UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
TRENTON DIVISION

JEANNE SHEA,

Plaintiff,

v.

NOVO NORDISK A/S, NOVO NORDISK NORTH AMERICA OPERATIONS A/S, NOVO NORDISK US HOLDINGS INC., NOVO NORDISK US COMMERCIAL HOLDINGS INC., NOVO NORDISK INC., NOVO NORDISK RESEARCH CENTER SEATTLE, INC., and NOVO NORDISK PHARMACEUTICAL INDUSTRIES LP,

Defendants.

Case No.

Judge

JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, Jeanne Shea, by Plaintiff's attorney, Parvin Aminolroaya of Seeger Weiss, LLP, hereby brings this action against Defendants NOVO NORDISK A/S, NOVO NORDISK NORTH AMERICA OPERATIONS A/S, NOVO NORDISK US HOLDINGS INC., NOVO NORDISK US COMMERCIAL HOLDINGS INC., NOVO NORDISK INC., NOