mortality*, JAMA OPEN (2024) (finding bariatric metabolic surgery to be "associated with a 62% reduction in mortality compared with GLP-1 RAs"), available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2819703.

[41] *See, e.g.*, T. Reed, *Bariatric surgery found more cost-effective than GLP-1s*, AXIOS (Oct. 21, 2024), available at https://www.axios.com/2024/10/21/bariatric-surgery-more-cost-effective-glp1; Sanchez, et al., *Comparative Cost-Effectiveness Analysis of Bariatric Surgery and GLP-1 Receptor Agonists for the Management of Obesity*, NORTHWESTERN UNIV. FEINBERG SCH. MED., available at https://www.surgery.northwestern.edu/docs/edelstone-bendix-research-poster/2024-posters/Sanchez-Joseph.pdf.

[42] Filippatos, et al., *Orlistat-associated adverse effects and drug interactions: a critical review.* 31(1) DRUG SAF. 53-65 (2008).

[43] Lei XG, et al., *Efficacy and Safety of Phentermine/Topiramate in Adults with Overweight or Obesity: A Systematic Review and Meta-Analysis.* 29(6) OBESITY 985-94 (Jun. 2021).

73. Similarly, an alternate treatment of type 2 diabetes is Metformin. Johns Hopkins' "Patient Guide to Diabetes" describes Metformin as the "treatment of choice for type 2 diabetes."[44] This guide also describes Metformin as "very effective at controlling blood glucose and lowers A1C as much as 1.5%." The listed side effects include diarrhea and rare lactic acidosis. Meanwhile, "in studies of GLP-1 receptor agonists used alone or in combination with oral antihyperglycemic therapies, mean changes in A1C ranged from −0.8 to −1.7%"[45]

74. A meta-analysis of Metformin found "there is no significant risk of GI AEs associated neither with the dose size of metformin nor metformin treatment duration." This same study found "GLP-1 RA and acarbose were ranked as having the highest incidence of GI AEs."[46]

75. Therefore, GLP-1 RAs offer minimal increased benefit as it relates to diabetes while increasing the frequence of gastrointestinal adverse injuries.

D. Regulatory History of GLP-1 RAs

1. Ozempic

76. On October 19, 2008, Novo filed an Investigational New Drug ("IND") application for Ozempic (semaglutide).[47]

77. On December 5, 2016, Novo announced submission of a New Drug Application ("NDA") 209637 to the FDA for regulatory approval of once-weekly injectable semaglutide, a new glucagon-like peptide-1 (GLP-1) medication for treatment of type 2 diabetes. In the

[44] Johns Hopkins staff, *Metformin*, available at https://hopkinsdiabetesinfo.org/medications-for-type-2-diabetes-metformin/.
[45] D. Hinnen, *Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes*, 30(3) DIABETES SPECTR. 202-10 (Aug. 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556578/.
[46] Nabrdalik, et al., *Gastrointestinal adverse events of metformin treatment in patients with type 2 diabetes mellitus: A systematic review, meta-analysis and meta-regression of randomized controlled trials*, 13 FRONT ENDOCRINOL. (Lausanne) 975912 (Sept. 14, 2022), doi: 10.3389/fendo.2022.975912, PMID: 36187122, PMCID: PMC9524196.
[47] U.S. Food & Drug Admin., *Determination of Regulatory Period for Ozempic* (Nov. 29, 2019), available at https://www.federalregister.gov/documents/2019/11/29/2019-25850/determination-of-regulatory-review-period-for-purposes-of-patent-extension-ozempic.

announcement, Novo represented that in clinical trials "once-weekly semaglutide had a safe and well tolerated profile with the most common adverse event being nausea."[48]

78. On December 5, 2016, Novo submitted NDA 209637, requesting that the FDA grant it approval to market and sell Ozempic (semaglutide) 0.5 mg or 1 mg injection in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On December 5, 2017, the FDA approved NDA 209637.[49]

79. On March 20, 2019, Novo submitted supplemental new drug application (sNDA) 209637/S-003 for Ozempic (semaglutide) 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.[50] On January 16, 2020, the FDA approved sNDA 209637/S-003 for cardiovascular risk reduction in adults with Type 2 diabetes and known heart disease.[51]

80. On May 28, 2021, Novo submitted sNDA 209637/S-009, requesting approval for a higher 2 mg dose of Ozempic (semaglutide) injection. On March 28, 2022, the FDA approved sNDA 209637/S-009 for a higher-dose Ozempic 2 mg injection for increased glycemic control in adults with type 2 diabetes.[52]

---

[48] Novo Nordisk, *Novo Nordisk files for regulatory approval of once-weekly semaglutide in the US and EU for the treatment of type 2 diabetes* (Dec. 5, 2016), available at https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183.

[49] FDA Approval Letter for NDA 209637 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf.

[50] *Novo Nordisk files for US FDA approval of oral semaglutide for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes*, Cision PR Newswire (Mar. 20, 2019), available at https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fdaapproval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-inadults-with-type-2-diabetes-300815668.html.

[51] FDA Supplement Approval Letter for NDA 209637/A-003 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf.

[52] FDA Supplement Approval Letter for NDA 209637/S-009 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209637Orig1s009ltr.pdf.

81. On September 22, 2023, Novo added "ileus" under Section 6-3 Postmarketing Experience of the Prescribing Information ("PI" or "label") in a revised Ozempic label. The new label listed ileus as an adverse reaction reported during post-approval use of semaglutide, the active ingredient of Ozempic.[53]

2. Mounjaro

82. On September 14, 2021, 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.[54]

83. On May 13, 2022, 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, Lilly disclosed a safety summary and provided a link to the Medication Guide and Prescribing Information, but gastrointestinal injuries like gastroparesis and other delayed emptying conditions were not warned of as a risk.[55]

84. On July 28, 2023, a supplemental approval added 'ileus' as a gastrointestinal adverse reaction reported during post-approval use of Mounjaro in the Prescribing Information (PI) to Section 6.2 Postmarketing Experience.[56]

E. Defendants Were on Notice of Reasonable Evidence of Association Between GLP-1 RAs and Gastroparesis, Ileus, Intestinal Obstruction, and Their Sequelae

85. As previously discussed, GLP-1RAs are treated as a class by the FDA, and the class of drugs shares a similar mechanism of action, physiologic effect, and chemical structure.

---

[53] Ozempic Label (dated 9/22/23), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf.
[54] FDA Approval Letter for NDA 215866 (Mounjaro) available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/215866Orig1s000ltr.pdf.
[55] Mounjaro Label (May 13, 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf.
[56] Mounjaro Label (dated July 28, 2023), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf.

86. Although natural GLP-1—which is released when food is consumed—causes slowed motility, multiple studies have shown that GLP-1 RAs like liraglutide can delay gastric emptying for as long as least 16 weeks in some patients.[57] Further, for some GLP-1 RA patients, the effect on gastric emptying is greater and longer lasting. In one study of obese liraglutide users, researchers found that 57% developed "very significant" delay in gastric emptying as early as 5 weeks. For some liraglutide patients, the delay in gastric emptying lessened by 16 weeks of use, through tachyphylaxis (rapidly diminishing response to successive doses). However, for 30% of liraglutide patients, significant delay in gastric emptying persisted at 16 weeks. The authors of that study concluded that "[c]onsideration of this complication should be included in appraising the benefit to risk ratio of GLP-1 RA therapy."[58]

87. Persistent delayed gastric emptying has been recognized in GLP-1 RA literature for several years.[59]

88. By 2002, it was known that GLP-1 RAs cause prolonged cessation of intestinal motility in rats.[60]

89. In 2010, a study published in The Journal of Clinical Endocrinology & Metabolism concluded that GLP-1 slows gastric emptying.[61]

---

[57] Halawi, et al., *Effects of liraglutide on weight, satiation, and gastric functions in obesity: a randomised, placebo-controlled pilot trial,* 2 LANCET 890 (2017); Maselli, et al., *Effects of liraglutide on gastrointestinal functions and weight in obesity: A randomized clinical and pharmacogenomic trial,* 30 OBESITY SOCIETY 1608 (2022).
[58] Camilleri, *Prevalence and variations in gastric emptying delay in response to GLP-1 receptor agonist*, OBESITY (2023).
[59] Halawi, et al., *Effects of liraglutide on weight, satiation, and gastric functions in obesity: a randomised, placebo-controlled pilot trial*, 2 LANCET 898 (2017) (noting "persistent slowing of gastric emptying of solids at 16 weeks of treatment, despite tachyphylaxis.").
[60] Näslund, et al., *Glucagon-like peptide 1 analogue LY315902: effect on intestinal motility and release of insulin and somatostain*, 106 REGUL. PEPT. 89 (2002).
[61] A.M. Deane, et al., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia*, 95(1) J. CLINICAL ENDO. METAB., 225-221 (January 1, 2010), available at https://academic.oup.com/jcem/article/95/1/215/2835243; American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (Jun. 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.

90. By January 2016, it was recognized that GLP-1 RAs "markedly" inhibit intestinal motility, even in healthy patients without type 2 diabetes.[62]

91. GLP-1 RAs can cause impaired digestion that can manifest as several forms of injury, including gastroparesis, ileus, debilitating cyclical vomiting for days and weeks requiring hospitalization, and intestinal obstruction.

92. Defendants knew or should have known of the risks of gastroparesis, ileus, intestinal obstruction, and their sequelae from the relevant clinical trials, medical literature, and adverse event reports.

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

94. Defendants' evaluation of gastrointestinal risks during clinical trials was inadequate, and despite mounting postmarketing evidence—discussed below—regarding the gastrointestinal risks associated with GLP-1 RAs, Defendants repeatedly failed to take steps necessary to re-analyze clinical trial data to assess the gastrointestinal side effects of GLP-1 RAs.

95. There are three validated methods to assess gastric emptying of solids: gastric emptying scintigraphy, the stable isotope gastric emptying breath test, and the wireless motility capsule.[63] However, "gastric emptying of liquids is often preserved in gastroparesis." Thus,

[62] Thazhath, et al., *The glucagon-like peptide 1 receptor agonist exenatide inhibits small intestinal motility, flow, transit, and absorption of glucose in healthy subjects and patients with type 2 diabetes: a randomized controlled trial*, 65 DIABETES 269 (2016).
[63] Sheng, *Management of Gastroparesis*, GASTROENTEROLOGY & HEPATOLOGY (Nov. 2021).

"liquids may empty normally" even with gastroparesis. For that reason, gastric emptying studies "based on a liquid challenge result in decreased sensitivity in the diagnosis of gastroparesis."[64]

96. Despite a plethora of evidence, consistent with the drugs' mechanism of action, that GLP-1 RAs affect motility, neither Novo nor Lilly assessed gastric emptying of solids during their clinical trials.[65] Rather than doing so, both companies used the acetaminophen absorption test to assess for emptying of liquids, which is often preserved in gastroparesis patients. As a result, Defendants' clinical trials for their GLP-1 RAs were not adequately designed to assess for gastroparesis.[66]

97. Dr. Michael Nauck, a clinical researcher of GLP-1 RAs and a Novo advisory board member, has acknowledged that clinical trials for GLP-1 RAs measured gastric emptying with the acetaminophen absorption test, which "has substantial limitations including poorly validated assumptions about its absorption kinetics and its unsuitability to measure gastric emptying of solids." He has further acknowledged that, in clinical trials, gastric emptying was often assessed "solely by participant self-report, which is unreliable." He concluded that, "[i]n clinical trials, GI symptoms should be evaluated by validated instruments. Measurement of gastric emptying, using a precise technique, should be a mandatory component of approval packages for GLP-1 RAs."[67]

98. In 2008, the New England Journal of Medicine noted that "serious complications" reported as adverse events for the GLP-1 RA exenatide included "suspected ileus."[68]

---

[64] Camilleri, *Clinical Guideline: Management of Gastroparesis*, Am. J. of Gastroenterology (Jan. 2013).
[65] Lilly performed a gastric emptying study of dulaglutide and submitted it to the FDA but it was never published in a peer-reviewed medical journal. See Clinical Study Report, A Study to Evaluate the Effect of Dulaglutide on Gastric Emptying Using Scintigraphy in Patients with Type 2 Diabetes Mellitus, LLY-GLPMDL-00026283 (July 7, 2012).
[66] *See* Goodman, *People using popular drugs for weight loss, diabetes are more likely to be diagnosed with stomach paralysis, studies find*, CNN (May 20, 2024), available at https://www.cnn.com/2024/05/20/health/glp-1-drugs-stomach-paralysis/index.html.
[67] Jalleh, et al., *Accurate measurements of gastric emptying and gastrointestinal symptoms in the evaluation of glucagon-like peptide-1 receptor agonists*, 176 ANN. INTERN. MED. 1542 (2023).
[68] Ahmad, et al., *Exenatide and Rare Adverse Events*, 358 NEW ENG. J. MED. 1969-72 (May 2008), available at https://www.nejm.org/doi/full/10.1056/nejmc0707137.

99. In a May 2008 case report published in the New England Journal of Medicine, a patient developed "severe gastroparesis," confirmed by a gastric emptying study, after eleven months of exenatide use. She also developed a bezoar, which was removed endoscopically. Exenatide was discontinued, and the patient was treated and improved. Three months after exenatide was re-started, symptoms returned and the patient had a second bezoar removed from her stomach. A follow-up gastroduodenoscopy performed five months after stopping the drug a second time revealed retained food, and the patient was treated with botulinum toxin injected into the pylorus.[69] This dechallenge/rechallenge case presents strong evidence of a causal association between GLP-1 RAs and gastroparesis.

100. In 2011, a gastroenterologist at the Mayo Clinic recognized that drugs such as GLP-1 RAs can cause iatrogenic gastroparesis due to pharmacologic blockage of the vagal nerve.[70]

101. In 2012, the Journal of the Japan Diabetes Society published two case reports of "transient paralytic ileus caused by the administration of Liraglutide." In both cases, the patients "recovered spontaneously after the cessation of Liraglutide." The authors concluded that "physicians and patients should be aware of this serious side effect."[71]

102. In 2012, Japan's Pharmaceutical and Food Safety Bureau advised that "[i]ntestinal obstruction may occur" in patients taking the GLP-1RAs exenatide and liraglutide, and as a result, "[p]atients should be carefully monitored, and if any abnormalities including severe constipation, abdominal distention, persistent abdominal pain, or vomiting are observed, administration of [the drugs] should be discontinued, and appropriate measures should be taken." The agency further

[69] Cure, et al., *Exenatide and rare adverse events*, 358 NEW ENG. J. MED. 1969-72 (May 2008), available at https://doi.org/10.1056/nejmc0707137.
[70] Camilleri, et al., *Epidemiology, Mechanisms, and Management of Diabetic Gastroparesis*, 9 CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 1 (2011). Lilly has likewise recognized the ability of drugs to induce gastroparesis. *See* LL Y-GLPMDL-08196268.
[71] Kitamura, et al., *Two cases of paralytic ileus associated with the administration of liraglutide*, 55 JAPAN DIAB. SOC. 982 (2012).

reported that in the previous 1 year and 8 months, three cases of intestinal obstruction had been reported in liraglutide users "for which causality [associated with] the drug could not be ruled out." At least one of those patients was diagnosed with ileus.[72]

103. A 2013 article, by a co-author who had participated on Novo advisory boards, explained that "[a]cute, intravenous infusion of GLP-1 (in pharmacological doses) slows gastric emptying markedly in both healthy subjects and patients with type 2 diabetes in a dose-dependent manner by mechanisms that include relaxation of the proximal stomach, reduction of antral and duodenal motility, and an increase in pyloric tone, and which involve vagal pathways."[73]

104. In 2013, the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) received a "safety communication from the Japanese medicines agency … reporting intestinal obstruction in patients treated with" GLP-1RAs. As a result, PRAC searched EudraVigilance "for intestinal obstruction and related terms" and retrieved 59 cases for the GLP-1RAs exenatide and liraglutide, leading PRAC to recommend appropriate amendments to the product information. EMA reported intestinal obstruction in 35 cases for exenatide and 24 for liraglutide (which the Novo Nordisk Defendants manufacture and market under the brand names Saxenda and Victoza).[74]

105. By 2014, animal studies with the GLP-1RA albiglutide demonstrated increased rates of morbidity and mortality in lactating mice, consistent with lactational ileus syndrome.

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

[72] Pharmaceutical and Food Safety Bureau, *Pharmaceuticals and Medical Devices Safety Information No. 291* (Jun. 2012), available at https://www.pmda.go.jp/files/000153459.pdf.
[73] C. Marathe, *Relationships Between Gastric Emptying, Postprandial Glycemia, and Incretin Hormones*, 36(5) DIABETES CARE 1396-1405 (Apr. 13, 2013), available at https://diabetesjournals.org/care/article/36/5/1396/29534/Relationships-Between-Gastric-Emptying.
[74] European Medicines Agency, Pharmacovigilance Risk Assessment Committee, minutes of meeting (Jan. 7-10, 2013) available at https://www.ema.europa.eu/en/documents/minutes/minutes-prac-meeting-7-10-january-2013_.pdf.

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.[75]

107. Two subjects in a semaglutide trial pool by Novo 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.

108. 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."[76]

109. 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

[75] S.P. Marso, et al., *Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes*, 375 N. ENG. J. MED. 1834-44 (Nov. 2016), available at https://www.nejm.org/doi/10.1056/NEJMoa1607141.
[76] Y. Nakatani, et al., *Effect of GLP-1 receptor agonist on gastrointestinal tract motility and residue rates as evaluated by capsule endoscopy*, 43(5) DIABETES & METAB., 430-37 (Oct. 2017), available at https://www.sciencedirect.com/science/article/pii/S1262363617301076.

reason (64.4%), followed by 'Made me throw up' (45.4%)."[77] As explained above, these are symptoms of gastroparesis, ileus, and intestinal obstruction.

110. An April 2018 published case series reported six cases involving upper gastrointestinal problems in liraglutide users:

- In the first case, a 50-year-old female developed "severely delayed gastric emptying" after three months of liraglutide use, and her symptoms improved significantly after discontinuation of liraglutide.

- In the second case, a 48-year-old female was diagnosed with "ineffective esophageal motility" after six months of liraglutide use. Her esophageal motility returned to "normal" after discontinuation of liraglutide.

- In the third case, a 62-year-old female experienced bloating, constipation, and "retained food products in the stomach" after starting liraglutide. After discontinuation of liraglutide, examination revealed "no evidence of ... retained food products in the stomach."

- In the fourth case, a 39-year-old female was started on liraglutide, and five months later she underwent a preoperative endoscopy, which "revealed a large amount [of] retained food in the stomach, despite having nothing by mouth for more than 12 h." One month after discontinuing liraglutide, a gastric emptying study came back "normal."

- In the fifth case, nine months after starting liraglutide, a 49-year-old female was found to have "a slight decrease in primary esophageal peristalsis," which had returned to normal two weeks after discontinuing liraglutide.

- In the sixth case, a 55-year-old female started liraglutide and was referred for bariatric surgery. A preoperative endoscopy showed "significant retained food in the body and antrum of the stomach." After discontinuing liraglutide for 2 weeks, a solid gastric emptying study revealed gastric emptying in the normal range.

The authors concluded that, "[w]hile liraglutide is known to cause gastric dysmotility," these case reports indicate that GLP-1 RAs also contribute to esophageal dysmotility, as "[i]n all cases" the patients' esophageal dysmotility and/or delayed gastric emptying "improved following

[77] M. Sikirica, et al., *Reasons for discontinuation of GLP1 receptor agonists: data from a real-world cross-sectional survey of physicians and their patients with type 2 diabetes*, 10 DIABETES METAB. SYNDR. OBES., 403-12 (Sept. 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5630073/

discontinuation." The authors also concluded that, on the strength of current medical knowledge, "Liraglutide should ... be considered as a culprit in any patient found to have gastroparesis" and that this effect on gastric emptying "appears to be a GLP-1 class effect" affecting some patients (delayers) but not others (non-delayers).[78]

111. A 2019 study of GLP-1 RA exenatide found that, out of 20 patients without preexisting gastroparesis, 15 became "gastroparetic after initiation of exenatide therapy," while the other 5 patients without preexisting gastroparesis experienced a moderate increase in gastric half-emptying time. Notably, the researchers used the stable isotope gastric emptying breath test to measure gastric emptying, rather than gastric scintigraphy.[79]

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

113. In a disproportionality analysis first published in May 2020, researchers analyzed adverse events reported in the WHO's worldwide database between January 2007 and January 2008. The researchers found 216 cases of intestinal obstruction reported for GLP-1 RA users, 37 of which were noted as "serious." The researchers "identified a pharmacovigilance signal that suggests a risk of potentially serious intestinal obstruction" associated with these drugs.[80]

114. A case study published in May 2020 reported on a patient who developed symptoms of partial bowel obstruction within one week of initiating dulaglutide. After "two weeks of severe nausea and vomiting, accompanied by four days of diffused abdominal pain," he was admitted to the hospital where he was diagnosed with "partial or evolving small bowel obstruction." The

[78] Modi, et al., *Liraglutide effects on upper gastrointestinal investigations: implications prior to bariatric surgery*, 28 OBES. SURG. 2113 (2018).
[79] Beti, et al., *Exenatide Delays Gastric Emptying in Patients with Type 2 Diabetes Mellitus but not in Those with Gastroparetic Conditions*, HORM. METAB. RES. (2019) (pub. online Jan 28, 2019).
[80] Gudin, et al., *Incretin-based drugs and intestinal obstruction: a pharmacovigilance study*, 75(6) THERAPIES 641-47 (Nov.-Dec. 2020).

patient deteriorated quickly, with the condition progressing to a full small bowel obstruction, a "life-threatening surgical emergency." The patient underwent a partial resection of his small bowel "due to severe ischemia." The treating physicians were able to rule out all other possible causes and were able to determine that "Trulicity [dulaglutide] was the culprit of this unfortunate case." Dulaglutide was discontinued, and the patient had no signs of bowel obstructions on follow-up. The authors noted that there was a known association between dulaglutide use and small bowel obstruction, with 8 cases reported in 2017, most of which required surgical intervention.[81]

115. In August of 2020, medical literature advised that some "patients do not know they have diabetic gastroparesis until they are put on a glucagon-like peptide 1 (GLP-1) receptor agonist such as ... semaglutide ... to manage their blood glucose." The article went on to explain that "[t]his class of drugs can exacerbate the symptoms of diabetic gastroparesis. ... Thus, GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis."[82]

116. In a September 2020 article funded and reviewed by Novo, scientists affiliated with Novo reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes. More patients permanently discontinued taking oral semaglutide (11.6%) than placebo (6.5%) due to adverse events. The most common adverse events associated with semaglutide were nausea (2.9% with semaglutide versus 0.5% with placebo), vomiting (1.5% with semaglutide versus 0.3% with placebo), and diarrhea (1.4% with semaglutide versus 0.4% with placebo). Injectable semaglutide had a discontinuation rate of 11.5-14.5% (versus 5.7-7.6% with placebo) over a two-year period. The authors acknowledged the potential for severe gastrointestinal events, warning that "[f]or patients reporting severe adverse

[81] Gandhi, et al., *Dulaglutide Commonly Known as Trulicity; An Anti-diabetic Medication Causing Small Bowel Obstruction,* 4 JESOCI A309 (2020).
[82] C.F. Young, et al., *Diabetic Gastroparesis: A Review*, 33(3) DIABETES SPECTR. 290–97 (Aug. 2020), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/.

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."[83]

117. In November 2020, a case report was published where an 18-year-old female presented to the emergency room with vomiting and upper abdominal discomfort after recently starting a high dose of liraglutide. On examination, she had a distended abdomen and was ultimately diagnosed with "liraglutide-induced gastroparesis." After cessation of liraglutide, "her symptoms resolved completely." The authors attributed the patient's gastroparesis to the high dose of liraglutide and recommended that "[p]atients exhibiting gastroparesis symptoms after taking liraglutide medication must be closely monitored" because "symptomatic gastroparesis can be triggered by the initiation of liraglutide."[84]

118. A 2021 retrospective review of upper endoscopies found that patients taking GLP-1 RAs 4.3-fold increased risk of retained gastric contents, which is associated with delayed gastric emptying.[85]

119. A May 2021 meta-analysis found an increased risk of impaired gastric emptying among GLP-1 RA users.[86]

---

[83] O. Mosenzon, et al., *Oral semaglutide in patients with type 2 diabetes and cardiovascular disease, renal impairment, or other comorbidities, and in older patients*, 132 (sup2) POSTGRADUATE MEDICINE 37-47 (2020), available at https://doi.org/10.1080/00325481.2020.1800286.

[84] Almustanyir, *Gastroparesis With the Initiation of Liraglutide: A Case Report*, CUREUS (Nov. 28, 2020), available at https://doi.org/10.7759/cureus.11735.

[85] Bi, et al., *Food Residue During Esophagogastroduodenoscopy Is Commonly Encountered and Is Not Pathognomonic of Delayed Gastric Emptying*, 66 DIGESTIVE DISEASES AND SCIENCE 2951, 3955 (2021).

[86] Yin, et al., *Comprehensive analysis of the safety of semaglutide in type 2 diabetes: a metaanalysis of the SUSTAIN and PIONEER trials*, 68 ENDOCR. J. 739 (2021). A meta-analysis is "a subset of systematic reviews; a method for systematically combining pertinent qualitative and quantitative study data from several selected studies to develop a

120. A July 2021 article funded and reviewed by Novo considered 23 randomized control trials conducted across the United States, Japan, and China and concluded that "gastrointestinal disturbances" were "well-known" side effects associated with semaglutide use. When compared with placebos, the subcutaneous (injection) form of the drug induced nausea in up to 20% of patients (versus up to 8% on the placebo group), vomiting in up to 11.5% of patients (versus up to 3% in the placebo group) and diarrhea in up to 11.3% of patients (versus up to 6% in the placebo group). Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for gastrointestinal related adverse events, with some trials experiencing 100% discontinuation due to gastrointestinal related adverse events. The mean value of gastrointestinal related adverse events that led to discontinuation averaged 57.75%. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"[87]

121. An October 2021 article in the Journal of Investigative Medicine ("JIM") concluded that because gastroparesis can be associated with several medications, "[i]t is crucial to identify the causative drugs as discontinuation of the drug can result in resolution of the symptoms[.]" In diabetics, making this determination can be particularly "tricky" because both diabetes and GLP-1RAs can cause delayed gastric emptying. As such, "the timeline of drug initiation and symptom onset becomes of the upmost importance." The authors reviewed two case reports (discussed

single conclusion that has greater statistical power." The conclusion reached by meta-analyses are often "statistically stronger than the analysis of any single study, due to increased numbers of subjects, greater diversity among subjects, or accumulated effects and results." *Study Design 101: Meta-Analysis*, Himmelfarb Health Sciences Library (Sept. 25, 2023), available at https://guides.himmelfarb.gwu.edu/studydesign101/metaanalysis.

[87] M.M. Smits & D.H. Van Raalte (2021), *Safety of Semaglutide*, FRONT. ENDOCRINOL. (July 7, 2021), doi: 10.3389/fendo.2021.645563, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8294388/.

below) and concluded that history taking and making an accurate diagnosis of diabetic gastroparesis versus medication-induced gastroparesis is critical.[88]

122. 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."[89]

123. Case Report #2 in JIM involved a 57-year-old female with long-standing (16 years) type 2 diabetes who had been taking weekly injections of dulaglutide (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.[90]

124. A large population-based study published in January 2022 concluded that GLP-1 RAs were associated with an increased risk of intestinal obstruction compared with SGLT-2 inhibitors (1.9 vs. 1.1 per 1,000 person-years, respectively; HR:1.69, 95% CI: 1.04–2.74).[91]

---

[88] M.A. Kalas, et al., *Medication-Induced Gastroparesis: A Case Report*, 9 J. INVESTIG. MED. HIGH IMPACT CASE REP. 23247096211051919 (2021), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/.
[89] *Id.*
[90] *Id.*
[91] Faille, et al., *Incretin-based drugs and risk of intestinal obstruction among patients with type 2 diabetes,* 111 CLIN. PHARMACOL. THER. 272 (2021).

125. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[92]

126. In July 2022, a case report was published of gastroparesis, with symptoms beginning a mere four days after initiation of low-dose liraglutide. The patient's symptoms resolved within days of discontinuing liraglutide. The authors concluded that gastroparesis "is a known serious side effect of GLP-1 agonist treatment," that "[p]hysicians should be cognizant of the side effects of GLP-1 agonists even in low dose in patients who have gastric emptying symptoms suggesting GP," and that the risk of developing gastroparesis "should be considered before initiating GLP-1 agonists in general."[93]

127. An August 2022 meta-analysis an increased risk of impaired gastric emptying among GLP-1 RA users.[94]

128. That same month, the Teikyo Medical Journal published a case report of a 29-year-old male who developed "nausea, vomiting, abdominal bloating, and constipation, starting one day after a single injection of semaglutide." "The patient became unable to take anything by mouth" and was admitted to the hospital, where an oral-enhanced abdominal CT-Scan revealed gastric dilatation and delayed gastric emptying with no evidence of mechanical obstruction. The patient was diagnosed with "semaglutide induced gastric outlet obstruction with euglycaemic ketosis." With conservative treatment, the patient improved, and two months after discontinuing semaglutide, the patient was symptom free.[95]

---

[92] Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N. ENGL. J. MED. 214 (Jun. 4, 2022), available at https://doi.org/10.1056/nejmoa2206038.
[93] Ishihara, *Suspected Gastroparesis With Concurrent Gastroesophageal Reflux Disease Induced by Low-Dose Liraglutide*, CUREUS (Jul. 16, 2022), available at https://doi.org/10.7759/cureus.26916.
[94] Wang, et al., *Meta-analysis of the association between new hypoglycemic agents and digestive diseases,* 101 MEDICINE (Baltimore) (2022).
[95] Shemies, et al., *Semaglutide induced gastric outlet obstruction: a case report*, 45 TMJ 6743 (2022).

129. An October 2022 study analyzed 5,442 GLP-1RA adverse gastrointestinal events. 32% were serious, including 40 deaths, 53 life-threatening conditions, and 772 hospitalizations. The primary events were nausea and vomiting. There were also adverse events for impaired gastric emptying.[96]

130. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[97]

131. A single-center study published in January 2023 found an increased risk of gastroparesis among GLP-1 RA patients.[98]

132. It was widely reported in the media that, in January 2023, Trish Webster, a woman without diabetes, died while taking Saxenda, after switching from Ozempic. She began using GLP-1 RAs to lose weight prior to her daughter's wedding. However, she developed persistent vomiting, diarrhea, and nausea and, on January 16, 2023, her husband found her unconscious and not breathing.[99]

133. 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.[100]

---

[96] Shu, *Gastrointestinal adverse events associated with semaglutide: A pharmacovigilance study based on FDA adverse event reporting system*, FRONT. PUBLIC HEALTH (Oct. 20, 2022), available at https://doi.org/10.3389%2Ffpubh.2022.996179.

[97] Mirsha, *Adverse Events Related to Tirzepatide*, J. ENDOCRINE SOCIETY (Jan. 26, 2023), available at https://doi.org/10.1210%2Fjendso%2Fbvad016.

[98] Kalas, et al., *Frequency of glp-1 receptor agonists use in diabetic patients diagnosed with delayed gastric emptying and their demographic profile*, 71 J. INVESTIG. MED. 11 (2023).

[99] *See Ozempic risk: could weight loss injections be fatal?*, 60 MINUTES AUSTRALIA (Nov. 5, 2023), available at https://www.youtube.com/watch?v=3nvoumJsjus; Amelia Neath, *Woman dies after taking Ozempic to lose weight for daughter's wedding*, INDEPENDENT (Nov. 10, 2023), available at https://www.independent.co.uk/news/world/americas/australia-woman-dies-ozempic-weight-loss-b2445052.html; Adriana Diaz, *Woman dies after taking Ozempic to slim down for daughter's wedding: 'She shouldn't be gone'*, NEW YORK POST (Nov. 6, 2023), available at https://nypost.com/2023/11/06/lifestyle/woman-dies-after-taking-ozempic-to-slim-down-for-wedding/.

[100] 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), available at https://doi.org/10.1111%2Fjdi.13932.

134. A February 2023 case series of 100 patients undergoing endoscopy found that 4 out of 23 patients treated with GLP-1 RAs had developed "moderately large" bezoars of 4cm or greater in diameter, while no patients who were not on the drugs had developed bezoars.[101]

135. 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."[102]

136. In a May 2023 letter to the editor published in Acta Pharmaceutica Sinica B, the authors commented on GLP-1RAs, including Ozempic, Wegovy and Rybelsus, and noted "adverse events such as increased risk of intestinal obstruction have been reported in diabetic patients, which is 4.5 times higher than those receiving other glucose control medications" based on a study published in 2020. The authors further noted a study published in 2022 "of 25,617 subjects demonstrated a 3.5-fold increase in the intestinal obstruction rate associated with GLP-1RA treatment."[103]

137. In May 2023, the risk of intestinal obstruction was specifically cited in the Lu study, concluding that the use of GLP-1RAs may result in continuous increases in intestinal length, causing the intestines to "become as inelastic and fibrotic as a loose spring." The study indicated

[101] Preda, *et al*., *Gastroparesis with bezoar formation in patients treated with glucagon-like peptide-1 receptor agonists: potential relevance for bariatric and other gastric surgery*, 7 BJS OPEN 1 (2023).
[102] Klein, *Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report*, CAN J. ANESTH (Mar. 28, 2023), available at https://doi.org/10.1007/s12630-023-02440-3.
[103] J. Lu, et al., *A Potentially Serious Adverse Effect of GLP-1 Receptor Agonists*, 13(5) ACTA PHARMACEUTICA SINICA B 2291-93 (May 2023), available at https://www.sciencedirect.com/science/article/pii/S2211383523000679; *see also* J.L. Faillie, et al., *Incretin-Based Drugs and Risk of Intestinal Obstruction Among Patients with Type 2 Diabetes*, 11(1) CLINICAL PHARMACOLOGY THERAPEUTICS (Jan. 2022), available at https://doi.org/10.1002/cpt.2430; B. Gudin, et al., *Incretin-based drugs and intestinal obstruction: a pharmacovigilance study*, 75(6) THERAPIES 641-47 (Nov.-Dec. 2020).

that intestinal blockage peaked after using GLP-1RAs for a year and a half, which the authors noted was longer than the duration of most clinical studies involving GLP-1RAs.[104]

138. In June 2023, a case report was published in the British Journal of Anesthesia regarding a tirzepatide patient undergoing hysteroscopy with polyp resection. Although the patient had "appropriately fasted" prior to the procedure, she aspirated a large volume of undigested food during the procedure. The authors recommended revised guidelines for GLP-1 RA patients undergoing anesthesia due to the risks posed by undigested food remaining in patients' stomachs during surgery.[105]

139. In a second case report published that same month, authors similarly reported that a patient on semaglutide, who had appropriately fasted and had no traditional risk factors for regurgitation or aspiration, had regurgitated a large volume of gastric contents upon induction of general anesthesia. Authors cautioned that "[p]atients taking long-acting GLP-1 RAs such as semaglutide may be at risk of pulmonary aspiration under anesthesia."[106]

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

[104] J. Lu, et al., *A Potentially Serious Adverse Effect of GLP-1 Receptor Agonists*, 13(5) ACTA PHARMACEUTICA SINICA B 2291-93 (May 2023), available at https://www.sciencedirect.com/science/article/pii/S2211383523000679.
[105] Weber, et al., *Clinically significant emesis in a patient taking a long-acting glp-1 receptor agonist for weight loss*, BR. J. ANAESTH. e37 (2023).
[106] Gulak, et al., *Regurgitation under anesthesia in a fasted patient prescribed semaglutide for weight loss: a case report*, 70 CAN. J. ANAESTH. 1397 (2023); *see also* Fujino, *et al*., *Anesthesia considerations for a patient on semaglutide and delayed gastric emptying*, CUREUS (2023) ("[R]egular fasting guidelines may not be adequate to prevent the risk of perioperative aspiration" among semaglutide users).

warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[107]

141. News sources have identified the potential for serious side effects in GLP-1 RA users, including gastroparesis, leading to hospitalization.[108] For instance, NBC News reported in January 2023 that some Ozempic users were discontinuing use because of unbearable symptoms, 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."[109] As another example, CNN reported in July 2023 that one Ozempic user diagnosed with gastroparesis vomits so frequently that she had to take a leave of absence from her teaching job.[110]

142. 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 have suffered severe gastrointestinal related events, including gastroparesis, as a result of their use of GLP-1RAs. Patient 1 (female, age 37) reported incidents of vomiting multiple times per day and being unable to eat. The patient's physician diagnosed her with severe gastroparesis and concluded that her problems were caused and/or exacerbated by her use of a GLP-1RA. Patient 2 (female)

---

[107] American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (Jun. 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.

[108] Penny Min, *Ozempic May Cause Potential Hospitalizations*, HEALTHNEWS (Jun. 26, 2023), available at https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/; 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/; Cara Shultz, *Ozempic and Wegovy May Cause Stomach Paralysis in Some Patients*, PEOPLE (Jul. 26, 2023), available at https://people.com/ozempic-wegovy-weight-loss-stomach-paralysis-7565833; CBS News Philadelphia, *Popular weight loss drugs Ozempic and Wegovy may cause stomach paralysis, doctors warn* (Jul. 23, 2023), available at https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomach-paralysis/.

[109] A. Bendix, B. Lovelace Jr., *What it's like to take the blockbuster drugs Ozempic and Wegovy, from severe side effects to losing 50 pounds*, NBC NEWS (Jan. 29, 2023), available at https://www.nbcnews.com/health/health-news/ozempic-wegovy-diabetes-weight-loss-side-effects-rcna66493.

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

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 acknowledged that "[t]he most common adverse reactions, as with all GLP-1 RAs, are gastrointestinal related." Novo 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 did not claim to have warned consumers about gastroparesis, ileus, intestinal obstruction, and their sequelae, or other debilitating gastrointestinal issues.[111]

143. 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.[112]

144. 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 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

[111] C.T. Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, ROLLING STONE (Jul. 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601.

[112] B. Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN HEALTH (Jul. 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis.

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.[113]

145. In an article published on September 29, 2023, Dr. Caroline Apovian, a Professor of Medicine at Harvard Medical School, indicated that "her team had observed ileus in patients who had been prescribed semaglutide well before the FDA's label change [on September 22, 2023]." In the same article, Dr. Dan Azagury, a Medical Director at Stanford University, explained that "ileus is a rare but potentially severe complication. So, we have to inform patients and we have to let them know that if they have these symptoms they need to check in with their physician."[114]

146. An October 1, 2023, published case series involved three GLP-1 RA users with retained solids despite 10 hours of preoperative fasting. The authors wrote that GLP-1 RA "drug-induced gastroparesis has been confirmed by acetaminophen absorption measurements, carbon-13 urea breath tests, and esophagogastroduodenoscopy." The authors also stressed the need for physicians to understand the risks associated with retained solids despite preoperative fasting because of the "high morbidity and mortality" associated with perioperative aspiration of gastric contents.[115]

147. 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,

---

[113] Montefiore Health Blog, *Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines* (Jul. 26, 2023), available at https://www.montefiorenyack.org/health-blog/what-you-need-know-about-gastroparesis.
[114] G. Mammoser, *Ozempic Label Updated to Include Blocked Intestines as Potential Side Effect*, HEALTHLINE (Sept. 29, 2023), available at https://www.healthline.com/health-news/fda-updates-ozempic-label-to-include-blocked-intestines-as-potential-side-effect.
[115] Kittner, *et al., Retained gastric contents after adequate fasting associated with glp-1 receptor agonist use*, 13 JBJS CASE CONNECT 1 (2023).

gastroparesis, and bowel obstruction.[116] 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.

148. Also on October 5, 2023, a medical journal reported a case of Mounjaro (tirzepatide) induced ileus. The authors concluded that the case "highlights the dangers of lack of … monitoring of Mounjaro," especially in "patients who may be more susceptible to the gastrointestinal side effects of Mounjaro," and noted the need to "rais[e] awareness of potential side effects" of the drug "and their severity."[117]

149. In a case report, also published October 5, 2023, authors reported on a patient who developed severe epigastric pressure and abdominal pain shortly after increasing his dose of tirzepatide from 2.5 mg to 5 mg. Abdominal X-ray and CT scans revealed a small bowel obstruction. The authors attributed the obstruction to the effect that GLP-1 RAs have on motility.[118]

150. In another case report published on October 5, 2023, a patient was hospitalized with abdominal pain, nausea, vomiting, and diarrhea three months after initiating liraglutide. Through diagnostic testing, she was found to have a small bowel obstruction (SBO) due to intussusception, "a rare condition in adults where one segment of the bowel telescopes into the adjacent segment, potentially causing intestinal ischemia." The authors noted that "[t]his case highlights the importance of providers being aware of potential adverse effects, including the rare but serious complication of SBO in patients receiving GLP-1 RA therapy." The authors theorized that "inhibition of intestinal motility" caused by GLP-1 RAs plays a role in causing such side effects

---

[116] M. Sodhi, et al., *Risk of Gastrointestinal Adverse Events Associated with Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss*, JAMA (pub. online Oct. 5, 2023), available at https://jamanetwork.com/journals/jama/fullarticle/2810542.
[117] K. Rao et al., *Mounjaro: A Side Effect,* 7 J. ENDOCRINE SOC. A69-70 (Oct.-Nov. 2023), available at https://academic.oup.com/jes/article/7/Supplement_1/bvad114.128/7290694.
[118] Mathew, *et al*., *Tirzepatide associated partial small bowl obstruction: a case report,* 7 J. ENDOCRINE SOC. A463 (2023).

and recommended that "clinicians should monitor patients for signs of gastrointestinal distress or obstruction and investigate suspected cases promptly for timely management."[119]

151. In a case study published October 9, 2023, the authors reported a case of a 27-year-old female who had been taking tirzepatide for four months. Shortly after an increase in her dosage of tirzepatide, she presented to the emergency department with "severe abdominal pain, nausea, bilious emesis, and watery diarrhea." A CT scan revealed "a high-grade large-bowel obstruction." Despite conservative intervention, the patient deteriorated, and a repeated x-ray indicated that the obstruction was increasing in size. She underwent an emergency "exploratory laparotomy and was noted to have a massively dilated colon" and "[a] firm fecalith in the mid-sigmoid colon." Doctors performed a total abdominal colectomy. After removing the patient's colon, further examination of the colon "showed extensive gangrenous necrosis" in addition to impacted fecal matter. She was discharged two weeks post-surgery. Aside from tirzepatide use, the patient had no other risk factors for bowel obstruction. The authors concluded that "[c]linicians should be aware that Tirzepatide, and other similar drugs, may cause rare yet life-threatening side effects which include an increased risk of bowel obstruction."[120]

152. A retrospective cohort study published in December 2023 noted a "particularly high discontinuation rate for GLP-1 RAs" and concluded that the high rate of discontinuation "was likely due to previously observed factors such as gastrointestinal adverse effects." Compared to other types of second-line treatment for type 2 diabetes, "GLP-1 RAs had the highest observed risk of discontinuation."[121]

---

[119] Alqaisi, *et al*., *GLP-1 RA Therapy And Intussusception: A Case Report Of Bowel Telescoping In An Obese Patient*, SAT675 J. ENDOCRINE SOC. A67 (2023).
[120] Gordon, *et al*., *A rare case of a large bowel obstruction due to Tirzepatide*, 164 CHEST 2334A (2023).
[121] Liss, et al., *Treatment Modification After Initiating Second-Line Medication for Type 2 Diabetes*, AM. J. OF MANAGED CARE (Dec. 2023), available at https://www.ajmc.com/view/treatment-modification-after-initiating-second-line-medication-for-type-2-diabetes.

153. Another case report of semaglutide-associated gastroparesis was published in January 2024. In that case, the gastroenterologist had a high degree of certainty in the diagnosis of gastroparesis, despite the fact that a gastric emptying study was not performed, due to the symptoms and findings on esophagogastroduodenoscopy. The authors concluded that the significant improvement of the patient's symptoms after discontinuation of semaglutide "highlights the need to recognize medication-induced gastroparesis as a possible diagnosis" among GLP-1 RA users with gastrointestinal symptoms.[122]

154. A systematic review and network meta-analysis published in January 2024 indicated "safety concerns for GLP-1 RAs, especially with high dose administration, regarding gastrointestinal adverse events." Semaglutide, liraglutide, and tirzepatide were all associated with increased rates of nausea, vomiting, and diarrhea. The odds ratios of these gastrointestinal adverse events were higher with increasing doses of GLP-1 RAs.[123]

155. Two large epidemiological studies published in 2024 found statistically significant increased risk of gastroparesis among GLP-1 RA users, offering further confirmation of the causal association between GLP-1 RAs and gastroparesis.[124]

156. Multiple medical reference sources now recognize GLP-1 RAs as a cause of gastroparesis, including Wolters Kluwer's UpToDate, Statpearls, and David Hui, *et al.*'s Approach to Internal Medicine (5th ed.), Huppert's Notes Pathophysiology and Clinical Pearls for Internal

[122] Chaudhry, et al., *Tendency of semaglutide to induce gastroparesis: a case report*, CUREUS (2024).
[123] Yao, et al., *Comparative effectiveness of GLP-1 receptor agonists on glycaemic control, body weight, and lipid profile for type 2 diabetes: systematic review and network meta-analysis*, BMJ (Jan. 2024), available at http://dx.doi.org/10.1136/bmj-2023-076410.
[124] Nathani, et al., *Incidence of gastrointestinal side effects in patients prescribed glucagon-like peptide-1 (glp-1) analogs: real-world evidence*, Sa1964 AGA ABSTRACTS S-598 (2024); Mesgun, et al., *Increased risk of de-novo gastroparesis in non-diabetic obese patients on glp-1 receptor agonists for weight loss: a multi-network study*, Sa1961 AGA ABSTRACTS S-596 (2024).

Medicine (2024 ed.), McCallum *et al.*'s Gastroparesis Pathophysiology, Clinical Presentation, Diagnosis and Treatment (1st ed.).

157. The medical literature listed above is not a comprehensive list, and several other case reports have indicated that GLP-1RAs can cause impaired gastric emptying, gastroparesis, ileus, intestinal obstruction, and their sequelae.[125]

158. Indeed, numerous cases have been reported to the FDA's Adverse Events Reporting System ("FAERS") database in which GLP-1 RA patients suffered gastroparesis, impaired gastric emptying, ileus, and intestinal obstruction. The FAERS database also indicates that GLP-1 RA users have reported symptoms consistent with gastroparesis, such as vomiting, nausea, abdominal pain, esophageal rupture, gastrointestinal hypomotility, Wernicke's Encephalopathy, and regurgitation and symptoms consistent with ileus or intestinal obstruction, such as fecal vomiting, discolored vomit, intestinal perforation, intestinal resection, intestinal sepsis, and gastrointestinal ischemia. The FAERS database also confirms that some GLP-1 RA users have suffered severe complications, including hospitalization, disability, and death. Although the FAERS database contains thousands of reports of GLP-1 RA users experiencing symptoms consistent with gastroparesis, ileus, and intestinal obstruction, it has been widely recognized that the FAERS database is an incomplete log of adverse event reports, as only a small percentage of adverse events are ever reported to the FDA. Thus, the number of these adverse events is likely much higher than reflected in FAERS data.

[125] *See, e.g.,* Rai, *Liraglutide-induced Acute Gastroparesis*, Cureus (Dec. 28, 2018), available at https://doi.org/10.7759%2Fcureus.3791; Guo, *A Post Hoc Pooled Analysis of Two Randomized Trials*, DIABETES THER (2020), available at https://doi.org/10.1007%2Fs13300-020-00869-z; Preda, *Gastroparesis with bezoar formation in patients treated with glucagon-like peptide-1 receptor agonists: potential relevance for bariatric and other gastric surgery*, BJS OPEN (Feb. 2023), available at https://doi.org/10.1093%2Fbjsopen%2Fzrac169.

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

160. Upon information and belief, Defendants not only knew or should have known that their GLP-1RAs cause delayed gastric emptying, resulting in risks of gastroparesis, ileus, intestinal obstruction, and their sequelae, but they may have sought out the delayed gastric emptying effect due to its association with weight loss. For example, a 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."[126]

F. Background on Pharmaceutical Marketing

1. Regulatory Framework for Pharmaceutical Advertising

161. Pharmaceutical marketing and promotional labeling are regulated by the FDA.

162. By statute, the FDA defines the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[127] The statute contemplates that certain marketing materials are part of the product's labeling: "brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips,

[126] M. Jensterle, et al., *Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity*, 25(4) DIABETES OBES. METAB. 975-984 (Apr. 2023), available at https://dom-pubs.onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944.
[127] 21 U.S.C. § 321(m).

lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published … for use by medical practitioners, pharmacists or nurses containing drug information supplied by the manufacturer, … of the drug and which are disseminated by or on behalf of its manufacturer … are hereby determined to be labeling as defined in section 201(m) of the act."[128]

163. The FDA recognizes a difference between direct-to-consumer ("DTC") advertisements and promotional labeling. According to the FDA: "DTC ads are published in magazines and newspapers that are distributed to a general audience rather than to healthcare providers such as doctors, nurses, and pharmacists. DTC ads can also be broadcast through television or radio."[129] In contrast to those direct-to-consumer ***advertisements***, the FDA notes: "Other types of materials, such as brochures, booklets, or pamphlets distributed to patients, caregivers, or other non-healthcare providers are considered DTC ***promotions***. While many people would think these are ads, they are technically considered a different category, called promotional labeling."[130]

164. The FDA distinguishes this separate category of "promotional labeling" from advertisements: "Promotional labeling and advertising are both used to help sell prescription drugs. Promotional labeling differs from advertising in the way it is distributed. Ads are usually broadcast on TV or radio, or are published in newspapers or magazines. Promotional labeling includes additional types of materials and ways to get them to the consumer … ."[131] Importantly, "[p]romotional labeling about a drug is said to 'accompany' that drug, even if the promotional

[128] 21 C.F.R. 202.1(k)(2).
[129] U.S. Food & Drug Admin., *Drug Advertising: A Glossary of Terms*, available at https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#dtc.
[130] *Id.* (emphasis added).
[131] U.S. Food & Drug Admin., *Drug Advertising: A Glossary of Terms*, available at https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#promotional_labeling.

labeling is not physically attached to a drug container. Promotional labeling must be accompanied by the drug's prescribing information.'"[132]

165. Under the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and FDA's implementing regulations, drug promotional labeling and prescription drug advertising must be truthful and non-misleading, convey information about the drug's efficacy and its risks in a balanced manner, and reveal material facts about the drug.[133]

166. FDA guidance indicates that "Firms generally have flexibility with respect to the presentation of efficacy and risk information about their products as long as the presentation is not false or misleading and complies with other applicable statutory and regulatory requirements."[134] Despite that flexibility, the FDA instructs firms that when they develop DTC promotional communications, "they should consider how to best convey information about a drug's efficacy and risks so the audience understands the information."[135]

167. When evaluating communication of the risks in a promotional piece, FDA guidance states that it "looks not just at specific risk-related statements, but at the ***net impression*** – i.e., the message communicated by all elements of the piece as a whole."[136] In other words, the FDA recognizes that pharmaceutical marketing must have fair balance, defined as follows:

> The law requires that product claim ads give a "fair balance" of information about drug risks as compared with information about drug benefits. This means that the content and presentation of a drug's most important risks must be reasonably similar to the content and presentation of its benefits.
>
> This does not mean that equal space must be given to risks and benefits in print ads, or equal time to risks and benefits in broadcast ads. The amount

[132] *Id.*
[133] U.S. Food & Drug Admin., *Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements: Guidance for Industry*, available at https://www.fda.gov/media/169803/download.
[134] *Id.*
[135] *Id.*
[136] U.S. Food & Drug Admin., *Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion*, available at https://www.fda.gov/media/76269/download (emphasis in original).

> of time or space needed to present risk information will depend on the drug's risks and the way that both the benefits and risks are presented.[137]

168. The definition of "fair balance" is not black and white. Indeed, the FDA recognizes the impact emotion can have on an individual's ability to understand risks or benefits of a drug. For example, in its Evidence-Based User's Guide for Pharmaceutical Marketing, the FDA notes that "[a]ffect and emotion influence perceptions of likelihood, value, and the risk-benefit balance. These feelings and thoughts interact but also separately predict risk perceptions and decisions. Feelings can limit effective risk communication sometimes, but are often critical to good decision-making; their power can be harnessed in persuasive and non-persuasive communication."[138]

169. The FDA also recognizes the fact that sophisticated marketing techniques influence physician prescribing behavior. This phenomenon is described in draft guidance, where the FDA explains that "[r]esearch demonstrates that promotional communications about medical products often employ marketing techniques that are effective at influencing attitudes and behaviors of HCPs [("Healthcare Providers")], and that how information is presented can impact HCP impressions of that information. These marketing techniques can influence attitudes and behavior, independent of the quality of the information, even among highly educated medical professionals."[139]

170. The power and influence of marketing, even on healthcare providers, is one reason the FDA forbids "off-label" marketing. Off-label marketing occurs when an FDA-approved drug or device is advertised for a purpose for which it is not approved. It is legal for a physician or other

---

[137] U.S. Food & Drug Admin., *Drug Advertising: A Glossary of Terms*, available at https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#fair_balance.

[138] U.S. Food & Drug Admin., *Communicating Risks and Benefits: An Evidence-Based User's Guide*, available at https://www.fda.gov/files/about%20fda/published/Communicating-Risk-and-Benefits---An-Evidence-Based-User%27s-Guide-%28Printer-Friendly%29.pdf.

[139] U.S. Food & Drug Admin., *Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products Questions and Answers: Draft Guidance for Industry*, available at https://www.fda.gov/media/173172/download.

prescriber to prescribe an FDA-approved drug for an off-label use, but it is illegal to market those drugs for such off-label use. If the manufacturer promotes or advertises a drug for anything other than its FDA-approved use, that is described as illegal "misbranding."[140] When a drug such as Ozempic is marketed or promoted for weight loss, that is considered off-label marketing and the products are considered "misbranded" under the governing FDA regulations.

171. It is recognized that off-label marketing can harm patients, third-party payors, competitor manufacturers, and researchers and clinicians in multiple ways.[141] This includes exposure to adverse side effects from drugs that have not been adequately tested for safety and effectiveness in treatment of a particular condition. This can occur when off-label promotion taps a market demand without spending the time or money for full safety clearance by the FDA.[142]

2. Methods of Pharmaceutical Marketing

172. Pharmaceutical marketing is a sophisticated industry that follows well-established practices. It is typically a well-integrated process, where customers targeted by a manufacturer's marketing receive a seamless experience and consistent messaging through advertising, personal selling, sales promotions, public relations, and branded and unbranded marketing.

173. "Branded" marketing is marketing that directly states the prescription drug name. Branded marketing for prescription drugs is overseen by the FDA and must meet certain requirements. These include requirements that it must not be false or misleading; must have fair

[140] G.A. Van Norman, *Off-Label Use vs Off-Label Marketing: Part 2: Off-Label Marketing-Consequences for Patients, Clinicians, and Researchers*, 8(3) JACC BASIC TRANSL. SCI. 359-70 (Mar. 27, 2023), doi: 10.1016/j.jacbts.2022.12.012, PMID: 37034284, PMCID: PMC10077121, available at https://pmc.ncbi.nlm.nih.gov/articles/PMC10077121/#bib5.
[141] *Id.*
[142] *Id.*

balance between efficacy and risk information; and must reveal material facts about the drug being promoted, including facts about the consequences that may result from use of the drug.[143]

174. "Unbranded" campaigns typically contain "help-seeking" advertisements. These advertisements describe a disease or condition – like obesity – but do not recommend a specific drug to treat this condition. Instead, the advertisement directs the patient to speak with their physician. These types of unbranded campaigns are not regulated by the FDA and are not held to the same FDA regulatory oversight.[144] Industry experts recognize that unbranded campaigns can be particularly helpful when focusing on a condition that may be stigmatized or difficult to talk about with a provider.[145]

175. Pharmaceutical marketing is most effective when it utilizes both branded and unbranded campaigns.

176. Branded and unbranded marketing campaigns can be conducted through a variety of marketing channels. Common channels of pharmaceutical marketing include the use of sales representatives, DTC marketing, advocacy groups, key opinion leaders / speaker programs, social media and online websites, partnerships with telehealth providers and clinicians, television, print and radio advertisements, and coupon programs.

177. Defendants utilize what is known as an Omnichannel marketing scheme. This highly sophisticated marketing scheme has data flow back and forth from each source of advertising in a highly efficient manner to better target health care providers and potential customers.

---

[143] U.S. Food & Drug Admin., *The Bad Ad Program*, available at https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program.
[144] U.S. Food & Drug Admin., *Basics of Drug Ads*, available at https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads.
[145] B. Snyder Bulik, *Unbranded pharma ads—what are they good for? Actually quite a bit, marketing panelists say*, FIERCE PHARMA (Mar. 11, 2018), available at https://www.fiercepharma.com/marketing/unbranded-pharma-ad-what-are-they-good-for-actually-quite-a-bit-marketer-panelists-say.

178. Novo combines this omnichannel strategy and the resulting data pool with the use of algorithms and machine learning to create some of the most powerful pharmaceutical marketing to date. As far back as 2012, Novo discussed the use of algorithms, noting that "[t]he algorithm is able to determine the patient's therapeutic readiness to initiate therapy, determine if they're looking for a change in product, if they just need more help and support in adhering to the therapy they're on. That's a game changer."[146]

179. Novo continues their use of big data and machine learning to create highly effective, targeted marketing campaigns today, including the use of predictive mathematical formulas to determine exactly which piece of marketing material should be delivered in which channel and at what time to a particular healthcare provider to maximize prescription rates.[147]

G. Defendants' Extensive and Multifaceted Marketing and Promotion of GLP-1 RAS

180. After Novo saw the positive weight-loss effect of liraglutide, it began to formulate a new strategy that would increase the long-term financial solvency of the company. To profit from a drug that purports to help with weight loss outside of the diabetes context, Novo sought to fundamentally change the paradigm that doctors and insurers applied to weight-loss treatments. Diet and exercise were long considered the treatment for healthy weight loss and no insurance company, including Medicare, would reimburse for weight-loss drugs.

181. During the early-2000s, there was substantial dispute as to whether obesity should be classified as a disease rather than a behavioral issue. In 2013, the American Medical Association ("AMA") House of Delegates voted to recognize obesity as a disease state that requires treatment and prevention in 2013. Obesity's classification as a disease opened medical professionals up to

[146] M. Arnold, *Patient Marketing Report: From A1C to Z*, MEDICAL MARKETING AND MEDIA (Aug. 31, 2012), available at https://www.mmm-online.com/home/channel/features/patient-marketing-report-from-a1c-to-z/.
[147] Hyperight AB, *Utilizing Advanced Marketing Analytics for Sales Optimization – Peter Vester, Novo Nordisk* (Dec. 22, 2022), available at https://www.youtube.com/watch?v=nCZR6wK7MlU.

considering pharmaceuticals as a possible treatment and opened insurers up to the possibility of reimbursing for that treatment. This change was supported by advocacy organizations associated with Defendants.

182. Novo began intentionally targeting the obesity market in 2012. In its 2012 annual investment report, it listed "establish presence in obesity" as a strategic focus area.[148]

183. Novo's first weight-loss drug was launched in 2014 when the FDA approved liraglutide for the treatment of obesity under the brand name Saxenda.[149] Saxenda, however, required daily injections and its effects on weight loss were modest. From that initial experience, Novo determined there was a large untapped market for weight loss drugs – particularly if they required fewer injections.

184. In an effort to find ways to make a longer-lasting GLP-1 agonist so patients would not have to inject themselves every day, Novo created a new molecule with the chemical name semaglutide.[150] The molecule was marketed under the brand name Ozempic and it was ultimately approved to treat diabetes.

185. Even though it was only approved for diabetes, Novo realized that there was potential to maximize its profits from Ozempic if it could turn Ozempic into an obesity drug. Novo could expand the market for Ozempic and have an endless supply of potential customers that far exceeded any profits it would see from Ozempic's use solely as a diabetes medication.

186. Novo's annual reports to investors and Capital Days presentations repeatedly state that they intend to change the perception of obesity and the way it's treated – to advocate that it

[148] Novo Nordisk, Annual Report (2012) at 16-17, available at https://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2012.pdf.
[149] Gina Kolata, *We Know Where New Weight Loss Drugs Came From, but Not Why They Work*, NEW YORK TIMES (Aug. 17, 2023) available at https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.
[150] *Id.*

must be classified as a disease, covered by insurance, and treated with its weight loss drugs.[151] In 2019, Novo wrote in its investor report that its mission was to "change how the world sees people with obesity and make obesity a healthcare priority";[152] and its presentation included a projection showing growth of the weight-loss drug market from approximately 15 million to 24 million patients, acknowledging that having obesity recognized as a chronic disease helped increase the market for Novo's GLP-1 RAs.[153]

187. Novo had already worked to have obesity classified as a disease, but creating and expanding the market for its weight-loss drugs required a multiprong approach. First, Novo flooded the medical community with money in an effort to change the medical consensus as it relates to treating obesity. This included, among other things, direct payments to physicians, involvement in advocacy organizations, funding research, promoting articles in well-respected journals, and controlling key opinion leaders.

188. As discussed below, Novo used the power of algorithms and machine-learning to target physicians and change prescribing behavior. Novo's efforts included undercutting the well-established health guidance that diet and exercise are key to a healthy weight loss and ultimately sustaining a health weight; and, in its place, pushing a pharmaceutical intervention as the only treatment option that will be successful.

---

[151] Novo Nordisk, Annual Report (2019), available at https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2020/Novo-Nordisk-Annual-Report-2019.pdf; *see also* Novo Nordisk, Annual Report (2015) at 28-29, available at https://www.novonordisk.com/content/dam/Denmark/HQ/Commons/documents/Novo-Nordisk-Annual-Report-2015.PDF (describing Novo's 10-year ambition to educate doctors and make sure that obesity is widely recognized as a disease); Novo Nordisk, Annual Report (2018) at 26-27, available at https://www.novonordisk.com/content/dam/nncorp/global/en/about-us/pdfs/corporate-governance/annual-general-meetings/agm2019/uk/annual-report-2018.pdf (detailing Novo's commitment to "making obesity a healthcare priority").

[152] Novo Nordisk, Capital Markets Day 2019 Consolidated Presentation, slide 55, available at https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/capital-markets-day/Capital%20markets%20day%202019%20presentation.pdf.

[153] *Id.*

189. Novo invested billions in marketing Ozempic and its other GLP-1 RAs to push Ozempic into the cultural zeitgeist, creating an image as a miracle drug and driving patients to pressure their doctors to prescribe a "weight-loss" drug. That marketing included off-label marketing, pushing Ozempic for weight loss when it was never approved for such an indication (and even Wegovy was not approved until June of 2021).

190. Ozempic's high cost, and the barriers to consumers' access to the drug, presented substantial hurdles to Novo's ability to profit on its GLP-1 RA. Therefore, Novo invested millions in lobbying efforts to ensure funding for consumers who wanted access to the drugs, and Novo did everything it could to broaden such access. For example, Novo first directly partnered with and then directly invested in well-known telemedicine company Noom, ensuring that Novo could sell Ozempic and other GLP-1 RAs to consumers without having to visit a doctor. The key qualifying factors for Wegovy, BMI and an additional confounding health factor, are especially vulnerable to manipulation in the telemedicine context.

191. Even though Lilly lagged behind Novo in introducing a GLP-1 RA, it reaped the benefits of the foundation that Novo laid and joined in the strategy. Lilly made a substantial monetary investment in swaying the medical consensus by making direct payments to physicians and financially supporting or infiltrating numerous healthcare advocacy groups, including many of the same groups being supported by Novo. Lilly also spent vast sums of money on all forms of advertising and marketing to grow consumer demand, including promoting off-label use of Mounjaro. In addition, Lilly spent millions of dollars on lobbying for changes in the law to support broader financial support and access for obesity treatments.

192. Much like Novo, Lilly executives admitted to investors that it: "need[ed] to shift the conversation for people to actually start thinking about obesity as a medical condition."[154] Lilly also understood the market was growing, comparing Mounjaro's launch in 2022 to its prior Trulicity launch, noting that "[t]he market has evolved quite a bit and so we will be putting much more horsepower around the launch than what we did with Trulicity."[155] That increase in "horsepower" involved "promoting to around 100,000 physicians for tirzepatide [Mounjaro]" at launch compared to what was approximately "40,000 physicians for Trulicity."[156]

193. Sales of Ozempic and Wegovy grew exponentially in 2022 and 2023 with shortages resulting from the huge demand. In August of 2023, Novo reported that in the first six months of 2023, sales of Wegovy soared 344% in the U.S. to nearly $1.7 Billion, while sales of Ozempic jumped 50% to more than $3.7 Billion.[157] The number of prescriptions filled reached what was, at that time, an all-time high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.[158] In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.[159] Later data showed that between January 2021

[154] Eli Lilly at Morgan Stanley's 20th Annual Global Healthcare Conference (Sep. 13, 2022), available at https://web.archive.org/web/20221001135415/https://investor.lilly.com/webcasts-and-presentations.
[155] Eli Lilly & Co. Conf. Presentation Call 2022524 DN000000002983664779.pdf.
[156] Eli Lilly & Co. Conf. Presentation Call 2022524 DN000000002983664779.pdf.
[157] Bob Woods, *Big pharma's blockbuster obesity drug battle is just getting started, and it's headed for $100 billion*, CNBC (Sept. 9, 2023), available at https://www.cnbc.com/2023/09/09/big-pharma-blockbuster-obesity-drug-battle-is-headed-for-100-billion.html.
[158] A. Choi and H. Vu, *Ozempic prescriptions can be easy to get online. Its popularity for weight loss is hurting those who need it most*, CNN (Mar. 17, 2023), available at https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/.
[159] Daniel Gilber, *Insurers clamping down on doctors who prescribe Ozempic for weight loss: A new class of drugs is causing a public sensation and an industry gold rush, but questions remain about their accessibility to an overweight nation*, THE WASHINGTON POST (Jun. 12, 2023), available at https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance.

and December 2023 prescriptions for semaglutide soared over 442%.[160] In May 2024, CNN published that 1 in 8 adults in the United States has taken Ozempic or another GLP-1 drug.[161]

194. At its Capital Markets Day held on March 7, 2024, where the company provides a progress update on its Strategic Aspirations for 2025, Novo admitted that it had "unlocked the market with Wegovy" noting that sales for "obesity care" had grown from 8 Billion Danish Krone ("DKK") in 2021 (approximately 1.16 Billion USD) to 42 Billion DKK ($6.1 Billion USD) in 2023. Over 75% of those sales were Wegovy with Saxenda making up the remainder. Novo admitted that its current aspiration is to "[c]ontinue efforts to expand the market by reaching more patients and establish obesity as a serious chronic disease."[162]

195. Lilly's efforts also paid off: Mounjaro, which only received FDA approval on May 13, 2022, "generated $5.2 billion in 2023" and "Zepbound, the same molecule rebadged for the weight-loss market, pulled in more than $175 Million in its first quarter on the market."[163]

196. To put it in perspective, data analytics and consulting company GlobalData "has put out a forecast that shows how GLP-1 RAs could rapidly redefine what big looks like in drug sales."[164] Indeed, with respect to Lilly, "[t]he analysts expect Mounjaro to bring in as much in 2029 as Lilly's entire portfolio did in 2023 … ."[165]

1. Defendants Spent Vast Sums of Money and Effort to "Medicalize" Obesity Treatment

[160] Sara Chernikoff, *Who gets Ozempic? People with private insurance and generous health plans, study shows*, USA TODAY (Aug. 7, 2024), available at https://www.usatoday.com/story/news/health/2024/08/07/ozempic-semaglutide-accessinsurance-study/74692296007/.
[161] Diedre McPhillips, *1 in 8 adults in the US has taken Ozempic or another GLP-1 drug, KFF survey finds*, CNN (May 10, 2024), available at https://www.cnn.com/2024/05/10/health/ozempicglp-1-survey-kff/index.html.
[162] *See* Obesity Care, Novo Nordisk Capital Markets Day, at Slide 8 (Mar. 7, 2024), available at https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/cmd/2024/P5-Obesity-Care.pdf.
[163] Nick Paul Taylor, *Eli Lilly's edge over GLP-1 rivals tipped to drive Mounjaro sales to $34B by 2029*, FIERCE PHARMA (April 17, 2024), available at https://www.fiercepharma.com/marketing/eli-lillys-edge-over-glp-1-rivals-tipped-drive-mounjaro-sales-34b-2029.
[164] *Id.*
[165] *Id.*

197. In the public conscious today, many characterize obesity as a disease, but when the AMA voted to take that stance in 2013, it was somewhat controversial, and it was against the recommendation of its Committee on Science and Public Health. The committee had been tasked with exploring the issue and written a five-page opinion identifying several reasons why obesity should not be officially labeled as a disease, including the concern that it could "hurt patients, creating even more stigma around weight and pushing people into unnecessary"—and ultimately useless—"treatments."[166]

198. Nonetheless, the AMA voted to characterize obesity as a disease "due to its prevalence and seriousness."[167] Some argued that the real reason was driven more by a desire for doctors to drive up reimbursements for visits that involve obesity counseling. The measure of obesity, typically BMI, provides subjective labeling of what qualifies as obese. As a result, when a panel of experts "lower[ed] the BMI cutoff for overweight from 27 (28 in men) to 25", millions of additional people were labeled "overweight" and "obese" without any change in their weight, rendering them "eligible for treatment."[168]

199. To this day, "… whether obesity should be considered a disease has been referred to by health experts as 'one of the most polarizing topics in modern medicine.'"[169]

200. Recognizing obesity as a disease did not require that its treatment involve pharmaceutical intervention. Traditionally, obesity treatment involved lifestyle interventions including, but not limited to, adopting a healthy diet, exercising, improving sleep, and addressing the underlying factors contributing to over-eating. When Novo discovered that GLP-1 RAs had

[166] Harriet Brown, *How Obesity Became a Disease: And, as a consequence, how weight loss became and industry*, THE ATLANTIC (Mar. 24, 2014), available at https://www.theatlantic.com/health/archive/2015/03/how-obesity-became-a-disease/388300/.
[167] *Id.*
[168] *Id.*
[169] Julia Belluz, *Are We Thinking About Obesity All Wrong?*, NEW YORK TIMES (Sept. 19, 2024), available at https://www.nytimes.com/2024/09/19/opinion/obesity-diseaseozempic-weight-loss.html.

potential as a weight-loss product, it began working to change the medical consensus relating to obesity treatment, including by advocating for pharmaceutical treatment for obesity and minimizing lifestyle interventions. In time, Lilly joined in that effort.

201. Defendants have spent millions of dollars marketing the belief that sustained weight loss is only achievable by using their medications, while minimizing the efficacy of the conventional, evidence-based lifestyle approaches to obesity.

202. For example, an unbranded Novo campaign "Share the Weight" features numerous DTC videos by Novo. One such exemplar video portrays an overweight woman consistently exercising and eating a healthy diet and saying, "if it was only about effort, we would have overcome obesity years ago", and that "getting healthy requires help from a doctor."[170]

203. Another Novo DTC campaign—"Truth about Weight"—features a series of videos showing overweight individuals eating health foods and exercising, while also showing their disappointment as they don't lose weight, and conveying messages such as "long term health goes beyond dieting", and "exercise alone may not be enough for you", before concluding with the individuals visiting a doctor for help.[171]

204. Lilly also has similar DTC advertisements. The campaign "Living with Obesity" features a woman talking about how "we've been conditioned to say that people who live in larger bodies are lazy, eating too much. They don't exercise … It's just not true."[172] The woman proceeds to talk about how exercise hasn't worked because even if she lost weight, it would "always stop working," and discusses how the "experts" at the Obesity Action Coalition (an advocacy group

[170] Novo Nordisk, *WOD 2022 Time for a new approach*, available at https://www.youtube.com/watch?v=sPrhwdl-xE8.
[171] Novo Nordisk, *Truth About Weight - NYE22 - Diet*, available at https://www.youtube.com/watch?v=7UYDWmaQmV4; Novo Nordisk, *Truth About Weight - NYE22 - Exercise*, available at https://www.youtube.com/watch?v=kcc4VFV_2gw.
[172] Eli Lilly & Co., *Living with Obesity: Liz's Story*, available at https://www.youtube.com/watch?v=Vouu1caRu4M.

funded by Novo and Lilly, as discussed below) say obesity is a disease that requires pharmaceutical treatment.

205. Lilly's Chief Customer Officer, Patrik Jonsson, acknowledged in 2022 that the over 100 million people suffering from obesity in the U.S. who were not being treated with pharmaceuticals were a "[v]ery huge opportunity in front of us", before continuing that there was a "lot of work required to ***medicalize obesity***."[173]

206. Mr. Jonsson also discussed other efforts being made to support pharmaceutical intervention as a treatment for obesity, including conducting research that would show other health conditions that were improved by weight loss: "And we are currently doing five outcome studies that we believe will have a high relevance in order to change the treatment landscape in NASH and chronic kidney disease (inaudible) and one in morbidity and mortality outcomes study as well, and all those will have the opportunity to really medicalize be the obesity market."[174]

207. Defendants also needed to make sure there was access to their drugs, which meant they would need to be covered by insurance. While at the UBS Global Healthcare Conference in May of 2022, Lilly's then-Executive Vice President and President of Diabetes and Obesity Mike Mason made clear that access in the obesity market would depend on the ability to get coverage: "the main driver in the evolution of the obesity market will be access. So you need to unlock [ph] Part D coverage, that's what the Treat and Reduce Obesity Act are trying to do. You also not only need to get access at the payers, but then employers got to opt into that coverage. So that's the most important thing to develop the obesity market."[175]

---

[173] Eli Lilly & Co. Conf. Presentation Call 2022315.pdf (emphasis added).
[174] *Id.*
[175] Eli Lilly & Co Conf. Presentation Call 2022524 DN000000002983664779.pdf; Eli Lilly at UBS Global Healthcare Conference (May 24, 2022), available at https://web.archive.org/web/20220603141033/https://investor.lilly.com/webcasts-and-presentations

208. Lilly knew there were limits to Medicare coverage for obesity, so they tried to create enough data to show that the GLP-1 RAs could be used to treat other health conditions that were covered by Medicare or would more likely be covered by Medicare. As Lilly's Chief Scientific Officer Dan Skovronsky explained during a Goldman Sachs Global Healthcare Conference on September 17, 2022: "in terms of monetizing the opportunity in the Medicare setting because it would seem the bar is high to expect Medicare to reimburse obesity, right? There are ***backdoors into increasing usage on the Medicare***, you're exploring sleep apnea, you're exploring NASH."[176]

209. The importance of Medicare and other insurance coverage was necessary to grow the obesity medication market and a key driver in the large monetary contributions and other efforts made to lobby and align with advocacy groups. Similarly, Novo recognized that they needed to lobby to expand Medicare coverage.[177] Novo's 2019 Capital Days presentation called for "engaging with a broad range of coalition partners" to advocate for obesity care and Medicare coverage.[178]

210. Defendants also went directly to the people and targeted consumers with buzzy social media campaigns, emotional impact videos, and top-notch celebrity endorsements. When Americans turned on their TV or logged into their computer, they were met with the message that they needed drugs for weight loss and assured by the happy, smiling faces of everyone taking the drug. And thanks to the post-COVID advent of telehealth providers, a prescription was just a click away from the comfort of their couch.

---

[176] Eli Lilly at Citi's 17th Annual BioPharma Conference (Sep. 7, 2022) (emphasis added), available at https://web.archive.org/web/20221001135415/https://investor.lilly.com/webcasts-and-presentations.

[177] Novo Nordisk, Capital Markets Day 2019 Consolidated Presentation, slide 60, available at https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/capital-markets-day/Capital%20markets%20day%202019%20presentation.pdf.

[178] *Id.*

211. In sum, Defendants took the public debate about "obesity as a disease" and expanded that to advocate for a pharmaceutical intervention as the best treatment for the disease of obesity, because traditional treatments such as diet, exercise, and improved sleep were simply not enough for most people.

212. In their quest to maximize the size of the new obesity market, Defendants disregarded the boundaries set by FDA approvals and ignored basic truths about the weight loss associated with their drugs. Defendants routinely promoted Ozempic and Mounjaro as contributing to weight loss even though the drugs were not approved for that indication. They targeted marketing in various forums, including social media, to vulnerable groups who would be receptive to weight loss messages regardless of their BMI or other health conditions. Defendants partnered with telemedicine companies to get widespread distribution of their drugs with as little supervision as possible. Defendants failed to disclose the risks of these drugs, and failed to disclose that patients would likely have to be on these drugs for the rest of their lives to maintain the weight loss, and that if they came off the drugs and gained some or all of the weight back, they would actually be less healthy than they were when they started.

2. Defendants Took a Multifaceted Approach and Spent Hundreds of Millions of Dollars to Change the Way Doctors Viewed Weight-Loss Drugs and Influence Prescriber Behavior

213. Defendants engaged in a multipronged approach to control and manipulate the universe of knowledge around GLP-1 RAs and obesity treatment including, but not limited to, making direct payments to doctors, many of whom were influential in the relevant disciplines, so that they would promote the use of GLP-1 RAs; writing, promoting or funding articles regarding the safety and efficacy of the GLP-1 RAs; speaking at conferences regarding the safety and efficacy of GLP-1 RAs; participating in and influencing health care advocacy groups focused on

obesity and obesity treatment; conducting continuing medical education seminars related to GLP-1 RAs; and spending millions of dollars lobbying for prescription drug coverage of GLP-1 RAs.

a. Direct Payments to Physicians

214. Not surprisingly, there is evidence that doctors prescribe more of a drug if they receive money from a pharmaceutical company linked to that drug.[179] Defendants made voluminous direct payments to physicians. This information is accessible through the federally mandated Open Payments database.

215. The Open Payments program is a national disclosure program intended to promote a more transparent and accountable health care system. It maintains a publicly accessible database of payments that reporting entities, including drug and medical device companies, make to covered recipients such as physicians. Generally, three categories of payments are reported: general payments, research payments, and ownership and investment interests.

216. According to Open Payments, between 2018 and 2023, Novo paid approximately $153 Million[180] in general payments (*e.g.*, marketing, consulting, travel, food and beverage, etc.) to doctors: $27.9 Million (2018); $26.8 Million (2019); $15.2 Million (2020); $27.3 Million (2021); $33.9 Million (2022); and $21.9 Million (2023). In 2022 alone, Novo purchased over 450,000 meals for doctors.[181]

[179] Hannah Fresques, *Doctors Prescribe More of a Drug If They Receive Money from a Pharma Company Tied to It*, PROPUBLICA (Dec. 20, 2019), available at https://www.propublica.org/article/doctorsprescribe-more-of-a-drug-if-they-receive-money-from-a-pharma-company-tied-to-it (including quotes from Novo).
[180] U.S. Centers for Medicare & Medicaid Services, Open Payments Data, Novo Nordisk, Inc., available at https://openpaymentsdata.cms.gov/company/100000000144.
[181] John LaMattina, *Fattening Doctors To Promote Weight Loss Drugs*, FORBES (Jul. 20, 2023), available at https://www.forbes.com/sites/johnlamattina/2023/07/20/fattening-doctors-to-promote-weightloss-drugs/; Nicholas Florko. *Novo Nordisk bought prescribers over 450,000 meals and snacks to promote drugs like Ozempic*, STAT (Jul. 5, 2023), available at https://www.statnews.com/2023/07/05/ozempicrybelsus-novo-nordisk-meals-for-doctors.

217. Similarly, in 2022, Lilly purchased 184,000 meals, amounting to roughly $3.5 Million, for doctors, in an effort to promote its GLP-1 RAs.[182]

218. Over the past decade, a minimum of 57 physicians in the United States each accepted at least $100,000 from Novo in payments associated solely with Wegovy or Saxenda. A Reuters special report found these physicians were an influential group: Forty-one were obesity specialists who run weight-management clinics, work at academic hospitals, write obesity-treatment guidelines or hold top positions at medical societies.[183]

219. Critically, Reuters examined Novo's spending among experts involved in crafting five prominent sets of obesity-treatment guidelines for doctors. Among the 109 authors and reviewers credited in the guidelines, 53 had accepted cash or in-kind payments between 2013 and 2022 from companies that were selling or developing obesity drugs.[184]

220. The Reuters analysis found that Novo accounted for $8 Million of the $12.4 Million spent on these authors and reviewers, not including payments related to research.[185]

b. Key Opinion Leaders

221. A key opinion leader ("KOL") is a trusted, well-respected professional with proven experience and expertise in a particular field. Often, in the pharmaceutical space, these thought leaders are physicians. These KOLs have extensive experience and carry significant influence which allows them to promote new drugs. Defendants have made paying and supporting KOLs a centerpiece of their influence strategy.

---

[182] John LaMattina, *Fattening Doctors To Promote Weight Loss Drugs*, FORBES (Jul. 20, 2023), available at https://www.forbes.com/sites/johnlamattina/2023/07/20/fattening-doctors-to-promote-weightloss-drugs/.
[183] Terhune and Respaut, *Maker of Wegovy, Ozempic showers money on U.S. obesity doctors*, REUTERS (Dec. 1, 2023) available at https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/.
[184] *Id.*
[185] *Id.*

222. By way of example, Dr. Fatima Cody Stanford is an obesity specialist who frequently speaks on behalf of Novo, has been featured on Novo's website, and has received payments directly from Novo.[186] Upon information and belief, Dr. Stanford is one of Novo's highest paid KOLs. Dr. Stanford also serves as an obesity consultant for Lilly.[187]

223. Dr. Stanford has spoken on the topic of Ozempic and Wegovy. One notable example occurred when she took part in an investigative piece conducted by the television news program "60 Minutes" where she promoted the safety and efficacy of GLP-1 RAs, and stated that obesity is a "brain disease" and that diet and exercise don't work.[188] Physicians Committee for Responsible Medicine later filed a complaint, alleging the 60 Minutes segment was an "unlawful weight loss drug ad" and that Dr. Stanford had not disclosed she received significant payments from Novo.[189] Dr. Stanford also appeared on Oprah discussing obesity and promoting obesity drugs in September of 2023.[190] Her financial ties to Novo were not fully disclosed during these appearances and not mentioned at all with respect to her appearance on Oprah.

224. Dr. Stanford also has sat on the advisory board of Calibrate, a telehealth provider for weight loss medications that has partnered with Novo; and she was included on Novo's website where she argued that access to Novo's weight-loss drugs is an issue of equity and disparity for

[186] U.S. Centers for Medicare & Medicaid Services, Open Payments Data, Fatima C. Stanford, available at https://openpaymentsdata.cms.gov/physician/807348; Novo Nordisk, *Changing the Mindset Around Obesity*, https://www.novonordisk-us.com/about/perspectives/changing-the-mindset-around-obesity.html (last visited Sept. 18, 2023).
[187] Melissa Suran, *As Ozempic's Popularity Soars, Here's What to Know About Semaglutide and Weight Loss*, JAMA (Apr. 26, 2023), available at https://jamanetwork.com/journals/jama/article-abstract/2804462.
[188] 60 Minutes, *Recognizing and treating obesity as a disease*, https://www.youtube.com/watch?v=uaYLApCdKBo.
[189] Physicians Committee for Responsible Medicine, *CBS's 60 Minutes News Segment Was an Unlawful Weight Loss Drug Ad, Physicians' Complaint Alleges* (Jan. 19, 2023), available at https://www.pcrm.org/news/news-releases/cbs-60-minutes-news-segment-was-unlawful-weight-loss-drug-ad-physicians.
[190] Melissa Suran, *As Ozempic's Popularity Soars, Here's What to Know About Semaglutide and Weight Loss*, JAMA (Apr. 26, 2023), available at https://jamanetwork.com/journals/jama/article-abstract/2804462.

communities of color.[191] Again, the full financial relationship between Dr. Stanford and Novo was not disclosed on Novo's website.

225. Similarly, Novo has also used Dr. Lee Kaplan to advocate for the use of weight-loss medicines, including Wegovy. Dr. Kaplan is the Chief of Obesity Medicine at Dartmouth College's medical school, and previously was the head of the Obesity, Metabolism and Nutrition Institute at Massachusetts General Hospital and a teacher at Harvard Medical School. He is a powerful messenger for Novo, and they paid him approximately $1.4 Million between 2013 and 2022.[192]

226. Lilly utilizes the same strategy. One of their KOLs is Dr. Marschall Runge, Executive Vice President for Medical Affairs and Chief Executive Officer of Michigan Medicine since March 2015 and Dean of the Medical School since January 2016.

227. Dr. Runge served on Ely Lilly's Board of Directors from 2013 until his recent retirement. During that time, on April 12, 2017, Dr. Runge published an article about obesity care without disclosing his financial relation to Lilly. Between 2021 and 2023, Lilly paid Dr. Runge a total of $926,147.

228. Lilly has also funded Dr. Ania Jastreboff since at least 2018. Dr. Jastreboff has appeared on Oprah discussing the benefits of GLP-1 RAs for the treatment of obesity.[193] Dr. Jastreboff has provided medical education through The Obesity Society, advocating for the use of

[191] Novo Nordisk, *Changing the Mindset Around Obesity*, https://www.novonordisk-us.com/about/perspectives/changing-the-mindset-around-obesity.html (last visited Sept. 18, 2023).
[192] Terhune and Respaut, *Maker of Wegovy, Ozempic showers money on U.S. obesity doctors*, REUTERS (Dec. 1, 2023), available at https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/.
[193] WeightWatchers, *What Exactly IS Obesity? A Yale Doctor Explains*, available at https://youtu.be/kMI9b3_TWt0?si=mmq6gSTu1W8igLun.

pharmaceutical treatment for obesity.[194] Between 2020 and 2023, Lilly paid Dr. Jastreboff nearly $100,000.[195]

229. Dr. Ania Jastreboff was the first author on The Obesity Society's 2018 position statement defining obesity as a disease and advocating for additional treatments, where she disclosed that she received consulting fees from both Novo and Lilly.[196]

230. EveryBODY Covered is a campaign for obesity care coverage that is led by the Alliance for Women's Health & Prevention and funded by Lilly.[197] It features articles from KOLs, such as Dr. Maria Abreu, who argue that "Obesity is Not a Lifestyle."[198] The article does not disclose that Dr. Abreu is a paid consultant for Lilly.[199]

c. Defendants Use Advocacy Groups to Influence Medical and Public Opinion Regarding Weight-Loss Drugs

231. Defendants directly or indirectly pay or influence numerous advocacy groups to influence medical and public opinion regarding obesity, the treatment for obesity, and the safety and efficacy of GLP-1 RAs. These include, among others, The Obesity Society, The Obesity Action Coalition, Obesity in Action Coalition, American Board of Obesity Medicine, and STOP (Strategies to Overcome and Prevent) Obesity Alliance.

[194] *See* The Obesity Society, *Meetings and Education: Grand Rounds*, available at https://www.obesity.org/meetings-education/grandrounds/.
[195] U.S. Centers for Medicare & Medicaid Services, Open Payments Data, Eli Lilly & Company, available at https://openpaymentsdata.cms.gov/company/100000000088.
[196] Ania Jastreboff, *Obesity as a Disease: The Obesity Society 2018 Position Statement*, OBESITY (2019), available at https://www.obesity.org/wp-content/uploads/2019/04/Jastreboff_et_al-2019-Obesity.pdf.
[197] *See* everybodycovered.org; *see also* https://www.instagram.com/everybodycovered/.
[198] University of Miami Miller School of Medicine, *Dr. Maria Abreu: Obesity is Not a Lifestyle*, available at https://news.med.miami.edu/dr-maria-abreu-obesity-is-not-a-lifestyle/ (linked at EveryBODY Covered Instagram).
[199] *But see* Practice Update, Maria Abreu, available at https://www.practiceupdate.com/author/maria-abreu/4098.

232. The Obesity Society. The Obesity Society bills itself as "the leading professional society focused on obesity science, treatment and prevention" claiming to have over 2,800 members worldwide.[200]

233. Former President of The Obesity Society, researcher Dr. Donna Ryan, was instrumental in persuading the U.S. Office of Personnel Management to cover Wegovy and similar drugs for millions of federal workers. One analysis found that she has accepted more than $1 Million from Novo over the last decade, including $600,691 related to Wegovy and Saxenda.[201]

234. Current President of The Obesity Society, Dr. Jamy Ard of Wake Forest University, oversees the group's effort to write new "standards of care," which primary-care doctors often use as a quick-reference guide, with advice on Wegovy and similar therapies. Dr. Ard has accepted more than $200,000 from Novo, according to Reuters.[202]

235. The Obesity Action Coalition. The Obesity Action Coalition ("OAC") claims to be "the nation's leading voice on obesity" with "more than 85,000" members.[203]

236. Novo is "a long-time supporter" of OAC, and routinely renews their support of OAC's Chairman's Council at the Platinum level.[204]

237. In 2012, Robert Kushner served on the Board of Directors for the OAC.[205] That same year, ahead of the vote by the AMA to classify obesity as a disease, Dr. Kushner published "Clinical Assessment and Management of Adult Obesity" in the American Heart Association

[200] The Obesity Society, *About Us*, available at https://www.obesity.org/about-us/.
[201] Terhune and Respaut, *Maker of Wegovy, Ozempic showers money on U.S. obesity doctors*, REUTERS (Dec. 1, 2023), available at https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/.
[202] *Id*.
[203] The Obesity Action Coalition, *Home Page*, available at https://www.obesityaction.org/.
[204] The Obesity Action Coalition, *Novo Nordisk Renews Support for OAC Chairman's Council at Platinum Level* (Apr. 1, 2023), available at https://www.obesityaction.org/novo-nordisk-renews-support-for-oac-chairmans-council-at-platinum-level/.
[205] Robert Kushner, *Clinical Assessment and Management of Adult Obesity*, 126 CIRCULATION 24 (Dec. 11, 2012).

Circulation Journal, arguing that obesity should be classified as a disease.[206] Dr. Kushner has previously disclosed that he received funding from Novo as a consultant for his research between 2008 and 2012.[207] Dr. Kushner has been a member of Novo's Medical Advisory Board from 2015 to the present.[208]

238. On March 21, 2013, Dr. Kushner and several co-authors published clinical practice guidelines.[209] An appendix listing the committee members reveals their relationships with industry, including Novo. Prior to the committee issuing guidelines that obesity should be treated as a disease, both committee co-chairs had received funding from Novo, and five additional committee members had received funding from Novo.[210] Two of the committee members also received funding from Lilly.[211]

239. Novo has referred to its partnership with the OAC and credited it with "making a big difference" in giving a voice to those living with obesity.[212]

240. Both Novo and Lilly contribute more than $100,000 annually to OAC.[213]

241. On September 10, 2024, it was reported that Novo supported the OAC's "Your Weight Matters" campaign in which Americans are encouraged to speak with their doctors about

---

[206] *Id*.
[207] M.D. Jensen, D.H. Ryan, K.A. Donato, C.M. Apovian, J.D. Ard, A.G. Comuzzie, F.B. Hu, V.S. Hubbard, J.M. Jakicic, R.F. Kushner, et al., *Executive summary: Guidelines (2013) for the management of overweight and obesity in adults*, 22 OBESITY S5-S39 (2014), available at https://doi.org/10.1002/oby.20821.
[208] Northwestern Medicine, *Faculty Profiles: Robert F. Kushner, M.D.: Activities*, available at https://www.feinberg.northwestern.edu/faculty-profiles/az/profile.html?xid=11686.
[209] Jeffrey Mechanick et al., *Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient—2013 update: Cosponsored by American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery*, 21 OBESITY S1-27 (Mar. 26, 2013).
[210] M.D. Jensen, D.H. Ryan, K.A. Donato, C.M. Apovian, J.D. Ard, A.G. Comuzzie, F.B. Hu, V.S. Hubbard, J.M. Jakicic, R.F. Kushner, et al., *Executive summary: Guidelines (2013) for the management of overweight and obesity in adults*, 22 OBESITY S5-S39 (2014), available at https://doi.org/10.1002/oby.20821.
[211] *Id.*
[212] Novo Nordisk, Annual Report (2015) at 29, available at https://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2015.PDF.
[213] The Obesity Action Coalition, *Corporate Council*, available at https://www.obesityaction.org/corporate-council/

their weight, and "the implicit understanding of these doctor conversations is the hope that they will be offered anti-obesity medications and up prescribing of the drugs in general."[214]

242. American Board of Obesity Medicine. The American Board of Obesity Medicine ("ABOM") is a professional credentialing organization for the practice of Obesity Medicine. One of its stated goals is "to improve access to high-quality clinical services for patients with obesity by increasing the number of competent physicians that can treat this complex, chronic disease."[215]

243. The former Medical Director of ABOM, Rekha Kumar, who served from 2017 to of 2021,[216] received payments from Novo during her time as the ABOM Medical Director.[217] She is also affiliated with a telehealth company that promotes GLP-1 RAs for weight loss.[218]

244. Another ABOM member, Karl Nadolsky, who co-authored the Clinical Practice Guidelines for Comprehensive Medical Care of Patients with Obesity,[219] has also received payments from Novo during the same time he wrote those guidelines.[220]

245. ABOM lists public health "partners" on their website.[221] Novo serves on the board and/or provides direct financial contributions to many of these partners: (1) OAC (discussed above); (2) American Society for Metabolic and Bariatric Surgery;[222] and (3) STOP Obesity Alliance.[223]

---

[214] Ben Adams, *Eli Lilly, Novo Nordisk and other Big Pharmas back OAC's 'Your Weight Matters' campaign challenge*, FIERCE PHARMA (Sep. 10, 2024), available at https://www.fiercepharma.com/marketing/eli-lilly-novo-nordisk-and-other-big-pharmas-back-oacs-your-weight-matters-campaign.
[215] American Board of Obesity Medicine, *History*, available at https://www.abom.org/history/.
[216] LinkedIn, *Rekha Kumar*, available at https://www.linkedin.com/in/rekha-kumar-m-d-m-s-70b481237/.
[217] U.S. Centers for Medicare & Medicaid Services, Open Payments Data, Rekha Babu Kumar, available at https://openpaymentsdata.cms.gov/physician/1294300.
[218] *See* Found, available at https://joinfound.com/ (identifying Dr. Rekha Kumar as Head of Medical Affairs, Former Medical Director of the American Board of Obesity Medicine).
[219] American Board of Obesity Medicine, *Dr. Karl Nadolsky*, available at https://www.abom.org/karl-nadolsky/.
[220] U.S. Centers for Medicare & Medicaid Services, Open Payments Data, Karl Zahlmann Nadolsky, available at https://openpaymentsdata.cms.gov/physician/1379381.
[221] American Board of Obesity Medicine, *Home*, available at https://www.abom.org/.
[222] American Society for Metabolic & Bariatric Surgery, *Corporate Council*, available at https://asmbs.org/corporate-council/.
[223] STOP Obesity Alliance, *Membership*, available at https://stop.publichealth.gwu.edu/membership.

246. STOP Obesity Alliance operates out of George Washington's Milken Institute School of Public Health and advocates for insurance coverage and expanded pharmaceutical obesity treatment.[224] Both Novo and Lilly are corporate sponsors of STOP Obesity Alliance.[225]

247. All About Obesity is yet another advocacy group pushing for treatment services for those living with obesity.[226] Its board members receive funding for grants, consulting, or speaking from Lilly and Novo, and Lilly is a corporate member of All About Obesity.[227] Novo went on and partly funded the creation of the website in 2021.

248. Lilly also sponsors The World Obesity Federation,[228] which is another advocacy group that runs the campaigns "Let's Talk About Obesity & ___" as well as World Obesity Day.[229] This campaign is unique in that it also advocates for increased treatment for youth and kids.

249. In addition, Novo and Lilly both:

- are Corporate Partners/Gold Sponsors for the American Association of Clinical Endocrinologists;[230]
- serve on the Endocrine Society Corporate Liaison Board;[231]
- are members of the American College of Cardiology "Industry Advisory Forum," for which they contribute at least $25,000 annually in exchange for "a front-row seat to discussions on topics of mutual interest and importance impacting the cardiovascular healthcare environment.";[232]

[224] STOP Obesity Alliance, available at https://stop.publichealth.gwu.edu/.
[225] STOP Obesity Alliance, Annual Report (2023), available at https://stop.publichealth.gwu.edu/sites/g/files/zaxdzs4356/files/2024-01/the-2023-stop-annual-report.pdf.
[226] All About Obesity, *About Us*, available at https://allaboutobesity.org/about-us/.
[227] All About Obesity, *Declaration of Interests*, available at https://allaboutobesity.org/declaration-of-interests/.
[228] World Obesity, *Champions*, available at https://www.worldobesity.org/our-network/partnerships/champions.
[229] World Obesity Day, *Homepage*, available at https://www.worldobesityday.org/.
[230] American Association of Clinical Endocrinologists, *About AACE: Corporate AACE Partnership (CAP)*, available at https://pro.aace.com/about/corporate-aace-partnership-cap.
[231] Endocrine Society, *Corporate Liaison Board*, available at https://www.endocrine.org/partnerships/clb.
[232] American College of Cardiology, *ACC Industry Advisory Forum*, available at https://www.acc.org/About-ACC/Industry-Relations/corporate-advisory.

- sit on the "Chairman's Council" for the OAC, and have done so for several years;[233] and

- provided financial backing to the OAC "Your Weight Matters" campaign.[234] As part of the campaign, a new public service announcement ("PSA") was launched to encourage Americans to "take control of their health" by starting "vital" conversations with their healthcare providers. Also, those who took part in the campaign (*i.e.*, took the challenge) received a book that included information on "medical weight management" and the "FDA-approved prescription medications, including injections and oral medications, designed to assist with chronic weight management".

d. Defendants Exert Influence over Continuing Medical Education Regarding Obesity and GLP-1 RAs

250. Defendants recognized that there was a historical reluctance among prescribers to prescribe weight loss medication – particularly if the resulting weight loss was a modest 5 to 7%.[235] In 2015, Novo admitted that "many people – including some doctors and healthcare professionals – simply don't accept that obesity is a disease. Until we can convince them otherwise, we'll struggle" to maximize sales.[236] Novo concluded that their 10-year plan to establish a leading position within treatment for obesity "starts by educating doctors."[237]

251. Defendants operate comprehensive, integrated education for health care providers as part of their online websites where the messaging consistently reinforces that obesity is a disease and advocates for pharmaceutical interventions.

252. For example, Novo offers robust continuing medical education through its website "Rethink Obesity." One of the first training modules available is one entitled "Virtual Obesity

---

[233] Obesity Action Coalition Annual Report (2023), available at https://www.obesityaction.org/wp-content/uploads/OAC-Annual-Report-2023.pdf.
[234] Ben Adams, *Eli Lilly, Novo Nordisk and other Big Pharmas back OAC's 'Your Weight Matters' campaign challenge*, FIERCE PHARMA (Sept. 10, 2024), available at https://www.fiercepharma.com/marketing/eli-lilly-novo-nordisk-and-other-big-pharmas-back-oacs-your-weight-matters-campaign.
[235] Eli Lilly at the UBS Virtual Global Healthcare Conference (May 19, 2020), available at https://web.archive.org/web/20201204114841/https://investor.lilly.com/webcasts-andpresentations.
[236] Novo Nordisk, Annual Report (2015) at 28, available at https://www.novonordisk.com/content/dam/Denmark/HQ/Commons/documents/Novo-Nordisk-Annual-Report-2015.PDF.
[237] *Id*.

Clinics Programme" with the promise that physicians will learn "how to introduce virtual patient consultations and best practices into an existing obesity clinic model."[238]

253. Lilly offers its own continuing medical education online portal that contains disease resources, trainings, CME, and lectures by KOLs.[239]

254. In addition to the educational materials available directly from Defendants, they have also funded education through various associations. For instance, Novo provides "independent educational grants" to Medscape, which in turn provides free continuing medical education on obesity and drugs for treating obesity.[240] These modules include education that encourages drugs for weight loss.[241] As another example, Lilly's funding of continuing medical education includes a session on "Redefining Obesity Management" at the 12th Annual Obesity Forum.[242]

255. Defendants also present at industry and academic conferences on the topic of obesity. For instance, Novo held an "unbranded" symposium discussing the need for increased care and insurance coverage in obesity.[243] Both Lilly and Novo are sponsors of the "Obesity Care Week" Conference in the United States, which includes advocacy for "clinically-based care" for obesity, which primarily means use of GLP-1 RAs.[244]

---

[238] Rethink Obesity, *Obesity eCME and medical education – a comprehensive collection*, available at https://www.rethinkobesity.global/global/en/resources/ecme-and-medical-education.html.
[239] Eli Lilly & Co., *Obesity Patient Education Resources*, available at https://medical.lilly.com/us/diseases/patient-education-resources/obesity/obesity.
[240] Medscape, *Clinical Advances in Treating Obesity as a Chronic Disease: Novel Insights and Strategies*, available at https://www.medscape.org/sites/advances/overcoming-obesity.
[241] Rethink Obesity, *Obesity eCME and medical education*, available at https://www.rethinkobesity.global/global/en/resources/ecme-and-medical-education.html.
[242] 12th Annual Obesity Forum, available at https://events.vindicocme.com/en/15kYU86/g/xM5BD6TC2R/12th-annual-obesity-forum-redefining-obesity-management-4a2BUmoci1/overview.
[243] Novo Nordisk, *Driving change in obesity care*, available at https://www.ispor.org/docs/default-source/intl2023/novo-nordisk-presentation.pdf?sfvrsn=3179cf91_0.
[244] Obesity Care Week, *Partners*, available at https://www.obesitycareweek.org/partners/.

256. Lilly has presented on the topic of Obesity at the American Diabetes Association,[245] Obesity Week, the European Association for the Study of Diabetes, American Heart Association, Endocrine Society, and European Association for the Study of Obesity/European Congress on Obesity.[246] Specific presentations include the "Development of the Pediatric Weight Questionnaire" and "Real-World Characteristics of Adults with Obesity or Overweight Treated with Tirzepatide in the US."[247] The Obesity Week presentation poster acknowledged that some patients are initiating tirzepatide when they are a normal body weight at baseline – in other words, the poster recognizes off-label usage of the drug.[248]

e. Defendants Influence the Relevant Literature

257. Defendants are involved directly or indirectly in significant amounts of literature intended to influence doctors' perceptions of obesity, treatment for obesity and the safety and efficacy of GLP-1 RAs.

258. For example, one analysis showed that Novo shifted public perception of obesity "thanks to the effective messaging of the company's spokespeople, who, according to our analysis of 3,263 English-language articles published in the last two years, became the most influential spokespeople in the whole obesity debate. . . ."[249]

259. Novo has been investing in relevant literature and research dating back to 2013:

---

[245] Eli Lilly & Co., *Lilly Obesity and Diabetes Presentations at ADA 2024*, available at https://medical.lilly.com/us/science/conferences/obesity/ada2024.
[246] Eli Lilly & Co., *Obesity Congress Events*, available at https://medical.lilly.com/us/science/conferences/obesity.
[247] Eli Lilly & Co., *Lilly Scientific Information Page for OW 2024*, available at https://medical.lilly.com/us/science/conferences/obesity/ow2024.
[248] *Real-World Characteristics of Adults with Obesity or Overweight Treated with Tirzepatide in the US*, available at https://assets.ctfassets.net/mpejy6umgthp/13JiVNYXvN7llHOHNRza8j/4c08788f73c6e6caa78a48d6a6c1ea5a/VV-TZPPT1_OW2024_KAN_REAL_WORLD_CHARACTERISTICS_DV-022561_V2.2.pdf.
[249] Maya Koleva, *Novo Nordisk changed the obesity debate. But its reputation is on the line*, COMETRIC (Mar. 13, 2024), available at https://commetric.com/2024/03/13/novo-nordisk-changed-the-obesity-debate-but-its-reputation-is-on-the-line/.

- On April 1, 2013, Holly R. Wyatt published an "update on Treatment Strategies for Obesity" in the Endocrine Society Journal and disclosed financial grant money from Novo.[250]

- In May of 2013, American Association of Clinical Endocrinologists released a Consensus Statement on "Comprehensive Diabetes Management Algorithm" that mentions obesity fifty (50) times; 12 of 19 authors had ties to Novo.[251]

- In May of 2013, Novo provided funding to a working group studying the impact of hypoglycemia on patients with diabetes.[252]

- On October 24, 2017, University of Leeds researchers called semaglutide "antiobesity drug" after Novo funded their research on appetite control.[253]

- In 2019, Novo provided funding for the 4th World Congress of Interventional Therapies for Type 2 Diabetes and is named 22 times in the "Ethics declarations – Competing interests" section of the subsequently published "joint international consensus statement for ending stigma of obesity."[254]

- In 2021, Novo funded research regarding the genetics of obesity,[255] which is consistent with Novo's approach of marketing the primary cause of obesity as genetics that requires pharmaceutical treatment.

- Novo has also funded research regarding the pervasiveness, impact, and implications of weight stigma.[256]

- In 2022, Novo published the results of its ACTION IO study focused on increasing treatment of teenagers with obesity, including the use of weight loss drugs. ACTION stands for Awareness, Care & Treatment in obesity Management – International Observation Among Teenagers.[257]

---

[250] Holly R. Wyatt, *Update on Treatment Strategies for Obesity*, J. CLINICAL ENDOCR. &. METAB., Volume 98, Issue 4, Pages 1299-1306 (April 1, 2013).
[251] A.J. Garber et al., *American Association of Clinical Endocrinologists' Comprehensive Diabetes Management Algorithm 2013 Consensus Statement*, 19(2) ENDOCR. PRACT. 1 (May/Jun. 2013), available at https://diabetesed.net/page/_files/AACE-2013-DM-consensus-statement.pdf.
[252] Elizabeth Seaquist et al., *Hypoglycemia and Diabetes: A Report of a Workgroup of the American Diabetes Association and The Endocrine Society*, 36 DIABETES CARE 1384-95 (May 2013).
[253] Univ. of Leeds, *Anti-obesity drug acts on brain's appetite control system* (Oct. 24, 2017), available at https://www.leeds.ac.uk/news-health/news/article/4122/anti-obesity-drug-acts-onbrain-s-appetite-control-system.
[254] F. Rubino et al., *Joint international consensus statement for ending stigma of obesity*, 26 NAT. MED. 485-97 (2020), available at https://www.nature.com/articles/s41591-020-0803-x.
[255] R.J.F. Loos et al., *The genetics of obesity: from discovery to biology: Author Information*, 23 NAT. REV. GENET. 120-33 (2022), available at https://www.nature.com/articles/s41576-021-00414-z#author-information.
[256] Adrian Brown et al., *Pervasiveness, impact and implications of weight stigma*, ECLINICALMEDICINE (April 21, 2022), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC9046114/.
[257] Rethink Obesity, *ACTION teens Study*, available at https://www.rethinkobesity.global/content/rthkobesity/global/en/resources/obesity-resources-for-physicians-and-patients.html#section18.

- In 2022, the author of a study involving weight stigmatization in the media reported that he had personal fees paid for by Novo.[258]

- The 2023 Cardiovascular outcomes of the SELECT Trial – which was the basis for FDA approval of a label change for cardiovascular benefits – was conducted by Novo and an "academic steering committee" with members who reportedly received over $7.5 Million dollars in payments from Novo between 2015-2022.[259]

260. Similarly, Lilly has been funding similar research dating back to 2010:

- As early as 2010, Lilly funded research that resulted in publications titled "Nonsurgical Weight Loss for Extreme Obesity in Primary Care Settings."[260]

- Lilly's clinical trials program includes almost 17,000 individuals being studied for just tirzepatide.[261]

- Lilly has also done significant research into the attitudes of patients, physicians, and employers regarding obesity in an attempt to increase the sales of their drugs.[262]

261. Novo and Lilly were both involved in funding other mutually beneficial research:

- In May of 2013, the American Association of Clinical Endocrinologists released its Consensus Statement on "Comprehensive Diabetes Management Algorithm" that mentions obesity fifty (50) times; 12 of the 19 named authors of that statement had ties to Novo or Lilly.[263]

- In May of 2013, Novo and Lilly, among others, provided grants to working groups that are publishing with the American Diabetes Association and Endocrine Society.[264] Under the Participants section, the Abstract says: "The workgroup

---

[258] James Kite et al., *Influence and effects of weight stigmatisation in media: A systematic review*, 48 ECLINICALMEDICINE 101464 (Jun. 2022), available at https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(22)00194-8/fulltext.

[259] Ragen Chastain, *The Semaglutide (Wegovy) Cardiovascular Outcome Trial - Part 1*, WEIGHT AND HEALTHCARE (Apr. 13, 2024), available at https://weightandhealthcare.substack.com/p/the-semaglutide-wegovy-cardiovascular.

[260] D.H. Ryan, et al., *Nonsurgical weight loss for extreme obesity in primary care settings: results of the Louisiana Obese Subjects Study*, 170(2) ARCH INTERN MED. 146-54 (Jan. 25, 2010), available at https://pubmed.ncbi.nlm.nih.gov/20101009/.

[261] Annalee Armstrong, *Lilly's Sprawling Obesity Clinical Program Underscores Challenges for Biotechs*, BIOSPACE (Oct. 9, 2024), available at https://www.biospace.com/business/lillys-sprawling-obesity-clinical-program-underscores-challenges-for-biotechs.

[262] Eli Lilly & Co., *OBSERVE: Study Overview*, available at https://medical.lilly.com/us/diseases/disease-education-resources/obesity/obesity/education-resources/observe-study-overview.

[263] A.J. Garber et al., *American Association of Clinical Endocrinologists' Comprehensive Diabetes Management Algorithm 2013 Consensus Statement*, 19(2) ENDOCR. PRACT. 1 (May/Jun. 2013), available at https://diabetesed.net/page/_files/AACE-2013-DM-consensus-statement.pdf.

[264] Seaquist et al., *Hypoglycemia and diabetes: a report of a workgroup of the American Diabetes Association and the*

meeting was supported by educational grants to the American Diabetes Association from Lilly USA, LLC and Novo and sponsorship to the American Diabetes Association from Sanofi. The sponsors had no input into the development of or content of the report."

- Lilly and Novo both paid personal fees to the author of the study "Influence and effects of weight stigmatization in the media."[265] Novo has separately funded the Joint International Consensus Statement for ending the Stigma of Obesity, and Lilly had paid speaker fees to one of the authors.[266] This research concluded that the prevailing view is that "obesity is a choice and that it can be entirely reversed by voluntary decisions to eat less and exercise more" and that this view can "exert negative influences" on access to treatments and research.[267]

- Lilly and Novo continue to partner together on obesity research and expanding obesity treatments.[268] To date these treatments have made Novo nearly $50 Billion in sales of Ozempic and Wegovy since 2018.[269] Mounjaro and Zepbound now account for approximately 40% of Lilly's total sales, which exceed billions of dollars.[270]

f. Defendants Pay Lobbying Groups to Support Legislation Authorizing Reimbursements for GLP-1 RAs

262. Medicalizing obesity treatment would do little for Defendants' profits if there was no access to GLP-1 RAs. All GLP-1 RA makers engage in efforts to increase accessibility and use of GLP-1 RAs and mutually benefit from each other's efforts. Access to GLP-1 RAs includes the ability to pay for these very expensive drugs –Wegovy (approx. $1,350/mo.), Mounjaro (approx. $1,023/mo.), and Zepbound (approx. $1,060/mo.).

Endocrine Society, 98(5) J. CLIN. ENDOCRINOL METAB. 1845-59 (May 2013), epub. Apr 15, 2013, PMID: 23589524, available at doi: 10.1210/jc.2012-4127.

[265] J. Kite et al., *Influence and effects of weight stigmatisation in media: A systematic review*, 48 ECLINICALMEDICINE 101464 (May/Jun. 2022), available at doi: 10.1016/j.eclinm.2022.101464; https://pmc.ncbi.nlm.nih.gov/articles/PMC9125650/.

[266] F. Rubino et al., *Joint international consensus statement for ending stigma of obesity*, 26 NAT. MED. 485-97 (2020), available at https://www.nature.com/articles/s41591-020-0803-x.

[267] *Id.* at https://www.nature.com/articles/s41591-020-0803-x#Sec1.

[268] SOPHIA: Stratification of Obesity Phenotypes to Optimize Future Therapy, *SOPHIA Partners*, available at https://www.imisophia.eu/partners.

[269] K. Alltucker, *Why does Ozempic cost so much? Senators grill Novo Nordisk CEO for answers*, USA TODAY (Sept. 24, 2024), available at https://www.usatoday.com/story/news/health/2024/09/24/senate-hearing-novo-nordisk-ceo-ozempic-wegovy-prices/75348020007/.

[270] P.R. LaMonica, *Eli Lilly Could Become the First $1 Trillion Pharma Stock. How Weight-Loss Drugs Can Get It There.*, BARRON'S (Aug. 30, 2024), available at https://www.barrons.com/articles/eli-lilly-stock-weight-loss-drugs-market-cap-681cf0f7.

263. Getting GLP-1 RAs covered by Medicare was key to making them more affordable. Not only would Medicare coverage make obesity drugs affordable for many people who currently find them out of reach, it would likely push private insurers to likewise cover these drugs.[271] As Lilly's Mike Mason previously noted, the key to expanding the market for obesity drugs was "unlock[ing]" coverage under Medicare Part D.[272]

264. Unfortunately for Defendants, drugs used for weight loss were excluded by Congress when it established Medicare's Part D prescription drug benefit in 2003. This ban effectively deprives drugmakers of millions of potential customers.[273]

265. So, Defendants spend millions of dollars per year on efforts to lobby for changes in the law. A primary focus of that lobbying is the proposed Treat and Reduce Obesity Act, which has been introduced in Congressional sessions annually since 2012. The Treat and Reduce Obesity Act would require Medicare to cover, among other treatments, chronic-weight-management drugs.[274]

266. From 2012 to 2023, Novo spent over $35 Million on lobbying for obesity drug coverage: $2.24 Million (2012); $2.06 Million (2013); $2.40 Million (2014); $2.61 Million (2015);

[271] Rachana Pradhan, *Ozempic and Wegovy maker courts prominent Black leaders to get Medicare's favor*, NPR (Aug. 7, 2023), available at https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor.

[272] Eli Lilly at UBS Global Healthcare Conference (May 24, 2022), available at https://web.archive.org/web/20220603141033/https://investor.lilly.com/webcasts-and-presentations

[273] Rachana Pradhan, *Ozempic and Wegovy maker courts prominent Black leaders to get Medicare's favor*, NPR (Aug. 7, 2023), available at https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor.

[274] Jia Tolentino, *Will the Ozempic Era Change How We Think About Being Fat and Being Thin?*, THE NEW YORKER (Mar. 20, 2023), available at https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin; *see also* Eric Sagonowsky, *Novo Nordisk, Eli Lilly and Boehringer Ingelheim back bill to bring obesity drug coverage to Medicare*, FIERCE PHARMA (Jul. 20, 2023), available at https://www.fiercepharma.com/pharma/novo-nordisk-eli-lilly-and-boehringer-get-behind-lawmakers-bill-enable-obesity-drug-coverage.

$2.51 Million (2016); $1.91 Million (2017); $4.01 Million (2018); $2.78 Million (2019); $4.63 Million (2020); $3.21 Million (2021); $4.6 3 Million (2022); and $4.07 Million (2023).[275]

267. In 2021, Novo also gave significant sums, in the hundreds of thousands, to the Congressional Black Caucus Foundation for Medicare coverage support, and has also contributed to the Congressional Hispanic Caucus and Congressional Asian Pacific American Caucus.[276] The Congressional Black Caucus, Congressional Hispanic Caucus and Congressional Asian Pacific American Caucus have all backed a bill on health disparities that was revised in 2022 to remove Medicare's prohibition on covering prescriptions for weight loss similar to The Treat and Reduce Obesity Act.[277]

268. While Lilly's efforts to influence such legislation came later, it benefitted from the groundwork laid by Novo and also sought to advance the effort to get passage of The Treat and Reduce Obesity Act, which would benefit all GLP-1 RA makers.[278]

269. From 2021 to August of 2024, Lilly spent over $2 Million lobbying for obesity drug coverage: $390,000 (2021); $400,000 (2022); $900,000 (2023); and $320,000 (2024).[279] As reported by the Associated Press in December of 2023, "Lilly spent roughly $2.4 million lobbying since 2021" on obesity drug coverage issues, including lobbying related to The Treat & Reduce Obesity Act.[280]

---

[275] *See, e.g.*, Open Secrets, *Novo Nordisk*, available at https://www.opensecrets.org/orgs/novo-nordisk/lobbying.
[276] Rachana Pradhan, *Ozempic and Wegovy maker courts prominent Black leaders to get Medicare's favor*, NPR (Aug. 7, 2023), available at https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor.
[277] *Id.*
[278] *See, e.g.*, Eli Lilly & Co., *Obesity*, available at https://www.lilly.com/disease-areas/obesity ("We also join the obesity advocacy community—including medical, patient and health equity groups—to support the Treat and Reduce Obesity Act. The act is a step in the right direction to help modernize Medicare Part D to treat obesity as a chronic disease with evidence-based practices.").
[279] *See, e.g.*, Open Secrets, *Eli Lilly & Co.*, available at https://www.opensecrets.org/orgs/eli-lilly-co/lobbying.
[280] Amanda Seitz, *New weight loss drugs are out of reach for millions of older Americans because Medicare won't pay*, ASSOC. PRESS (Dec. 28, 2023), available at https://apnews.com/article/wegovy-ozempic-zepbound-medicare-obesity-weight-loss-02d4500e737d30d070d70907521a4fe0.

270. The lobbying activities and contributions referenced above do not include the money that Defendants spend lobbying for inclusion of weight-loss drugs in prescription drug coverage through advocacy groups, such as the Obesity Care Advocacy Network,[281] and direct contributions to political campaigns for members for Congress.[282]

271. Morgan Stanley anticipates passage of The Treat and Reduce Obesity Act within the next few years and forecasts that U.S. revenue from weight-loss drugs will increase four-hundredfold by the end of the decade. Obesity looks "set to become the next blockbuster pharma category," it declared in a report last year, which also predicted that social media and word of mouth will create an "exponential virtuous cycle" around the new medications: a quarter of people with obesity will seek treatment from physicians, up from the current seven per cent, and more than half of those who do will begin taking medicine.[283]

272. *Yahoo! Finance* reported that Novo and Lilly are trying to pursue a second avenue to gain Medicare coverage of GLP-1 RAs, by relying on other benefits from the drugs that might warrant reimbursement. For instance, Wegovy recently added a cardiovascular benefit and Lilly applied to expand Zepbound for sleep apnea.[284] These would be the "backdoors" referred to by Lilly's Dan Skovronsky regarding increasing usage on Medicare.[285]

---

[281] Obesity Care Advocacy Network, Treat and Reduce Obesity Act of 2021 (TROA) fact sheet, available at https://assets.obesitycareadvocacynetwork.com/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0.pdf.

[282] Ben Adams, *Health group lambasts CBS '60 Minutes' segment for overt promotion of Novo Nordisk's obesity med Wegovy*, FIERCE PHARMA (Jan. 20, 2023), available at https://www.fiercepharma.com/marketing/health-group-lambasts-novo-nordisk-60-minutes-paid-news-program-weight-loss-med-wegovy.

[283] Jia Tolentino, *Will the Ozempic Era Change How We Think About Being Fat and Being Thin?*, THE NEW YORKER (Mar. 20, 2023), available at https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin.

[284] Anjalee Khemlani, *How Lilly is joining Novo in the crusade to circumvent Medicare's block on weight loss drugs*, YAHOO! FINANCE (Jun. 24, 2024), https://finance.yahoo.com/news/how-lilly-is-joining-novo-in-the-crusade-to-circumvent-medicares-block-on-weight-loss-drugs-180112580.html.

[285] Eli Lilly at Citi's 17th Annual BioPharma Conference (Sep. 7, 2022), available at https://web.archive.org/web/20221001135415/https://investor.lilly.com/webcasts-and-presentations.

273. There have also been efforts to push for employer-sponsored health plans to cover obesity medications. For example, Novo has published content on the Pittsburgh Business Group on Health's website regarding the need for obesity care.[286] This group advocates for employers' ability to provide healthcare coverage.

274. The push for Medicare coverage for GLP-1 RAs and making pharmaceuticals a primary treatment for weight loss is not without consequences. While Medicare coverage for weight-loss drugs may be a boom to Defendants, it has significant public policy ramifications. Researchers at Vanderbilt University and the University of Chicago found that, even with modest uptake of the medications, annual Medicare Part D expenses could cost the program between $13.6 to $26.8 Billion even if only 10% of people with obesity use them. It is likely that premiums would need to increase and other changes in priorities would need to occur. Authors of the study questioned the economics of including semaglutide in Medicare Part D because it is not cost-effective compared to other methods of treating obesity (*e.g.*, lifestyle interventions) and "cannot be the only way – or even the main way – we address obesity as a society."[287]

3. Defendants' Extensive Advertising Has Changed Prescriber Behavior While Driving Up Demand by Engraining Their Drugs in the Popular Culture

a. Defendants Have Collectively Spent Over a Billion Dollars on Branded Direct-to-Consumer and Unbranded Advertising

275. Once Novo recognized the significant potential of Ozempic, it took an aggressive marketing approach to make its GLP-1 RAs a household name.

[286] Annie Kasler, *From Novo Nordisk Works: Why People Struggle to Maintain Weight Loss*, PITTSBURGH BUSINESS GROUP ON HEALTH (Jul. 13, 2021), available at https://pbghpa.org/why-people-struggle-to-maintain-weight-loss/.
[287] Vanderbilt University Medical Center (VUMC) Department of Health Policy, *Cost of covering antiobesity drugs could be billions to Medicare despite, a new analysis finds*, VUMC.org (Mar. 15, 2023), available at https://www.vumc.org/health-policy/medicare-antiobesity-medications-nejm.

276. Novo's marketing for Ozempic was so pervasive that, on July 10, 2023, the leading publication for the marketing and media industry, Advertising Age, declared Ozempic as "2023's buzziest drug" and one of the "Hottest Brands, disrupting U.S. culture and industry."[288]

277. The advertising blitz began on July 30, 2018, when Novo launched its first Ozempic television advertisement – "Magic" – that that repeated the catchy phrase "Oh, oh, oh, Ozempic!" set to the tune of the 1970s hit song "Magic" by Pilot. The catchy jingle helped Ozempic become widely recognized. Even though Ozempic is not approved for weight loss, the ad stated that "you may lose weight" and that "adults lost on average up to 12 pounds."[289]

278. From that time through 2023, Novo spent approximately $884 Million on television advertising in the United States to promote Ozempic and later, its other semaglutide, Wegovy (and another of its lesser known GLP-1 agonists, Rybelsus).[290]

279. One report indicated that Novo spent approximately $100 Million in advertising Ozempic in 2022 alone.[291] That year, Ozempic ranked as the sixth most advertised prescription drug brand with a U.S. measured media spend of $181 million, according to Vivvix spending data and Pathmatics paid social data.[292]

280. This massive spending resulted in cultural saturation and caused Ozempic to become a household name and engrained in pop culture. In 2022, "[e]arned media coverage of

---

[288] Phoebe Bain. *Ozempic was 2023's Buzziest Drug*, ADAGE (Jul. 10, 2023), available at https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571; *see also* Lecia Bushak, *Spending on Ozempic, Wegovy and other 'diabesity' drugs surges*, MEDICAL MARKETING AND MEDIA (Sept. 29, 2023), available at https://www.mmm-online.com/home/channel/spending-on-ozempic-wegovy-surges/.

[289] Ozempic TV Spot, 'Oh!', available at https://www.ispot.tv/ad/d6Xz/ozempic-oh.

[290] Ritzau, translated by Daniel Pedersen, *Novo Nordisk runs TV ads in US for multimillion-dollar sum*, MEDWATCH (Apr. 26, 2023), available at https://medwatch.com/News/Pharma___Biotech/article15680727.ece.

[291] Jia Tolentino, *Will the Ozempic Era Change How We Think About Being Fat and Being Thin?*, THE NEW YORKER (Mar. 20, 2023), available at https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin.

[292] Phoebe Bain. *Ozempic was 2023's Buzziest Drug*, ADAGE (Jul. 10, 2023), available at https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571.

semaglutide" (coverage Novo did not pay for) went "off the charts." In fall of that year, "Variety labeled Ozempic as 'Hollywood's Secret New Weight Loss Drug.'" Notably, in response to the press about Ozempic being used for weight loss, Novo stepped up its TV promotion of the drug even though it is not approved for weight-loss.[293]

281. Ozempic's place in the culture was unquestionable. Jimmy Kimmel joked about Ozempic at the Oscars;[294] Howard Stern joked about and discussed Ozempic (interestingly, Stern noted that the "catchy" theme song "distracts" the listener from actually hearing any of the listed side effects);[295] celebrities such as Queen Latifah became spokespersons; and other celebrities, such as Elon Musk and Chelsea Handler, admitted to using the drug, again for weight loss.[296]

282. All of this extensive marketing made demand for Ozempic and other GLP-1 RAs skyrocket. People wanted to use these drugs to lose weight, regardless of whether the drugs had been approved for that purpose or not. In some instances, it led to patients seeking prescriptions for GLP-1 RAs from their doctor rather than their doctor suggesting it as a treatment for obesity.

283. Lilly engaged in its own aggressive marketing campaign, intending to establish itself as a legitimate rival in the market, in addition to piggybacking off of Novo's efforts and benefitting from Novo's extensive marketing and the ensuing demand for GLP-1 RAs. Indeed, all

[293] Ben Adams, *The top 10 pharma drug ad spenders for 2022*, FIERCE PHARMA (May 1, 2023), available at https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022#efe86620-8ff5-4ad8-9542-59565806f3ed.
[294] Hannah Yasharoff, *Jimmy Kimmel joked about Ozempic at the Oscars. We need to actually talk about it.*, USA TODAY (Mar. 13, 2023), available at https://www.usatoday.com/story/life/health-wellness/2023/03/13/ozempic-sweeping-hollywood-celebrities-weight-loss/11428801002/.
[295] The Howard Stern Show, *Howard Goofs on the Ozempic Commercial*, available at https://www.youtube.com/watch?v=QD-nCQn1Ads.
[296] R. Hoise and A. Middleton, *Celebrities can't lose weight without people speculating they're on Ozempic*, BUSINESS INSIDER (Aug. 14, 2024), available at https://www.businessinsider.com/ozempic-celebrities-denied-semaglutide-wegovy-weight-loss-drugs-khloe-kardashian-2023-3#chelsea-handler-said-she-was-on-semaglutide-without-realizing-it-7.

GLP-1 RA makers mutually benefitted from each other's marketing efforts and the demand for GLP-1 RAs created by such marketing.

284. Drugmakers spent over $1 Billion marketing diabetes and weight loss drugs in 2023, including $139 Million spent by Lilly to promote Mounjaro – 16 times more than in 2022.[297] Again, such efforts mutually benefitted all makers of GLP-1 RAs.

285. Lilly, which had been advertising its diabetes medication Trulicity since 2015, began marketing it with an eye toward weight loss in 2018, although it was not approved for weight loss. In its 2018 Trulicity advertising campaign "Do More," an overweight firefighter exclaims, "[Trulicity] comes in an easy-to-use pen, and I may even lose a little weight!"[298]

286. This weight loss messaging continued in a series of advertisements in 2021 and 2022 called "On His Game," "Father-Son," and "My Sister," where the voiceover indicates that taking Trulicity can help you "lose up to 10lbs."[299] These advertisements were even targeted to Spanish speaking populations, proclaiming "puedes perder hasta 10 LBS" in an advertisement from 2022.[300]

287. On February 13, 2020, Lilly partnered with Team USA and NBC for the Olympics.[301] In addition to partnering specifically with Team USA, Lilly also engaged many Team USA athletes as "brand ambassadors" on marketing health-related issues like diabetes. A Lilly

[297] A. Constantino and A. Capoot, *Healthy Returns: Weight loss, diabetes drug ad spending tops $1 billion*, CNBC (Apr. 3, 2024), available at https://www.cnbc.com/2024/04/03/weight-loss-diabetes-drug-ad-spending-tops-1-billion.html.
[298] Trulicity TV Spot, 'Do More: Firefighter: $25 a Month for Two Years', available at https://www.ispot.tv/ad/dBhL/trulicity-do-more-firefighter.
[299] Trulicity TV Spot, 'On His Game', available at https://www.ispot.tv/ad/Oqgb/trulicity-on-his-game; Trulicity TV Spot, 'Father-Son', available at https://www.ispot.tv/ad/q4Kl/trulicityfather-son; Trulicity TV Spot, 'My Sister', available at https://www.ispot.tv/ad/bffc/trulicity-my-sister.
[300] Trulicity TV Spot, 'Reduce el azúcar', available at https://www.ispot.tv/ad/bKNt/trulicity-reduce-el-azcar-spanish.
[301] *U.S. Olympic & Paralympic Committee and NBCUniversal Announce Partnership With Eli Lilly And Company*, COMCAST (Feb. 13, 2020), available at https://corporate.comcast.com/press/releases/us-olympic-paralympic-committee-nbcuniversal-eli-lilly-and-company.

spokesperson said the goal of the marketing campaign was clear: "to connect with Americans that may benefit from our medicines" and adding that "as a global healthcare leader, we can think of no better example of health and wellness than these elite athletes."[302]

288. In July of 2023, Lilly extended its marketing deal with Team USA and NBC, securing this partnership through the 2028 Olympic Games and Paralympic Games, both of which will be held in Los Angeles.[303] In that same month, Lilly released a television commercial for Mounjaro featuring Simone Biles, one of the most recognizable members of Team USA. The advertisement featured Simone Biles engaging with fans and then saying "you can do diabetes differently, with Mounjaro."[304]

289. In the run up to the 2024 Olympics in Paris, Simone Biles posted to her Instagram account a Mounjaro commercial in which she starred with her mom. The advertisement noted that she is not a diabetic and that her mom, Nellie, who is a type 2 diabetic, is not taking Mounjaro. The ad further says in a voiceover that "people taking Mounjaro lost up to 25 pounds" while noting in text that it is not approved for weight loss. In her comments, Simone Biles states: "It's always so exciting to get to work with my mom, especially on something so personal to us."[305]

290. On February 12, 2023, Lilly's first TV advertisement for Mounjaro—titled "What If"—aired during the Super Bowl. Lilly spent $19.6 Million on the advertisement.[306] The

---

[302] *Id.*

[303] Nick Paul Taylor, *Lilly inks expanded Olympics deal, positioning it to push diabetes, cancer messaging through 2028*, FIERCE PHARMA (Jul. 12, 2023), available at https://www.fiercepharma.com/marketing/lilly-inks-expanded-olympics-deal-positioning-it-push-diabetes-cancer-messaging-through.

[304] Nick Paul Taylor, *Eli Lilly vaults Simone Biles to head of Mounjaro ad campaign, partnering with Olympian for TV spot*, FIERCE PHARMA (Jul. 16, 2024), available at https://www.fiercepharma.com/marketing/eli-lilly-vaults-simone-biles-head-mounjaro-ad-campaign-partnering-olympian-tv-spot.

[305] *See* https://www.instagram.com/simonebiles/?hl=en (last accessed Oct. 9, 2024).

[306] A. Rashid, *Eli Lilly Spends Big on First Mounjaro TV Commercial for Diabetes*, XTALKS (Apr. 6, 2023), available at https://xtalks.com/eli-lilly-spends-big-on-first-mounjaro-tv-commercial-for-diabetes-3424/; *Eli Lilly Invests Heavily in Debut Mounjaro TV Ad Campaign for Diabetes*, PharmExec.com (Apr. 7, 2023), available at https://www.pharmexec.com/view/eli-lilly-invests-heavily-in-debut-mounjaro-tv-ad-campaign-for-diabetes (discussing $19.6 million expenditure).

commercial featured patients pondering the possibility of managing their type 2 diabetes "differently" and included statements that Mounjaro "helps your body regulate blood sugar"; "can help decrease how much food you eat"; and that "people taking Mounjaro lost up to 25 lbs."[307] On a list for pharmaceutical advertising spending for the month, Lilly's "What If" ad ranked 5th.[308]

291. The net effect of these advertisements was to heighten interest in a medicated solution to weight-loss, balloon the market for GLP-1 RAs, encourage off-label use for Ozempic and Mounjaro, and to target users of other diabetes medications to switch to GLP-1 RAs, even though they never would have switched absent this unprecedented marketing. This expansion of the GLP-1 RA market came without concern for the safety and efficacy of these drugs.

b. Defendants' Use of Various Online or Digital Platforms

292. Defendants have created numerous marketing campaigns and online platforms designed to promote recognition of obesity as a disease and advocate for pharmaceutical treatment of obesity.[309]

293. Novo created campaigns named "It's Bigger than Me," "Rethinking Obesity," and "The Truth About Weight." All of these Novo marketing campaigns featured DTC websites that gave consumers the opportunity to sign up for email and other marketing materials.

294. Through these websites, Novo collected extensive data through quizzes and questionnaires completed by potential customers who were seeking information on weight loss.

[307] Mounjaro TV Spot, 'What If', available at https://www.ispot.tv/ad/1VpJ/mounjaro-what-if.
[308] A. Rashid, *Eli Lilly Spends Big on First Mounjaro TV Commercial for Diabetes*, XTALKS (Apr. 6, 2023), available at https://xtalks.com/eli-lilly-spends-big-on-first-mounjaro-tv-commercial-for-diabetes-3424/.
[309] Novo Nordisk, Annual Report (2018) at 28, available at https://www.novonordisk.com/content/dam/nncorp/global/en/about-us/pdfs/corporate-governance/annual-general-meetings/agm2019/uk/annual-report-2018.pdf.

Upon information and belief, this data was funneled – as part of their omnichannel strategy – back into Novo's market strategy so that Novo could better target its marketing campaigns.

295. Novo also owns and operates several marketing campaign websites, such as "The Truth about Weight,"[310] which were purportedly created to educate on the science of obesity and create change in how obesity is understood and treated. It also created the advertising campaign website "It's Bigger Than Me," which promotes the message that obesity is a chronic health condition that requires pharmaceutical drugs to manage.[311]

296. The "Truth about Weight" website is also specifically intended to target minority communities, some of which have heightened rates of obesity. It has included the tag line "my weight, my culture" intended to convey the message that struggles to achieve weight loss through more traditional methods such as lifestyle interventions (*e.g.*, diet and exercise) will not work in light of cultural hurdles. The goal is to move this community toward believing that pharmaceutical interventions are the only answer. The website also suggests pushing back against doctors because they just might not get it, stating: "Many health care professionals know there's a science behind weight loss, but they may not know the impact that culture has on weight loss needs." There are also "my weight, my culture" hashtags appearing on Instagram with an apparent focus to target Black, Brown, and Hispanic individuals.[312]

297. Lilly likewise was involved in various unbranded online platforms, which were mutually beneficial for all GLP-1 RA makers. For example, on October 18, 2024, Lilly announced[313] that it was partnering with the OAC to launch a "bias-free obesity image gallery" as

[310] https://www.truthaboutweight.com/.
[311] https://www.itsbiggerthan.com (last accessed Sept. 18, 2023).
[312] https://www.truthaboutweight.com/understanding-excess-weight/my-weight-my-culture.html.
[313] Eli Lilly & Co., *Combatting Weight Bias Against People Living with Obesity*, lilly.com (Oct. 18, 2024), available at https://www.lilly.com/news/stories/combatting-weight-bias.

part of the OAC's website, "Stop Weight Bias."[314] The purpose of this website was to promote pharmaceutical intervention for obesity. In addition, much like Novo's websites discussed above, the Stop Weight Bias website requires the user to provide personal information to access the "bias free image gallery."[315]

298. Defendants have used the unique targeting capabilities and viral nature of social media to further drive demand and promote pharmaceuticals as the right treatment for weight loss.[316]

299. Novo had long been a proponent of using analytics to target and maximize sales.[317] Novo's aggressive marketing included a number of different platforms, including over 4,000 marketing advertisements for Ozempic and similar weight-loss medications on Facebook and Instagram.[318]

300. These platforms allow for invasive targeted advertising. For example, on Facebook, an advertiser can define the precise parameters of the audience they want to target (*e.g.*, young women who struggle with weight, etc.), and Facebook can push an advertisement out to that exact audience based on its data analytics and algorithm.[319] Instagram, which is owned by the same parent company, Meta, has similar features.

301. Social media advertising is also effective at targeting teenagers. The volume of weight loss drug advertisements and paid influencers is so high that Parents Together, a nonprofit

---

[314] https://stopweightbias.com/.
[315] https://stopweightbias.com/image-gallery/.
[316] Gina Kolata, *We Know Where New Weight Loss Drugs Came From, but Not Why They Work*, NEW YORK TIMES (Aug. 17, 2023), available at https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.
[317] Hyperight AB, *Utilizing Advanced Marketing Analytics for Sales Optimization – Peter Vester, Novo Nordisk* (Dec. 22, 2022), available at https://www.youtube.com/watch?v=nCZR6wK7MlU.
[318] David Ingram, *More than 4,000 ads for Ozempic-style drugs found running on Instagram and Facebook*, NBC NEWS (Jun. 15, 2023), available at https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602.
[319] Meta, *Audience ad targeting*, available at https://www.facebook.com/business/ads/ad-targeting.

focused on pushing news to parents, has issued an advisory to parents and provided talking points about how to navigate these advertisements with their teenager.[320] The organization warns parents that "Companies that make semaglutide weight loss drugs are explicitly targeting social media influencers to promote them, especially plus size and body positive fashion influencers who have large followings of young people."[321]

302. It is recognized by the medical community and literature that weight loss drugs are contributing to worsening eating disorders.[322] And adolescent girls are among the most susceptible to eating disorders.

303. As noted, Novo partnered directly with Meta and Instagram to run marketing campaigns. One diabetes marketing campaign achieved a dramatic 28% direct engagement rate with video poll ads.[323] This was a lauded result presented in a case study by Meta.

304. Marketing on social media, including Instagram and TikTok, often uses a hashtag. A hashtag is a word or phrase preceded by the # symbol that helps categorize and track content. When people or companies post content, they can add a hashtag which will make the content more searchable and help users find related posts. It can also help brands reach their target audience and optimize the brand's reach.

305. Novo's hashtags such as #Ozempic, #wegovyweightloss, #ozempicjourney all had hundreds of millions of views, representing the scope of its social media presence.

---

[320] *Parent Advisory: Social Media Companies Push Weight Loss Drugs Like Ozempic on Teens Despite Risks*, PARENTS TOGETHER (Mar. 6, 2024), available at https://parentstogetheraction.org/2024/03/06/parent-advisory-social-media-companies-push-weight-loss-drugs-like-ozempic-on-teens-despite-risks/.

[321] *Id.*

[322] Sazbo et al., *Weight loss drugs like Wegovy may trigger eating disorders in some patients, doctors warn*, NBC NEWS (Jul. 31, 2024), available at https://www.nbcnews.com/health/mental-health/eating-disorders-increase-weight-loss-drugs-wegovy-zepbound-rcna162124.

[323] Meta, *Novo Nordisk*, available at https://www.facebook.com/business/success/instagram/novo-nordisk.

306. Lilly ran a similar social media marketing campaign about its drug Trulicity.[324]

307. As part of that social media campaign, Lilly launched #Trulikeme which was "aimed to reduce the stigma surrounding diabetes while encouraging individuals to share their stories." This hashtag was launched on Instagram and Facebook and resulted in "thousands" of patients sharing their stories.[325]

308. These hashtags can also be used to facilitate engagement with the Defendants' website. For example, the hashtag #ItsBiggerThan was an advertising campaign on Instagram, with a stated purpose to educate the public about obesity and to change the conversation around weight "bias." This campaign was part of the partnership between Novo and It's Bigger Than Me. As part of the campaign, paid influencers would use the hashtag, and it would be linked back to Novo's website. All of these campaigns were intended to sell consumers on the idea that a pharmaceutical intervention was the best treatment for obesity, in this case by coopting the "body positivity" movement. Again, such campaigns were mutually beneficial to all GLP-1 RA makers.

4. Defendants Have Consistently Promoted Their GLP-1 RAs for Off-Label Use

309. As set forth repeatedly above, Defendants consistently promoted their GLP-1 RAs for weight loss even before they were approved for weight loss.

310. Novo's Ozempic was not approved for weight loss. Saxenda was approved for weight loss on December 23, 2014, and Wegovy was approved for weight loss on December 23, 2023.

311. Novo was not permitted to market Ozempic for weight loss without FDA approval for that specific indication, but before Wegovy ever received separate approval for treatment of

[324] Ahmed Moustafa, *Eli Lilly's Strategic Social Media Management: A Case Study of Trulicity*, LINKEDIN (Sept. 21, 2024), available at https://www.linkedin.com/pulse/eli-lillys-strategic-social-media-management-case-ahmed-dz6pf/.
[325] *Id.*

weight loss, Novo had already begun mentioning weight loss in their Ozempic marketing, advertising, commercials and other promotional materials.[326]

312. This did not go unnoticed by the Office of Prescription Drug Promotion ("OPDP") which helps enforce FDA regulations that drug promotions be truthful, balanced, and non-misleading.

313. OPDP has issued letters to Novo finding that their marketing materials may be misleading. For example, OPDP sent Novo a letter on March 14, 2018, stating that the Ozempic marketing materials it reviewed "may create the misleading impression that Ozempic is indicated for weight loss, when that is not the case." Importantly, the OPDP found that even though the materials had a disclaimer that "Ozempic is not indicated for chronic weight management" (emphasis added), that disclaimer did not mitigate the misleading impression that Ozempic is indicated for weight loss.[327]

314. On July 30, 2018, Novo launched its first television ad for Ozempic to the tune of the 1970s hit song "Magic" by Pilot, wherein the Novo advertised that "adults lost on average up to 14 pounds" when taking Ozempic.[328]

315. Novo's Ozempic website has consistently touted weight loss:

- From 2018 to 2020, Novo's Ozempic.com FAQ page acknowledged that Ozempic is not a weight-loss drug, but reported findings from a 1-year study that adults taking Ozempic with an average starting weight of 197 pounds lost around 9 pounds on the 0.5 mg dose of Ozempic, or 12 pounds on the 1mg dose.[329]

[326] Gina Kolata, *We Know Where New Weight Loss Drugs Came From, but Not Why They Work*, NEW YORK TIMES (Aug. 17, 2023), available at https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.
[327] OPDP Letter, Mar. 14, 2018 (Novo_GLP_MDL_OZM_NDA_000001286); Proposed Detail Aid (Novo_GLP_MDL_OZM_NDA_003605495).
[328] Ozempic TV Spot, 'Oh!', available at https://www.ispot.tv/ad/d6Xz/ozempic-oh.
[329] Ozempic, *Questions About Ozempic*, available at https://web.archive.org/web/20180820075728/https:/www.ozempic.com/FAQ/aboutozempic.html.

- From 2018 to 2019, Novo's OzempicPro.com page claimed "Superior weight reduction."[330]

- From 2018 to 2019, Novo's OzempicPro.com page also claimed superior weight reduction vs. Trulicity and Bydureon, plus "more than double the weight reduction for each dose comparison vs. Trulicity."[331]

- In 2020, Novo's OzempicPro.com page touted "significant weight reduction" with a link to "Examine weight data."[332]

- In 2021, Novo's Ozempic.com page said, "Ozempic may help you lose some weight"[333] and "Adults taking Ozempic lost on average up to 12 pounds."[334]

- In 2021, Novo's Ozempic.com page said, "People lost more than double the weight on Ozempic vs Trulicity."[335]

- From 2022 to 2024, Novo's Ozempic.com homepage said, "Discover the Ozempic Tri-Zone," and the third zone was "Ozempic may help you lose some weight."[336]

- From 2022 to 2024, Novo's Ozempic.com page said the following under "What is Ozempic?": "Adults taking Ozempic lost up to 14 pounds."[337]

- From 2022 to 2024, Novo's Ozempic.com page said, "People lost more than double the weight on Ozempic vs. Trulicity."[338]

- From 2022 to 2024, Novo's NovoMedLink.com page touted Ozempic Tri-Zone with "compelling weight loss."[339]

---

[330] Ozempic, *Realize the Potential with Ozempic*, available at https://web.archive.org/web/20180826124503/https://www.ozempicpro.com/.
[331] Ozempic, *Superior weight reduction vs Trulicity and Bydureon*, available at https://web.archive.org/web/20190402075103/https://www.ozempicpro.com/clinical-data/ozempic-and-weight.html.
[332] Ozempic, *Realize the Potential with Ozempic*, available at https://web.archive.org/web/20200814002835/https://www.ozempicpro.com/.
[333] Ozempic, available at https://web.archive.org/web/20211006213958/https:/www.ozempic.com/.
[334] Ozempic, *What is Ozempic?*, available at https://web.archive.org/web/20210917221158/https://www.ozempic.com/why-ozempic/what-is-ozempic.html#weight.
[335] Ozempic, *Ozempic vs Other Type 2 Diabetes Medicines*, available at https://web.archive.org/web/20210917230838/https://www.ozempic.com/why-ozempic/diabetes-medicines-comparison.html.
[336] Ozempic, available at https://web.archive.org/web/20220808142658/https://www.ozempic.com/.
[337] Ozempic, *What is Ozempic?*, available at https://web.archive.org/web/20220818181119/https://www.ozempic.com/why-ozempic/what-is-ozempic.html.
[338] Ozempic, *Ozempic vs Other Type 2 Diabetes Medicines*, available at https://web.archive.org/web/20221003122256/https://www.ozempic.com/why-ozempic/diabetes-medicines-comparison.html#weightInfo.
[339] NovoMedLink, *Ozempic*, available at https://web.archive.org/web/20240919183819/https://www.novomedlink.com/diabetes/products/treatments/ozempic.html.

- In 2023, Novo's Ozempic.com FAQ page added a new disclaimer: "At this time, Novo Nordisk has not conducted studies to evaluate the effect on weight after discontinuation of Ozempic."[340]

316. Novo has also promoted weight loss in its public statements. On March 28, 2022, Novo Nordisk announced approval of a higher dose of Ozempic (2 mg) for adults with type 2 diabetes; the press release said, "it can help many patients lose some weight."[341]

317. Novo knew that Ozempic was being prescribed off-label.

318. Trulicity and Mounjaro were never approved for weight-loss. Zepbound was approved for weight loss on November 8, 2023.

319. Lilly was also well aware that its GLP-1 RAs were being prescribed off-label for weight loss.

320. Lilly repeatedly promoted weight loss on its website:

- On September 26, 2022, Lilly's website stated that Mounjaro is "designed for patients like Julia" who are "unhappy with her A1C and weight" and "with her T2D, she struggles with her weight despite her efforts with diet and exercise."[342]
- On September 26, 2022, Lilly's Mounjaro website stated that recent studies suggest additional functions for GLP-1, such as regulating body weight.[343]
- On September 30, 2022, Lilly's Mounjaro website claimed "[u]nmatched weight results across clinical trials" (while noting "Mounjaro is not indicated for weight loss. Change in weight was as secondary endpoint.").[344]

---

[340] Ozempic, *Considering Ozempic: Will I regain weight if I stop using Ozempic?*, available at https://www.ozempic.com/faqs.html.
[341] Novo Nordisk, *Novo Nordisk receives FDA approval of higher-dose Ozempic 2 mg providing increased glycemic control for adults with type 2 diabetes*, PR NEWSWIRE (Mar. 28, 2022), available at https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-higher-dose-ozempic-2-mg-providing-increased-glycemic-control-for-adults-with-type-2-diabetes-301512209.html.
[342] Mounjaro, *The Mounjaro Experience, Designed For Patients Like Julia*, available at https://web.archive.org/web/20220926035852/https://www.mounjaro.com/hcp/getting-patients-started.
[343] Mounjaro, *GIP Is 1 of 2 Incretin Hormones—Along With GLP-1—That Has Diverse Metabolic Roles*, available at https://web.archive.org/web/20220926024807/https://www.mounjaro.com/hcp/what-is-gip.
[344] Mounjaro, available at https://web.archive.org/web/20220930171231/https://www.mounjaro.com/hcp.

- On September 30, 2022, Lilly's Mounjaro HCP website included significant clinical trial data comparing weight-loss to Ozempic.[345]

- On January 27, 2023, Lilly's Mounjaro website cited data on weight loss, leading with "Reset Your Expectations."[346]

- On January 27, 2023, Lilly's Mounjaro website advertised that people on Mounjaro lost up to 25 lbs (while also stating that Mounjaro is not a weight loss drug).[347]

321. Lilly's marketing also promoted off-label use. In addition to those previously discussed:

- On September 1, 2023, a television ad for Mounjaro, Mounjaro Commercial #2 (2023), stated that people lost up to 25 lbs.

- On September 25, 2023, another television ad for Mounjaro, Lilly Mounjaro Commercial #3 (2023), stated that people lost up to 25 lbs.

- On November 15, 2023, television ads for Mounjaro, Mounjaro Moments & Brittany's Story, again mentioned weight loss benefits: "I've also been able to lose weight, and I'm finding clothes in my closet that I haven't worn since I had my first kid. I just feel healthier these days."

5. Defendants Partnered with Telehealth Providers Making GLP-1 RAs More Accessible and Lowering Safeguards Against Off-Label Use

322. On October 1, 2019, Novo announced a partnership with Noom, a leading online weight loss platform, for "digital health solutions to help people with obesity lose weight and keep it off."[348]

---

[345] Mounjaro, *Reset Your Expectations with Mounjaro: Mounjaro demonstrated significant weight reduction across all 3 doses vs Ozempic 1 mg*, available at https://web.archive.org/web/20220930171237/https://www.mounjaro.com/hcp/a1c-weight#mounjaro-weight.

[346] Mounjaro, *Reset Your Expectations*, available at https://web.archive.org/web/20230127014022/https://www.mounjaro.com/hcp/a1c-weight.

[347] Mounjaro, *Reset Your Expectations with Mounjaro: Mounjaro demonstrated significant weight reduction across all 3 doses vs Ozempic 1 mg*, available at https://web.archive.org/web/20230127014022/https://www.mounjaro.com/hcp/a1c-weight#mounjaro-weight.

[348] *Novo Nordisk and Noom to Partner Around Digital Health Solutions to Help People With Obesity Lose Weight and Keep it Off*, DISTILINFO (Oct. 8, 2019), available at https://www.distilnfo.com/lifesciences/2019/10/08/novo-nordisk-and-noom-to-partner-around-digital-health-solutions-to-help-people-with-obesity-lose-weight-and-keep-it-off-2/.

323. In 2021, Novo participated in a $540 Million round of financing with Noom.[349] The Novo Holdings website lists "venture investments" in Noom.[350]

324. Noom Med, using physicians hired by Noom, provides prescriptions for GLP-1 RAs directly to patients.[351] Noom Med also promotes off-label usage of GLP-1 RAs on its website.[352] Noom reports having over 45 million users.[353]

325. Other telehealth providers mirrored Noom's approach, offering prescriptions directly to consumers for GLP-1 RAs:

- This includes Weight Watchers ("WW"), who purchased telehealth startup Sequence for $132 Million so that it could provide weight loss medications to its subscribers.[354] WW projected having 3.5 million subscribers at the end of 2023.[355]
- This also includes Calibrate, yet another telehealth provider for GLP-1 RAs, which raised $100 Million in capital funding from investors in 2021.

326. Collectively, the telehealth providers that Novo directly and indirectly partnered with and/or promotes account for approximately half of all weight loss prescriptions in 2022.[356]

327. Telehealth presents unique challenges with respect to GLP-1 RAs. Outside of the diabetes context, qualifying for GLP-1 RAs as a treatment for obesity requires only BMI and potential one additional health condition. BMI is a simple calculation that includes only weight

---

[349] *Noom Announces $540 Million in Growth Funding to Further Accelerate Expansion of its Digital Health Platform*, BUSINESSWIRE (May 25, 2021), available at https://www.businesswire.com/news/home/20210525005492/en/Noom-Announces-%24540-Million-in-Growth-Funding-to-Further-Accelerate-Expansion-of-its-Digital-Health-Platform.
[350] Novo Holdings, *Noom*, available at https://novoholdings.dk/investments/noom.
[351] GMA Team, *Noom joins Weight Watchers in offering medications like Wegovy for weight loss: What to know*, ABC NEWS (Jun. 5, 2023), available at https://abcnews.go.com/GMA/Wellness/noom-joins-weight-watchers-offering-medications-wegovy-weight/story?id=99841160.
[352] Noom, *Noom Med*, https://www.noom.com/med/.
[353] *Free excerpt from The Noom Report: A 45 million moat*, EXITS & OUTCOMES (Nov. 15, 2021), available at https://exitsandoutcomes.com/free-excerpt-from-the-noom-report-a-45-million-moat/.
[354] Karen Weintraub, *WeightWatchers is adding next-generation weight loss drugs like Wegovy to its program*, USA TODAY (Mar. 7, 2023), available at https://www.usatoday.com/story/news/health/2023/03/07/weightwatchers-sequence-wegovy-obesity-weight-loss-drugs/11415201002/.
[355] *WW International, Inc. Announces First Quarter 2023 Results*, YAHOO! FINANCE (May 4, 2023), available at https://finance.yahoo.com/news/ww-international-inc-announces-first-200100340.html.
[356] Katie Palmer, *Where are patients getting their prescriptions for GLP-1 drugs like Wegovy and Ozempic?*, STAT (Aug. 10, 2023), available at https://www.statnews.com/2023/08/10/wegovy-ozempic-weight-loss-telehealth-prescriptions/.

and height.[357] Without seeing a patient in person, these figures are dependent upon the inputs of the patient, with a difference of 5 to 10 pounds of weight or 1 to 2 inches in height making the difference for drug eligibility. For this and other reasons, telehealth facilitates off-label usage.

328. Upon information and belief, these telehealth providers now provide access to GLP-1 RAs manufactured by both Novo and Lilly.

329. Lilly took accessibility even further when, on January 4, 2024, it launched LillyDirect, where patients can purchase Mounjaro and Zepbound through Lilly's portal.[358]

330. LillyDirect is comprised of a website which offers healthcare information for patients, as well a digital pharmacy for select Lilly medicines, and the LillyDirect website also connects patients with "independent" telehealth providers – FormHealth and 9amHealth – to facilitate prescriptions.[359]

331. Some experts have cautioned that Lilly offering Mounjaro and Zepbound via this website "is just an evolution of direct-to-consumer advertising," and such practices make it easier for Lilly and other pharmaceutical giants to target patients with their products.[360]

332. The American College of Physicians released a statement that the organization "is concerned by the development of websites that enable patients to order prescription medications directly from the drugmaker," adding that the approach "is primarily oriented around the use of telehealth services to prescribe a drugmaker's products."[361]

---

[357] *Why body mass index doesn't give the whole health picture*, UW MEDICINE NEWSROOM (Jun. 20, 2023), available at https://newsroom.uw.edu/video-library/why-body-mass-index-doesnt-give-the-whole-health-picture.
[358] Dani Blum, *As Eli Lilly Wades Into Telehealth for Weight Loss, Doctors Are Wary*, NEW YORK TIMES (Jan. 5, 2024), available at https://www.nytimes.com/2024/01/05/well/weight-loss-tirzepatide-lilly-telehealth.html.
[359] LillyDirect, available at https://lillydirect.lilly.com/faq; https://lillydirect.lilly.com/pharmacy; https://lillydirect.lilly.com/telehealth/obesity.
[360] Dani Blum, *As Eli Lilly Wades Into Telehealth for Weight Loss, Doctors Are Wary*, NEW YORK TIMES (Jan. 5, 2024), available at https://www.nytimes.com/2024/01/05/well/weight-loss-tirzepatide-lilly-telehealth.html.
[361] *Id.*

333. Telemedicine and other DTC services have the "potential to leave patients confused and misinformed about medications." Therefore, the American College of Physicians has stated that, for telemedicine services to take place "responsibly," there should be an "established and valid patient-physician relationship, or the care should happen in consultation with a physician who does have an established relationship with the patient."[362]

334. In an October 21, 2024 letter to Lilly, Senator Durbin raised concerns, relating to telehealth providers and their potential conflicts of interest.[363] For example, the Senator wrote that the "launch of Eli Lilly's telehealth platform raises questions about the nature of Eli Lilly's relationship with its contracted telehealth prescribers." The letter details how in 2022, the Office of Inspector General for the HHS ("OIG") issued a Special Fraud Alert to notify health care practitioners of the specific risks of schemes involving telehealth platforms. According to the Senator, the "nature of the LillyDirect platform" appears to reflect many aspects detailed in the OIG's warning for potential fraud.

335. Senator Durbin's letter also questions Lilly's partnership with telehealth provider FormHealth, detailing an Instagram post from FormHealth labeled "When do you start losing weight on Zepbound?" According to the Senator, the advertisement "appears to promote Eli Lilly's medications and erodes the appearance of independence between the telehealth company and Eli Lilly."

6. Defendants Used Coupon Programs and Other Discounts to Make Their GLP-1 RAs More Accessible for New Consumers

[362] Omar T. Atiq, *Internal Medicine Physicians Concerned by Direct-to-Consumer Pharmaceutical Sales of Prescription Medications*, AMERICAN COLLEGE OF PHYSICIANS (Jan. 5, 2024), available at https://www.acponline.org/acp-newsroom/internal-medicine-physicians-concerned-by-direct-to-consumer-pharmaceutical-sales-of-prescription.

[363] Richard J. Durbin et al., Letter to David Ricks, Chair & CEO, Eli Lilly & Co. (Oct. 21, 2024), available at https://www.durbin.senate.gov/imo/media/doc/senate_ltr_eli_lilly_dtc_telehealth_platformpdf.pdf.

336. When Novo announced that they had started selling Ozempic in the United States, they touted the medication as a "new treatment option[]" that "addresses the concerns and needs of people with diabetes[.]" Novo offered an "Instant Savings Card to reduce co-pays to as low as $25 per prescription fill for up to two years."[364]

337. On May 24, 2022, Lilly's Mike Mason discussed a similar strategy of offering discounts and sample to market Mounjaro: "If patients are able to get access to it, who are able to have a good start on the medication, that just wonderfully supports your position in the marketplace [… W]e will have a $25 copay cards, so people can get access at affordable price. We're going to be providing month-long samples at 2.5 milligram dose, so that patients can experience the product for a month at 2.5."[365] Lilly took a similar approach with Zepbound where they have offered single dose vials at a 50% discount when fulfilled through their online pharmacy.[366]

338. These programs allowed patients to get on the GLP-1 RAs without the significant cost barrier that comes with continued use. Of course, once the patient stops using the drug, they gain back the weight.

H. Defendants Failed to Warn of the Serious Risks of Their GLP-1 RA Drugs and Downplayed These Risks in Their Unprecedented Marketing to Healthcare Providers and Patients

339. As set forth previously in this Complaint, Defendants knew, or should have known, based on preclinical trials, premarket clinical trials, post-market surveillance, and adverse event

[364] *Novo Nordisk Launches Ozempic and Fiasp, Expanding Treatment Options for Adults With Diabetes*, BioSpace (Feb. 5, 2018), available at https://www.biospace.com/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment-options-for-adults-with-diabetes.
[365] Eli Lilly & Co Conf Presentation Call 2022524 DN000000002983664779.pdf.
[366] Brooke McCormick, *Eli Lilly Expands Zepbound Access With Discounted Single-Dose Vials, Self-Pay Options*, AJMC (Aug. 28, 2024), available at https://www.ajmc.com/view/eli-lilly-expands-zepbound-access-with-discounted-single-dose-vials-self-pay-options.

reports, that there was reasonable evidence of a causal association and of the causal association between the use of GLP-1 RAs and the risks of developing cyclical vomiting and its sequelae.

340. Despite this knowledge, Defendants spent hundreds of millions of dollars to aggressively expand the market for the GLP-1 RAs while misleading users and healthcare providers about the serious dangers of the drugs.

341. Defendants purposefully downplayed, understated and ignored the health hazards and risks associated with using GLP-1 RAs.

342. They deceived healthcare providers and potential GLP-1 RA users by communicating positive information through the press, medical organizations, and testimonials from social media influencers while expanding the definition of obesity and downplaying the known adverse and serious health effects of their GLP-1 RA drugs.

343. The FDA's Changes Being Effected ("CBE") process permits pharmaceutical manufacturers to unilaterally update their labels without prior FDA approval, including by adding or strengthening warnings and descriptions of adverse reactions, and by deleting false or misleading claims.

344. Defendants' research into their products put them in a position to become aware, in the post-approval context, of the risks and danger of the use of GLP-1 RAs, including the risks of developing cyclical vomiting and its sequelae.

345. Defendants were also obligated under 21 C.F.R. §§ 310.305 and 314.80 to investigate each adverse event associated with their GLP-1 RAs, and Defendants failed to conduct such investigations reasonably, including by failing to take or record unsuccessful steps to seek additional information regarding serious unexpected adverse drug experiences.

346. Defendants likewise violated 21 C.F.R. § 312.32 through their failure to review all information relevant to the safety of their GLP-1 RAs and report such information to the FDA.

347. As Defendants developed information regarding those risks and dangers after the FDA's initial approval of the original label, Defendants were required to make unilateral changes under the CBE process to these products' labels in order to warn physicians and consumers of those risks.

348. Defendants failed to warn doctors and consumers of these dangers.

349. Defendants intentionally withheld from or misrepresented to the FDA post-approval information concerning their GLP-1 RAs that was required to be submitted under the Federal Food, Drug, and Cosmetic Act. Had Defendants not withheld or misrepresented such information relating to the risks of GLP-1 RA use to the FDA, the FDA would have recommended that Defendants add warnings relating to the risks of the injuries suffered by Plaintiff.

350. Despite developing this knowledge, Defendants did not disclose these risks and/or intentionally downplayed these risks in their labeling, promotion materials, marketing, advertising, and other public facing communications. Defendants' failure to disclose and/or intentional downplaying of these conditions prevented patients and doctors from taking appropriate precautions to reduce or mitigate the risk of these conditions. Defendants' failure deprived patients, like Plaintiff, and doctors, like Plaintiff's physician(s), from having the full information necessary to weigh the risks and benefits of using the Defendants' GLP-1 RAs.

1. The Sponsor of a Drug is Responsible for Ensuring the Safety of Its Drug and for Warning

351. The Sponsor of a drug is responsible for the safety of its product.

352. A drug company is responsible for alerting healthcare providers and patients of risks that are unknown or not well understood.

353. The Institute of Medicine has stated that FDA's ability to oversee drug safety is limited, especially after approval of a drug.

354. The Institute of Medicine wrote the following in a report entitled *The Future of Drug Safety: Promoting and Protecting the Health of the Public*: "The drug safety system is impaired by the following factors: serious resource constraints that weaken the quality and quantity of the science that is brought to bear on drug safety; an organizational culture in CDER (FDA Center for Drug Evaluation and Research) that is not optimally functional; and unclear and insufficient regulatory authorities particularly with respect to enforcement." The Report further stated that "FDA, contrary to its public health mission, and the pharmaceutical industry, contrary to its responsibility to the users of its products (and its shareholders), do not consistently demonstrate accountability and transparency to the public by communicating safety concerns in a timely and effective fashion."

355. The FDA has insufficient resources to monitor the 11,000 drugs on the market.

356. Manufacturers have access to information about their drugs, especially in the post-approval phase as new risks emerge, that is superior to the access that FDA has.

357. Uncommon risks, or those that appear as common conditions, develop after long periods of time, or have adverse impacts on special populations, may go undetected in clinical trials.

358. If a drug company has reason to know the risks of a drug may result in adverse events, even if it develops that knowledge in the post-approval context, that company has a responsibility to investigate those risks and to provide necessary information healthcare providers.

359. The following FDA standards govern a manufacturer's duty to warn: 21 C.F.R. § 201.57(c)(6): Warnings and precautions: "This section must describe clinically significant

adverse reactions … the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association of a serious hazard with a drug; a causal relationship need not have been definitely established …"

360. In addition, under 21 C.F.R. § 201.57(c)(6), the Warning and Precaution Section of prescription drug labels must "describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards …"

361. It is a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times.

362. A manufacturer is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.

363. According to industry guidance on warnings in labeling from the FDA in 2011, "The WARNINGS AND PRECAUTIONS section is intended to identify and describe a discrete set of adverse reactions and other potential safety hazards that are *serious* or are *otherwise clinically significant* because they have implications for prescribing decisions or for patient management."[367]

364. FDA's Guidance also states, "Adverse reactions that do not meet the definition of a serious adverse reaction, but are otherwise clinically significant because they have implications for prescribing decisions or patient management, should also be included in the WARNINGS AND PRECAUTIONS section."[368]

---

[367] U.S. Dept. of Health & Human Services, Food & Drug Admin., *Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format* (Oct. 2011), at 5, available at https://www.fda.gov/files/drugs/published/Warnings-and-Precautions--Contraindications--and-Boxed-Warning-Sections-of-Labeling-for-Human-Prescription-Drug-and-Biological-Products-%E2%80%94-Content-and-Format.pdf.

[368] *Id.* at 6.

365. The medical literature discussing gastroparesis describes the distressing nature of the condition and its potential to profoundly limits a person's quality of life.[369]

2. The Labels for Defendants' GLP-1 RAs Were Inadequate at All Relevant Times from Launch to Present

a. Gastrointestinal Injuries

366. At all relevant times, the "Warnings and Precautions" sections of the Prescribing Information for Novo Nordisk's Ozempic (semaglutide) and Rybelsus (semaglutide) omitted and continue to omit any "Warnings and Precautions" concerning gastroparesis, the potential for emergent care, hospitalization, long term treatment or death.

367. At all relevant times, these drugs noted (under the heading "Acute Kidney Injury") that clinicians should "[m]onitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions."

368. At all relevant times, Wegovy's (semaglutide) Prescribing Information stated that clinicians should "[m]onitor renal function when initiating or escalating doses of Wegovy in patients reporting severe adverse gastrointestinal reactions or in those with renal impairment reporting severe gastrointestinal reactions."

369. At all relevant times, this Wegovy Prescribing Information failed to state that these drugs have been associated with gastroparesis or other GI-related complications of similar acuity.

370. At all relevant times, Victoza (liraglutide) and Saxenda (liraglutide) stated similar warnings in the context of "Renal Impairment" in their warnings, but also failed to state any association with these drugs and gastroparesis or other GI-related complications of similar acuity.

[369] *See generally, e.g.*, Lee et al, *Health-Related Social Needs in Patients With Gastroparesis: Relationships to Symptom Severity and Quality of Life*, 6 GASTRO. HEP. ADV. 48 (2023); Simons & Kline, *Scoping review: the social and emotional impacts of gastroparesis*, TRANSL. GASTROENTEROL. HEPATOL. (2024).

371. At all relevant times, the "Adverse Reactions" sections of Novo Nordisk's labels for Ozempic (semaglutide), Rybelsus (semaglutide), Wegovy (semaglutide) Victoza (liraglutide) and Saxenda (liraglutide) all inadequately referenced "common adverse reactions" including "nausea, vomiting, diarrhea, stomach (abdominal) pain, and constipation." These vague references provided no notice of the magnitude of these conditions, effectively downplaying the risks while simultaneously failing to disclose gastroparesis or other GI-related complications. The vague and inadequate description of "common adverse reactions" inaccurately suggested these conditions will decrease over time and downplayed the intensity and range of conditions that patients face, including the potential for hospitalization, long-term damage to vital organs and the need for surgical intervention, disability and death.

372. Likewise, at all relevant times, the "Warnings and Precautions" sections of the Prescribing Information for Eli Lilly's drugs Trulicity (dulaglutide) and Mounjaro (tirzepatide) stated that use of the drugs "may be associated with gastrointestinal adverse reactions, sometimes severe" without disclosure that these adverse reactions may actually be symptoms of gastroparesis, which can be persistent, life-threatening, require hospitalization, lead to disabling secondary conditions or even death.

373. At all relevant times, the Warnings and Precautions section for Eli Lilly's Zepbound (tirzepatide) stated a similarly deficient generalized statement in its "Warnings and Precautions" section of the Prescribing Information.

374. The vague and inadequate description of "gastrointestinal adverse reactions, sometimes severe" inaccurately suggested these conditions will decrease over time and downplayed the intensity and range of conditions that patients face, including the potential for

hospitalization, long-term damage to vital organs and the need for surgical intervention, disability and death.

375. At all relevant times, the Mounjaro and Zepbound labels also downplayed the risk of gastroparesis with a statement that the drugs have "not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients" and similarly downplayed the seriousness of nausea, vomiting and/or diarrhea with the statement that the majority of these reactions occurred during dose escalation and decreased over time.

376. Further, the labels misleadingly suggested that the risk of delayed gastric emptying with tirzepatide always "diminishes over time" without acknowledging that other GLP1-RA drugs in the class that similarly delay gastric emptying have been shown to persistently delay gastric emptying well after dose escalation.

377. At all relevant times, in the "Adverse Reactions" section of their labels, Eli Lilly's Trulicity (dulaglutide), Mounjaro (tirzepatide), and Zepbound (tirzepatide) inadequately mentioned certain specific gastrointestinal disorders, including nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain. These vague references provide no notice of the magnitude of these conditions effectively downplaying the risks while simultaneously failing to mention gastroparesis or other GI-related complications of similar acuity.

378. The vague and inadequate description inaccurately suggested these conditions will decrease over time and downplayed the intensity and range of conditions that patients face, including the potential for emergent care of hospitalization, long-term damage to vital organs, the need for surgical intervention, disability and death.

379. Moreover, any references to the delay of gastric motility as part of the mechanism of action of Defendants' GLP-1 RAs did not warn patients and doctors that the Products could lead to a harmful delay in gastric emptying known as gastroparesis or that such conditions could last well after cessation of the GLP-1 RAs.

380. In November 2024, Defendants finally acknowledged some of the serious risks that can occur because of delayed gastric emptying with their GLP-1 RA drugs. In November 2024, all Defendants added a warning to Section 5 of their drugs labels cautioning prescribers that reasonable evidence of a causal association exists with respect to their GLP-1 RA drugs and post-market reports of pulmonary aspiration in patients undergoing elective surgeries or procedures requiring general anesthesia or deep sedation who had residual gastric contents despite adherence to preoperative fasting recommendations. In other words, there is reasonable evidence of a causal association that the delay in gastric emptying caused by the drugs may lead to the retention of food or liquid in the stomach after fasting, which presents the risk of food or liquid getting into the lungs.

381. Defendants' acknowledgement that delayed gastric emptying is not only a known mechanism of action of their GLP-1 RA drugs but also a serious risk of the drugs should have been disclosed years earlier.

382. Prior to 2023, at least 89 cases of gastroparesis that were life-threatening, required hospitalization or medical intervention, and/or led to disability or death were reported.[370]

[370] U.S Food & Drug Admin., *FAERS Public Dashboard*, available at https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard.

383. Between 2008 and 2024, six case reports were published describing patients on GLP-1 RA drugs who developed gastroparesis and required hospitalization, including for endoscopic bezoar removal and botulinum toxin injections.[371]

384. As cited above, peer-reviewed medical literature, Clinical Guidelines, and commonly used medical references acknowledge the risk of gastroparesis with GLP-1 RA drugs.[372]

385. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

386. At all relevant times, Defendants failed to reevaluate and re-assess the risks of gastroparesis in light of newly available information.

387. At all relevant times, Defendants failed to disclose information regarding the serious risks of gastroparesis with their GLP-1 RA drugs.

388. At all relevant times, Defendants failed to evaluate safety data in their possession and reassess such data in light of newly acquired information.

---

[371] Cure, et al., *Exenatide and Rare Adverse Events*, 358 NEJM 1969 (2008) (patient treated with exenatide developed gastroparesis; developed bezoars on two occasions that were removed endoscopically and required injections of botulinum toxin); Ishihara, *et al*., *Suspected Gastroparesis With Concurrent Gastroesophageal Reflux Disease Induced by Low-Dose Liraglutide*, CUREUS (2022) (patient treated with liraglutide hospitalized for six days due to gastroparesis); Rai et al, *Liraglutide-induced Acute Gastroparesis*, CUREUS (2022) (patient treated with liraglutide admitted to hospital due to gastroparesis); Almustanyir, et al., *Gastroparesis with the initiation of Liraglutide*, CUREUS (patient treated with liraglutide hospitalized for three days due to gastroparesis); Shemies, et al., *Semaglutide Induced Gastric Outlet Obstruction*, 45 TEIKYO MED. J. 6743 (2022) (patient treated with semaglutide hospitalized for five days due to gastroparesis); Chaudhry, et al., *Tendency of semaglutide to induce gastroparesis*, CUREUS (2024) (patient treated with semaglutide hospitalized due to gastroparesis).

[372] UpToDate, Dungan & DeSantis, *Glucagon-like peptide 1-based therapies for the treatment of type 2 diabetes mellitus* (2024), available at https://www.uptodate.com/contents/glucagon-like-peptide-1-based-therapies-for-the-treatment-of-type-2-diabetes-mellitus; StatPearls, Reddivari & Mehta, GASTROPARESIS (2024), available at https://www.ncbi.nlm.nih.gov/books/NBK551528/; Hui, *et al*., APPROACH TO INTERNAL MEDICINE (5th ed.); Huppert's Notes, PATHOPHYSIOLOGY AND CLINICAL PEARLS FOR INTERNAL MEDICINE (2024 ed.), McCallum, et al., GASTROPARESIS PATHOPHYSIOLOGY, CLINICAL PRESENTATION, DIAGNOSIS AND TREATMENT (1st ed.); Tack & Camilleri, *New developments in the treatment of gastroparesis and functional dyspepsia*, 43 CURRENT OPINION IN PHARMACOLOGY 111 (2018); Lacy, et al., *AGA Clinical Practice Update on Management of Medically Refractory Gastroparesis: Expert Review*, 20 CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 491 (2022).

389. Had Defendants affirmatively and specifically presented such safety information regarding the risk of gastroparesis with their GLP-1 RA drugs to the FDA, the FDA would have permitted Defendants to add the risk of gastroparesis and/or harmful delayed gastric emptying to the labels of their GLP-1 RA drugs.

390. This failure to adequately warn patients and healthcare providers has caused or substantially contributed to physical injury and emotional suffering, and resulted in the need for emergent care, hospitalizations requiring among other treatments, parenteral nutrition, hydration, pharmacologic treatments and surgical intervention.

391. GLP-1 RAs and the rapid weight loss reasonably associated with their use also create the risk of micronutrient deficiencies and unfavorable changes to body composition.[373] Individuals who go through rapid weight loss may suffer deficiencies in nutrients including thiamine, Vitamin C, and Vitamin D, which deficiencies can in turn cause a variety of additional symptoms.[374] Defendants' labels do not and did not warn of the risk of these injuries, and that omission prevented Plaintiff and Plaintiff's doctors from making informed decisions about Plaintiff's potential use of GLP-1 RAs or taking steps to mitigate this potential risk.

392. Gastroparesis is also reasonably associated with micronutrient deficiencies.[375] Defendants' failure to warn of this potential risk prevented Plaintiff and Plaintiff's doctors from making informed decisions about Plaintiff's potential use of GLP-1 RAs or taking steps to mitigate this potential risk.

b. Cyclical Vomiting

[373] O'Donnell, *Severe Micronutrient Deficiencies in RYGB Patients, Nutrition Issues in Gastroenterology, Series #100*, PRACTICAL GASTROENTEROLOGY at 24 (Nov. 2011).
[374] *Id.* at 14.
[375] Ogorek et al, *Idiopathic Gastroparesis is Associated with a Multiplicity of Severe Dietary Deficiencies*, 86(4) AM. J. GASTROENTEROLOGY at 426 (1991).

393. As discussed above, Defendants knew or should have known that there was reasonable evidence of a causal association between their GLP-1 RAs and severe and debilitating vomiting and related injuries, but at no time did the labels for the GLP-1 RAs or any accompanying materials identify the risk of debilitating and life-threatening cyclical vomiting.

394. Likewise, the "Adverse Reactions" sections of Novo Nordisk's labels for Ozempic (semaglutide), Rybelsus (semaglutide), Wegovy (semaglutide) Victoza (liraglutide) and Saxenda (liraglutide) each inadequately reference "common adverse reactions" including "nausea, vomiting, diarrhea, stomach (abdominal) pain, and constipation." These references provide no notice of the magnitude of these conditions, effectively downplaying the risks while simultaneously failing to disclose debilitating cyclical vomiting. The vague and inadequate description of "common adverse reactions" inaccurately suggested these conditions will decrease over time and downplayed the intensity and range of conditions that patients face, including the potential for hospitalization, long-term damage to vital organs and the need for surgical intervention, disability and death.

395. Defendants' failure further deprived patients and doctors alike from having the full information necessary to weigh the risks and benefits of taking Defendants' GLP-1 RAs.

396. At all relevant times, Defendants did not fully inform the FDA about the justification for the warnings set forth above and required by state law.

397. At all relevant times, Defendants failed to reevaluate and reassess the risks of cyclical vomiting in light of newly available information.

398. At all relevant times, Defendants failed to disclose information regarding the serious risks of cyclical vomiting with their GLP-1 RA drugs.

399. At all relevant times, Defendants failed to evaluate safety data in their possession and reassess such data in light of newly acquired information.

400. Had Defendants affirmatively and specifically presented such safety information regarding the risk of cyclical vomiting with their GLP-1 RA drugs to the FDA, the FDA would have permitted Defendants to add the risk of cyclical vomiting to the labels of their GLP-1 RA drugs.

401. This failure to adequately warn patients and healthcare providers has caused or substantially contributed to physical injury and emotional suffering, and resulted in the need for emergent care, hospitalizations requiring among other treatments, parenteral nutrition, hydration, pharmacologic treatments and surgical intervention.

* * *

402. Upon information and belief, as a result of Defendants' inadequate warnings, the medical community at large, and Plaintiff's prescribing physician(s) in particular, were not aware that GLP-1 RAs can cause cyclical vomiting and its sequelae, nor were they aware that "common adverse reactions" listed on the GLP-1 RAs' labels might be symptoms of more serious conditions.

403. Upon information and belief, had Defendants adequately warned Plaintiff's prescribing physician(s) of reasonable evidence of a causal association between GLP-1 RAs and cyclical vomiting and its sequelae, then the physicians' prescribing decisions would have changed, either by not prescribing the GLP-1 RAs, or by monitoring Plaintiff's health for symptoms of the conditions listed above, and discontinuing the GLP-1 RAs when such symptoms started.

404. By reason of the foregoing acts and omissions, Plaintiff was caused to suffer from cyclical vomiting and its sequelae, which resulted in severe and debilitating personal injuries,

physical pain, and mental anguish, including diminished enjoyment of life, and fear of developing any of the above-named health consequences and/or dying.

3. Defendants' Marketing of GLP-1 RAs Was Intentionally Deceptive and Misleading and Lacked Fair Balance

405. Defendants' extensive multifaceted advertising, marketing and promotion of GLP-1 RAs discussed at length above consistently highlighted and overstated the weight loss benefits of taking a GLP-1 RA while failing to disclose the risks identified with those drugs and concealing other information that would be material to any Plaintiff and their physician(s) in weighing the risks and benefits of using a GLP-1 RA.

406. Defendants did not disclose and/or minimized the risks of developing cyclical vomiting and its sequelae.

407. In addition, Defendants intentionally omitted other facts that they knew to be true from their labels, physician communications, marketing, website, public statements, and other public facing communications. These documents omit facts that include: (1) the average person only loses a small percentage of their body weight while on a GLP-1 RA; (2) GLP-1 RAs are not effective for everyone; (3) patients gain the weight back when they stop taking the GLP-1 RA (*i.e.*, patients have to stay on the drug forever); (4) the weight loss achieved while on a GLP-1 RA is not a healthy weight loss; (5) when a patient regains the weight loss achieved while on a GLP-1 RA, they are typically less healthy than when they began the medication; and (6) many people stop taking a GLP-1 RA relatively quickly because of trouble tolerating the drugs. These facts are critical to the balancing of risks and benefits facing most patients.

a. Average Weight Loss is Modest

408. Studies show that the real number are much lower. Measured across the first 12 weeks of the drug, when most people are on the drug, the numbers are closer to 3.6% to 5.9% of

body weight.[376] On July 8, 2024, a JAMA Internal Medicine article suggested that both Novo and Lilly overstated the weight loss benefits of their drug in advertisements. Over a year's time, those on tirzepatide (Mounjaro/Zepbound) lost an average of 15.3% of their body weight compared to 8.3% for semaglutide (Ozempic/Wegovy) users. Only 18% of those on semaglutide reported a weight loss of at least 15% of their body weight after one year of treatment.[377] More importantly, Novo's claim that their drugs create lasting weight loss are also misleading: their own data shows that only 9.4% of patients on the highest dose available sustain weight loss over a four-year period.[378]

b. Non-Responders

409. Some research suggests that patients taking semaglutide (*i.e.*, Ozempic and Wegovy) "found about 14% of patients lost less than 5% of their body weight and one-third lost less than 10%" while a separate trial focused on tirzepatide (Mounjaro and Zepbound) "demonstrated similar results."[379] Notably, the article discussing the research states that "Wegovy and Zepbound have been approved by the FDA for weight loss, while Ozempic and Mounajro have been prescribed for that purpose in an off-label fashion."

c. Patients Must Remain on the Drug to Sustain Weight Loss

[376] *See* https://www.wegovy.com/aboutwegovy/why-wegovy.html for Novo Nordisk and https://zepbound.lilly.com/ for Lilly.
[377] Rodriguez et al., *Semaglutide vs Tirzepatide for Weight Loss in Adults With Overweight or Obesity*, 184(9) JAMA INTERN. MED. 1056–64 (2024), doi:10.1001/jamainternmed.2024.2525, available at https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2821080.
[378] Novo Nordisk, *Obesity care*, CMD24: Capital Markets Day (Mar. 7, 2024), available at https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/cmd/2024/P5-Obesity-Care.pdf.
[379] Carbajal, Erica, *Up to 15% of patients on weight loss drugs may be 'non-responders*, BECKER'S HOSPITAL REV. (April 1, 2024) available at https://www.beckershospitalreview.com/glp-1s/upto-15-of-patients-on-weight-loss-drugs-non-responders.html.

410. For those who lose weight, they typically need to stay on the drug forever to maintain the weight loss.[380] A Medscape article from March of 2024 explains that when "patients stop taking GLP-1s, they tend to regain most of that weight within a year, studies showed."[381]

411. Novo has publicly recognized that most individuals will regain all the weight back within five years of stopping Ozempic or Wegovy.[382] A trial published by Novo showed that, after a year, participants had gained back two thirds of the weight lost after they stopped taking semaglutide.[383] Indeed, Novo has acknowledged that some individuals will regain even more weight after stopping Ozempic or Wegovy than they initially lost.[384]

412. As noted by Novo's Martin Holst Lange: "once the majority of the weight loss is accrued, you don't go back and start to increase in weight ***if you stay on the drug***."[385]

413. Wegovy and Ozempic are often marketed as part of a "metabolic reset"[386] even though studies show that weight will be regained upon cessation and even though it has been widely recognized that GLP-1 RAs do not rewire "your neural networks to really define a new

[380] M. Karth, *Is Semaglutide a Miracle Weight-Loss Drug?*, PSYCHOLOGY TODAY (Apr. 1, 2023), available at https://www.psychologytoday.com/ie/blog/the-neuroscience-of-eating-disorders/202303/ozempic-and-wegovy-is-semaglutide-a-miracle-weight.
[381] Julie Stewart, *Help Patients Prevent Weight Gain After Stopping GLP-1s*, MEDSCAPE MED. NEWS (Mar. 18, 2024), available at https://www.medscape.com/viewarticle/help-patients-prevent-weightgain-after-stopping-glp-1s-2024a10004z9?form=fpf.
[382] A. Constantino, *People taking obesity drugs Ozempic and Wegovy gain weight once they stop medication*, CNBC (Mar. 29, 2023), available at https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html.
[383] Wilding et al., *Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension*, 24(8) DIABETES OBES METAB. 1553-64 (2022), doi:10.1111/dom.14725, available at https://dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.14725.
[384] A. Constantino, *People taking obesity drugs Ozempic and Wegovy gain weight once they stop medication*, CNBC (Mar. 29, 2023), available at https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html.
[385] K. Kindelan, *New study focuses on what happens if you stay on weight loss drug Wegovy for years*, ABC NEWS (May 20, 2024), available at https://abcnews.go.com/GMA/Wellness/new-study-focuses-stay-weight-loss-drug-wegovy/story?id=110401021 (emphasis added).
[386] Calibrate, *How long does it take to lose weight on Ozempic?* (Jun. 5, 2022), available at https://www.joincalibrate.com/resources/how-long-does-it-take-to-lose-weight-on-ozempic.

body weight setpoint."[387] Not only is it not a "reset," but some patients will actually regain even more weight after stopping the drug.[388]

414. This was consistent with Lilly's sponsored SURMOUNT-4 study of tirzepatide, which showed that patients regained 14% of their body weight after switching from tirzepatide to a placebo.[389] On average, patients were able to maintain only about 10% of the weight they lost from the time they started taking tirzepatide.[390] Notably, the trend towards weigh regain was on clear upward trajectory at the study endpoint, suggesting patients who had ceased taking the drug would continue to regain weight over time.

415. A meta-analysis of GLP-1 RA clinical trials found that "several GLP-1 RAs showed a gradual decline in effects on body weight throughout the long term intervention. In comparison to placebo, semaglutide resulted in a reduction of body weight from a mean difference of −3.28 kg (95% confidence interval −4.20 to −2.37) with medium term intervention to −2.75 kg (−4.60 to −0.89) with long term intervention. Liraglutide and dulaglutide also showed a similar trend."[391]

d. Not a Healthy Weight Loss

416. Taking GLP-1 RAs may actually result in patients being less healthy. Defendants fully understand that overall health is more than a number, whether that number is purely weight or BMI. Despite this, the focus of prescribing GLP-1 RAs for obesity is on a person's BMI, and to

[387] A. Constantino, *People taking obesity drugs Ozempic and Wegovy gain weight once they stop medication*, CNBC (Mar. 29, 2023), available at https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html.
[388] *Id.*
[389] Arone et al., *Continued Treatment With Tirzepatide for Maintenance of Weight Reduction in Adults With Obesity: the SURMOUNT-4 Randomized Clinical Trial*, 331 JAMA 38 (2023).
[390] *Id.* at 45.
[391] Yao et al., *Comparative effectiveness of GLP-1 receptor agonists on glycaemic control, body weight, and lipid profile for type 2 diabetes: systematic review and network meta-analysis*, BMJ OPEN 8 (2023).

the extent that BMI is less than 30, whether they also have a weight-related health condition (*i.e.*, cardiovascular disease, etc.).

417. As previously noted, BMI is a simple calculation that includes only weight and height. This poses limitations for its usefulness on an individual basis, rather than a population basis. For example, Jalen Hurts, Quarterback of the Philadelphia Eagles, is 6 feet and 1 inch tall and weighs 223 pounds, putting his BMI at 29.4 and making him extremely overweight and borderline obese if considering BMI alone. However, this does not account for the fact that he is an elite athlete with a body fat percentage under 10 percent. Nonetheless, if he suffers additional health condition or gains 5 pounds (or simply says he weighs 5 pounds more during a telehealth visit), he would qualify for one of the Defendants' weight loss drugs.

418. Because of these obvious limitations of BMI, the AMA has urged doctors to deemphasize their use of BMI in determining healthy weights for patients.[392] On June 14, 2023, the AMA adopted a new policy clarifying how BMI should be used as a measure in medicine.[393] The AMA suggests that BMI be used in conjunction with other valid measures of risk such as, but not limited to, measurements of visceral fat, body adiposity index, body composition, relative fat mass, waist circumference and genetic/metabolic factors.[394]

419. Weight loss as the sole indicator of health has also been rejected by many clinicians in favor of improvements in other health outcomes and the assess the whole health of an individual.[395] These clinicians have cautioned that "a lower body weight does not always mean a

---

[392] *Id.*
[393] AMA, *AMA adopts new policy clarifying role of BMI as a measure in medicine* (Jun. 14, 2023), available at https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measure-medicine.
[394] *Id.*
[395] Hagan & Nelson, *Are Current Guidelines Perpetuating Weight Stigma? A Weight-Skeptical Approach to the Care of Patients with Obesity*, 38(3) J. GEN. INTERN. MED. 793–8 (Sept. 2022), available at https://link.springer.com/content/pdf/10.1007/s11606-022-07821-w.pdf?pdf=button; *Why body mass index doesn't*

person is healthier."[396] In many instances, when someone loses weight, they lose fat (a good result), but also lose muscle mass (bad).

420. It is recognized in the medical community that weight loss achieved by Ozempic and Wegovy is often a result of a significant loss of muscle mass.[397] As a result, individuals may be lighter than they were initially but have a higher percentage of body fat.[398]

421. To further exacerbate the problem, if patients stop taking a GLP-1 RA and regain weight, as discussed above, that weight gain is typically not adding muscle but instead adding fat. Therefore, the resulting "new you" is less healthy—weighing the same but having a higher percentage of body fat.

422. The loss of too much muscle mass can lead to sarcopenia, a condition called being "skinny fat," in which the patient has decreased muscle mass, lessened bone density, and lower resting metabolic rate—all of which results in a loss of strength and functionality.[399]

423. Lilly recognizes that much of the weight loss is actually healthy muscle tissue, but rather than warn consumers that most of the weight loss on tirzepatide will be muscle loss, Lilly has instead invested in developing combination drugs to combat the muscle loss.[400]

424. Defendants did not warn about the dangers of the type of unhealthy weight loss occurring with GLP-1 RAs. Novo personnel refer to weight loss resulting from Wegovy as a

---

give the whole health picture, UW Medicine Newsroom (Jun. 20, 2023), available at https://newsroom.uw.edu/video-library/why-body-mass-index-doesnt-give-the-whole-health-picture.

[396] C. Cassata, *Ozempic Can Cause Major Loss of Muscle Mass and Reduce Bone Density*, HEALTHLINE (May 2, 2023), available at https://www.healthline.com/health-news/ozempic-muscle-mass-loss.

[397] K. Sullivan, *Weight loss drugs can lead to muscle loss, too. Is that a bad thing?*, NBC News (May 20, 2023), available at https://www.nbcnews.com/health/health-news/weight-loss-drugs-muscle-loss-rcna84936.

[398] J. Margo, *The alarming twist when using Ozempic for weight loss*, THE AUSTRALIAN FINANCIAL REVIEW (Jul. 21, 2023), available at https://www.afr.com/policy/health-and-education/lighter-but-fatter-the-ozempic-paradox-20230718-p5dp5w.

[399] C. Cassata, *Ozempic Can Cause Major Loss of Muscle Mass and Reduce Bone Density*, HEALTHLINE (May 2, 2023), available at https://www.healthline.com/health-news/ozempic-muscle-mass-loss.

[400] Dani Blum, *The Race Is On to Stop Ozempic Muscle Loss*, NEW YORK TIMES (Feb. 8, 2024), available at https://www.nytimes.com/2024/02/08/well/live/ozempic-muscle-loss-exercise.html.

"healthy" weight loss.[401] At the same time, Novo told investors: "Healthy weight loss is, I don't want to call it the next frontier. But it is certainly important … There is a risk if you do introduce very fast and dramatic weight loss you will lose almost 50-50 lean body mass and fat mass. So the tempered but consistent body weight loss could potentially be healthier than a very dramatic fast weight loss."[402] Novo also stated that reasonable preservation of lean body mass "has to be a focus area, and you will probably see [it] in our pipeline."[403]

425. Similarly for Lilly, it was a "big investor question around [the] muscle issue"[404] and Lilly knew that "the quality of weight loss" mattered.[405] Lilly recognized that there could be some patients who "could benefit from both weight loss and maybe more muscle," hence why Lilly was investing in further research on products that would prevent muscle loss.[406]

426. Because Defendants do not warn of or disclose the type of weight loss occurring with GLP-1 RAs, patients do not factor that into their analysis of risks and benefits when considering taking a GLP-1 RA and are not aware that they should take specific steps to mitigate this muscle loss, like dietary changes and strength training.[407]

e. Many Patients Do Not Stay on the Drugs Long Enough to See Benefits

427. Approximately 58% of patients stop taking a GLP-1 RA within 12 weeks, and 30 percent stop in the first 4 weeks. In May of 2024, Blue Cross Blue Shield published "Real-World Trends in GLP-1 Treatment Persistence and Prescribing for Weight Management" noting these

[401] A. Pawlowski, *Is it safe to take the anti-obesity drug Wegovy long-term? Doctors weigh in*, TODAY (Jan. 25, 2023), available at https://www.today.com/health/diet-fitness/is-wegovy-safe-for-weight-loss-rcna67277.
[402] *See* 2022-11-03 Q3 Earnings Call.
[403] *Id.*
[404] 20231128 Evercore ISI 6th Annual HealthCONx Conference.
[405] 2024430 Q1 2024 Earnings Call.
[406] 20231128 Evercore ISI 6th Annual HealthCONx Conference.
[407] J. Margo, *The alarming twist when using Ozempic for weight loss*, THE AUSTRALIAN FINANCIAL REVIEW (Jul. 21, 2023), available at https://www.afr.com/policy/health-and-education/lighter-but-fatter-the-ozempic-paradox-20230718-p5dp5w.

statistics.[408] This means that "[the] value [GLP-1 RA treatment] is not likely to be realized" in most patients.[409]

428. This is perhaps caused by the fact that side effects are most likely to present themselves in the first 12 weeks of use as the dosage increases. Lilly itself has noted that the risks of the medicine are often seen within just 12 weeks of use as patients are escalating the dosage up.[410] Physicians also recognize that adverse events are also more likely to occur during dose escalation with Ozempic and Wegovy.[411]

429. Neither Novo nor Lilly warns or highlights that most people are unable to tolerate the drug and stay on it long enough for it to make a meaningful difference. These are clear indications that could impact a patient's decision to take a GLP-1 RA.

430. Federal regulators have raised misleading promotional, marketing and advertising materials with Novo and Lilly (the OPDP's March 14, 2008 letter was previously discussed):

- On September 23, 2021, Health and Human Services ("HHS") issued a response letter to Novo regarding Wegovy's misleading statements and that fact that it was minimizing the risk of nausea.[412]
- In a June 1, 2015 letter to Lilly related to a proposed print advertisement, the OPDP remarked that Lilly "downplays the risk of nausea experienced in clinical trials."
- In the same 2015 letter, the OPDP said that the promotional materials "misleadingly" implied that Trulicity was indicated for weight-loss and that patients would see substantial loss in weight. While these promotional materials did contain some language in small print that Trulicity was "not indicated for weight loss," the OPDP found that the inclusion of such disclosures did not

[408] Blue Health Intelligence, *Real-World Trends in GLP-1 Treatment Persistence and Prescribing for Weight Management*, Issue Brief (May 2024), available at https://www.bcbs.com/media/pdf/BHI_Issue_Brief_GLP1_Trends.pdf.
[409] Gleason et al., *Real-world persistence and adherence to glucagon-like peptide-1 receptor agonists among obese commercially insured adults without diabetes*, 30 JMCP 2 (2024).
[410] D. Ovalle et al., *Patients grapple with side effects of popular weight-loss drugs*, THE WASHINGTON POST (Aug. 8, 2023), available at https://www.washingtonpost.com/health/2023/08/08/weight-loss-drugs-side-effects-wegovy-ozempic/.
[411] Braxton Medical Clinic, *Understanding the Side Effects of Semaglutide and Tirzepatide* (Jun. 2, 2024), available at https://www.braxtonmedicalclinic.com/post/understanding-the-side-effects-of-semaglutide-and-tirzepatide-a-comprehensive-guide-for-patients-of.
[412] OPDP Letter, Sept. 23, 2021 (Novo_GLP_MDL_WEG_NDA_000531088).

"mitigate the overwhelmingly powerful weight loss claims and presentations conveyed in the proposed detailed aid."

- A mere 3 months later, on September 16, 2014, the FDA wrote again, finding many significant issues related to Trulicity marketing. In addition to repeated comments about minimization of risk and overstatement of efficacy, this time the OPDP noted that Lilly's marketing materials were broadening the patient population for Trulicity. Indeed, the OPDP wrote that Lilly's marketing was "misleading because they suggest that Trulicity is useful in a broader range of patients or conditions than has been demonstrated by substantial evidence." In a January 30, 2018 letter to Lilly, the OPDP repeated its concerns about the "Net impression" of the Trulicity marketing, specifically regarding the prominence and readability of the small print text in the ads, and referring to letters from 2015, 2016 and 2017 as to this point.

- A February 12, 2019 letter from OPDP to Lilly repeated the concern about the small print text at the bottom of the commercials.

- In a December 17, 2020 letter to Lilly, the OPDP found that Lilly was creating a "misleading impression" that Trulicity was indicated for "weight loss."

- Specifically, the OPDO found that Lilly was omitting information that patients were receiving additional medications during the trials which showed weight loss. The OPDO found that the "omission of this information undermines the ability of the viewer to understand and evaluate the efficacy claims presented in the proposed TV Ad."

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

431. Defendants are estopped from relying on the statute of limitations defense because Defendants actively concealed information concerning known risks, side effects, and defects in their GLP-1 RA Products. Instead of revealing such information to the FDA or the public, Defendants have continued to represent their GLP-1 RA Products as safe for their intended use.

432. Defendants are and were under a continuing duty to disclose the true character, quality and nature of risks and dangers associated with their GLP-1 RA Products. Because of Defendants' purposeful and fraudulent concealment of material information concerning the true

character, quality and nature of risks of their GLP-1 RA Products, Defendants are estopped from relying on any statute of limitations defense.

FIRST CAUSE OF ACTION –
VIOLATION OF NEW JERSEY PRODUCT LIABILITY ACT,
N.J.S.A. § 2A:58C-1 *et seq.* – AGAINST ALL DEFENDANTS

433. 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.

434. At all relevant times, in the course of their business, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, packaged, labeled, supplied, distributed, and/or sold the above-named GLP-1 RA Products that were used by Plaintiff.

435. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, promotion, advertising, packaging, labeling, supplying, distribution, and/or sale of their GLP-1 RA Products into the stream of commerce, including a duty to warn of dangers that they knew or should have known on the basis of reasonably obtainable or available knowledge.

436. Defendants' GLP-1 RA Products were expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, labeled, marketed, supplied, distributed, and/or sold by Defendants.

437. At all relevant times, including before and at the times Defendants' GLP-1 RA Products left their control, Defendants knew or should have known that their GLP-1 RA Products were unreasonably dangerous because they did not adequately warn of the risks of cyclical vomiting, especially when the drugs were used in the form and manner as provided by Defendants.

438. Defendants knew or should have known of the causal association between the use of their GLP-1 RA Products and the risks of developing cyclical vomiting, but they ignored the causal association. Defendants' actual and constructive knowledge derived from their clinical studies, case reports, medical literature, including the medical literature and case reports available at the time of manufacture and distribution.

439. At all relevant times, Defendants knew or should have known that their GLP-1 RA Products had not been sufficiently and/or adequately tested for safety.

440. Despite the fact that Defendants knew or should have known that their GLP-1 RA Products are causally associated with unreasonably dangerous injuries and had not been sufficiently and/or adequately tested for safety, Defendants continued to market, distribute, and/or sell their GLP-1 RA Products to consumers, including Plaintiff, without adequate warnings.

441. Despite the fact that Defendants knew or should have known that their GLP-1 RA Products are causally associated with unreasonably dangerous injuries and had not been sufficiently and/or adequately tested for safety risks, Defendants continued to market their GLP-1 RA Products to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

442. At all relevant times, Defendants reasonably foresaw, anticipated, expected, and knew or should have known that prescribing physicians, such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Defendants' GLP-1 RA Products for use by their patients to improve glycemic control in adults with type 2 diabetes and reduce cardiovascular risk.

443. At all relevant times, Defendants reasonably foresaw, anticipated, expected, and knew or should have known that individuals, such as Plaintiff, would use and/or consume

Defendants' GLP-1 RA Products for the drugs' ordinary purposes and would foreseeably suffer injury as a result of the inadequate warnings and defects described herein.

444. At all relevant times, given their increased safety risks and inadequate warnings, Defendants' GLP-1 RA Products were not reasonably fit, suitable, or safe for the ordinary purposes for which they were intended.

445. At all relevant times, given their increased safety risks and inadequate warnings, Defendants' GLP-1 RA Products did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

446. At all relevant times, Plaintiff was using Defendants' GLP-1 RA Products for the purposes and in a manner normally intended—namely, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and reduce cardiovascular risk.

447. The GLP-1 RA Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate warnings or instructions, as Defendants knew or should have known that the products created risks of serious and dangerous injuries, including cyclical vomiting and its sequelae, as well as other severe and debilitating personal injuries and Defendants failed to adequately warn of said risks.

448. The GLP-1 RA Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including cyclical vomiting and its sequelae, as well as other severe health consequences from their GLP-1 RA Products, Defendants failed to provide adequate warnings to users and/or prescribers of the products, and continued to improperly advertise, market and/or promote their products, Ozempic and Mounjaro.

449. The labels for Ozempic and Mounjaro were inadequate because they did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic and Mounjaro, including the increased risks of cyclical vomiting and its sequelae.

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

451. The labels for Ozempic and Mounjaro were inadequate because they did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Ozempic and Mounjaro.

452. The labels for Ozempic and Mounjaro were inadequate because they did not warn and/or adequately warn of the severity and duration of adverse effects, as the warnings given did not accurately reflect the symptoms or severity of the side effects.

453. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of their GLP-1 RA Products, including the increased risks of cyclical vomiting and its sequelae.

454. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn that their GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including cyclical vomiting and its sequelae.

455. The unreasonably dangerous characteristics of Defendants' GLP-1 RA Products were beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drugs' characteristics.

456. The unreasonably dangerous characteristics of Defendants' GLP-1 RA Products were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physicians as to the drugs' characteristics.

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

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

459. Upon information and belief, if Plaintiff's prescribing physician(s) had been warned about the increased risks of cyclical vomiting and its sequelae, which are causally associated with Defendants' GLP-1 RA Products, then Plaintiff's prescribing physician(s) would not have prescribed Defendants' GLP-1 RA Products, and/or would have provided Plaintiff with adequate warnings regarding the dangers of Defendants' GLP-1 RA Products, so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Defendants' GLP-1 RA Products.

460. Upon information and belief, if Plaintiff's prescribing physician(s) had been warned that Defendants' GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including cyclical vomiting and its sequelae, then Plaintiff's prescribing physician(s) would not have prescribed Defendants' GLP-1 RA Products, and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Defendants' GLP-1 RA Products' so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Defendants' GLP-1 RA Products.

461. If Plaintiff had been warned of the increased risks of cyclical vomiting and its sequelae, which are causally associated with Defendants' GLP-1 RA Products, then Plaintiff would not have used Defendants' GLP-1 RA Products and/or suffered from cyclical vomiting and its sequelae.

462. If Plaintiff had been warned that Defendants' GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including cyclical vomiting and its sequelae, then Plaintiff would not have used Defendants' GLP-1 RA Products and/or suffered from cyclical vomiting and its sequelae.

463. If Plaintiff had been warned of the increased risks of cyclical vomiting and its sequelae, which are causally associated with Defendants' GLP-1 RA Products, and/or warned that Defendants' GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, then Plaintiff would have informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Defendants' GLP-1 RA Products.

464. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Defendants' GLP-1 RA Products due to the risks of cyclical vomiting and its sequelae, and/or the lack of sufficient and/or adequate testing for safety risks, then Plaintiff's prescribing physician(s) would not have prescribed Defendants' GLP-1 RA Products.

465. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, packaged, labeled, supplied, distributed, and/or sold defective products which created unreasonable risks to the health of consumers and to Plaintiff in particular, and Defendants are therefore liable for the injuries sustained by Plaintiff.

466. Defendants' inadequate warnings for their GLP-1 RA Products were a substantial factor in causing Plaintiff's injuries.

467. Plaintiff's injuries were a foreseeable consequence of Defendants' actions in designing, manufacturing, labeling, marketing, promoting, supplying, distributing, and/or selling unreasonably dangerous products with inadequate warnings.

468. By reason of the foregoing, Defendants have become liable to Plaintiff for the designing, manufacturing, labeling, marketing, promoting, supplying, distributing, and/or selling of unreasonably dangerous products, Ozempic and Mounjaro.

469. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including cyclical vomiting and its sequelae, which resulted in other severe and debilitating personal injuries, including physical pain, mental anguish, diminished enjoyment of life, and fear of developing any of the above-named health consequences.

470. As a result of the foregoing acts and omissions, Plaintiff did incur medical, health, incidental, and related expenses, and presently requires and/or will in the future require more health care and services. Plaintiff is informed and believe and further allege that Plaintiff will require future medical and/or hospital care, attention, and services.

471. Defendants' inadequate warnings for their GLP-1 RA Products and other acts and omissions amounted to wanton and willful disregard by Defendants of persons who foreseeably might be harmed by their conduct, and/or actual malice or reckless indifference to the likelihood of harm and other consequences of their conduct.

472. The acts and omissions of Defendants described herein consisted of oppression, fraud, and/or malice, and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendants' officers, directors, and/or managing agents.

473. Defendants misled both the medical community and the public, including Plaintiff and Plaintiff's prescribing physician(s), by making false representations about the safety and effectiveness of Defendants' GLP-1 RA Products and by failing to provide adequate warnings, instructions, and training concerning their products' use.

474. Defendants downplayed, understated, and/or disregarded their knowledge of the serious side effects and risks associated with the use of their GLP-1 RA Products despite available information demonstrating that their GLP-1 RA Products caused serious and dangerous injuries, including cyclical vomiting and its sequelae.

475. Defendants were or should have been in possession of evidence demonstrating that their GLP-1 RA Products caused serious and dangerous injuries, including cyclical vomiting and its sequelae. Nevertheless, Defendants continued to market their GLP-1 RA Products by providing false and misleading information with regard to the drugs' safety and effectiveness.

476. Defendants failed to provide warnings that would have dissuaded health care professionals from prescribing Defendants' GLP-1 RA Products, thus preventing health care professionals, including Plaintiff's prescribing physician(s), and consumers, including Plaintiff, from weighing the true risks against the benefits of using Defendants' GLP-1 RA Products.

477. As a proximate result of Defendants' acts and omissions, Plaintiff suffers from serious and dangerous injuries resulting from Plaintiff's use of Defendants' GLP-1 RA Products, including cyclical vomiting and its sequelae.

478. As a result of Plaintiff's injuries, Plaintiff has endured substantial pain and suffering, has incurred significant expenses for medical care, and will remain economically challenged and emotionally harmed.

479. Plaintiff has suffered and will continue to suffer economic loss and has otherwise been emotionally and economically injured.

480. Defendants' actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff and the public.

481. Plaintiff's injuries and damages are severe. As a result, Plaintiff seeks actual and punitive damages from Defendants.

482. Defendants' conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

483. Consequently, Defendants are liable for punitive damages in an amount to be determined by the jury.

WHEREFORE, Plaintiff demands judgment against Defendants individually, jointly, severally and/or in the alternative, for damages, interest, attorneys' fees, costs of suit and such other and further relief as this Court may deem just and proper.

SECOND CAUSE OF ACTION –
BREACH OF EXPRESS WARRANTY,
N.J.S.A. § 12A:2-313 – AGAINST ALL DEFENDANTS

484. 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.

485. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, packaged, labeled, supplied, distributed, and/or sold, and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted,

marketed, packaged, labeled, supplied, distributed, and/or sold the above-named GLP-1 RA Products used by Plaintiff as hereinabove described.

486. At all relevant times, Defendants expressly warranted to Plaintiff and Plaintiff's prescribing physician(s) that their GLP-1 RA Products were safe as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, reduce cardiovascular risk.

487. The aforementioned express warranties were made to Plaintiff and Plaintiff's prescribing physician(s) by way of the labels, website, advertisements, promotional materials for Ozempic and Mounjaro, and through other statements. As a result of Defendants' express warranties, Plaintiff's prescribing physician(s) were induced to prescribe the above-named GLP-1 RA Products to Plaintiff, and Plaintiff was induced to use them.

488. At all relevant times, Defendants reasonably foresaw, anticipated, and expected that individuals, such as Plaintiff, would use and/or consume Defendants' GLP-1 RA Products based upon their express warranties.

489. At all relevant times, Defendants reasonably foresaw, anticipated, and expected that prescribing physicians, such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Defendants' GLP-1 RA Products based upon their express warranties.

490. At all relevant times, Defendants knew or should have known that their GLP-1 RA Products were unreasonably dangerous because of their increased risks of cyclical vomiting and its sequelae, especially when the drugs were used in the form and manner as provided by Defendants.

491. At all relevant times, Defendants knew or should have known that their GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks.

492. The unreasonably dangerous characteristics of Defendants' GLP-1 RA Products were beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drugs' characteristics.

493. The unreasonably dangerous characteristics of Defendants' GLP-1 RA Products were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physicians as to the drugs' characteristics.

494. At the time their GLP-1 RA Products left Defendants' control, they did not conform to Defendants' express warranties because they were not safe to use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and reduce cardiovascular risk in that they were causally associated with increased risks of cyclical vomiting and its sequelae.

495. Defendants materially failed to conform their GLP-1 RA Products to the representations in their labels, websites, advertisements, promotional materials, and other statements, concerning the properties of Defendants' GLP-1 RA Products, which Plaintiff's physician(s) prescribed and which Plaintiff used in direct or indirect reliance upon Defendants' express representations. Such failures by Defendants constitute a material breach of express warranties made, directly or indirectly, to Plaintiff's prescribing physician(s) and Plaintiff concerning Defendants' GLP-1 RA Products.

496. The express warranties made by Defendants regarding the safety, effectiveness, and other properties of their GLP-1 RA Products were made with the intent to induce Plaintiff to use the products and/or Plaintiff's prescribing physician(s) to prescribe the products.

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

to use Defendants' GLP-1 RA Products and/or the natural tendency of Plaintiff's prescribing physician(s) to prescribe Defendants' GLP-1 RA Products.

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

499. If Defendants had not made these express warranties, then Plaintiff would not have used Defendants' GLP-1 RA Products and/or, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Defendants' GLP-1 RA Products, and/or Plaintiff's prescribing physician(s) would have provided Plaintiff with adequate warnings regarding the dangers of Defendants' GLP-1 RA Products, so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Defendants' GLP-1 RA Products.

500. If Plaintiff had been warned of the increased risk of cyclical vomiting and their sequelae, which are causally associated with Defendants' GLP-1 RA Products, then Plaintiff would not have used Defendants' GLP-1 RA Products and/or suffered from cyclical vomiting and its sequelae.

501. If Plaintiff had been warned that Defendants' GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including cyclical vomiting and its sequelae, then Plaintiff would not have used Defendants' GLP-1 RA Products and/or suffered from cyclical vomiting and its sequelae.

502. Defendants' aforementioned express warranties were part of the basis of the parties' bargain for the products.

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

504. Plaintiff's injuries and damages arose from Plaintiff's reasonably anticipated use of Defendants' GLP-1 RA Products.

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

506. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries, including cyclical vomiting and its sequelae, as well as other severe and debilitating personal injuries, including physical pain, mental anguish, diminished enjoyment of life, and fear of developing any of the above-named health consequences.

507. By reason of the foregoing, Plaintiff has been severely injured and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' GLP-1 RA Products.

508. As a result of the foregoing acts and omissions, Plaintiff did incur medical, health, incidental, and related expenses, and Plaintiff presently requires and/or will in the future require more health care and services. Plaintiff is informed and believe and further allege that Plaintiff will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants individually, jointly, severally and/or in the alternative, for damages, interest, attorneys' fees, costs of suit and such other and further relief as this Court may deem just and proper.

THIRD CAUSE OF ACTION – VIOLATION OF THE CONSUMER FRAUD ACT, AGAINST ALL DEFENDANTS

509. 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.

510. The CFA, N.J.S.A. 56:8-2, prohibits, in relevant part:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice…

511. N.J.S.A. 56:8-19 further provides as follows:

> Any person who suffers any ascertainable loss of moneys or property, real or personal, as a result of the use or employment by another person of any method, act, or practice declared unlawful under this act … may bring an action … in any court of competent jurisdiction. In any action under this section the court shall, in addition to any other appropriate legal or equitable relief, award threefold the damages sustained by any person in interest. In all actions under this section the court shall also award reasonable attorneys' fees, filing fees and reasonable costs of suit.

512. The CFA defines "merchandise" as including "any objects, wares, goods, commodities, services or anything offered, directly, or indirectly to the public for sale." N.J.S.A. 56:8-1(c).

513. Defendants engaged in the sale of merchandise within the meaning of N.J.S.A. 56:8-1(c).

514. Defendants violated the CFA by engaging in unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts as set forth above.

515. Defendants' conduct in violation of the CFA includes, but is not limited to, the above listed unconscionable commercial practice, deception, fraud, false pretense, false promise, and/or misrepresentations.

516. Defendants' unconscionable commercial practices, deception, fraud, false promises, misrepresentations, concealment, suppression, and/or omission of material facts constitutes multiple, separate violations of the CFA, N.J.S.A. 56:8-1 et seq.

517. Defendants' unconscionable commercial practices, deception, fraud, false promises, misrepresentations, concealment, suppression, and/or omissions are material for the reasons set forth above.

518. As a direct and proximate result of each of Defendants' violation of the CFA, Plaintiff suffered and continues to suffer ascertainable losses.

WHEREFORE, Plaintiff demands judgment against Defendants individually, jointly, severally and/or in the alternative, for damages, interest, attorneys' fees, costs of suit and such other and further relief as this Court may deem just and proper.

PRAYER FOR RELIEF

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

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe 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, in an amount sufficient to punish Defendants and deter future similar conduct, for the wanton, willful, fraudulent, reckless conduct of Defendants, who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff the costs of these proceedings; and

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

Dated: Jersey City, New Jersey
March 9, 2026

MORGAN & MORGAN PHILADELPHIA, PLLC

Alexander Bylinkin, Esq.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

DEMAND FOR ANSWERS TO UNIFORM INTERROGATORIES

PLEASE TAKE NOTICE that pursuant to R. 4:-17-1(b), Plaintiff hereby demands that Defendants serve Answers to Uniform Interrogatories within the time prescribed by the Court Rules.

DEMAND FOR DISCOVERY OF INSURANCE INFORMATION

Pursuant to R. 4:10-2, demand is hereby made that you disclose to Plaintiff's attorneys whether there are any insurance agreements or policies under which any person or firm carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in this action or to indemnify or reimburse for payments made to satisfy the judgment.

NOTICE OF TRIAL COUNSEL

Pursuant to R. 4:25-4, ALEXANDER BYLINKIN is hereby designated as trial counsel.

Dated: Jersey City, New Jersey
March 9, 2026

RESPECTFULLY SUBMITTED,

MORGAN & MORGAN PHILADELPHIA, PLLC
Alexander Bylinkin, Esq. (125212014)
Email Address: ABylinkin@forthepeople.com
30 Montgomery Street, Suite 410
Jersey City, New Jersey 07302
Tel: (917) 344-7038
Attorneys for Plaintiff

CERTIFICATION

In accordance with R. 4:5-1, I hereby Certify that at the time of filing this Complaint, the matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration proceeding.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: Jersey City, New Jersey
March 9, 2026

MORGAN & MORGAN PHILADELPHIA, PLLC
Alexander Bylinkin, Esq. (125212014)
Email Address: ABylinkin@forthepeople.com
30 Montgomery Street, Suite 410
Jersey City, New Jersey 07302
Tel: (917) 344-7038
Attorneys for Plaintiff

CERTIFICATION OF NOTICE TO ATTORNEY GENERAL

I hereby certify that in accord with *N.J.S.A.*§56:8-20 a copy of this Complaint will be emailed the Attorney General within twenty-four hours of filing.

Dated: Jersey City, New Jersey
March 9, 2026

MORGAN & MORGAN PHILADELPHIA, PLLC
Alexander Bylinkin, Esq. (125212014)
Email Address: ABylinkin@forthepeople.com
30 Montgomery Street, Suite 410
Jersey City, New Jersey 07302
Tel: (917) 344-7038
Attorneys for Plaintiff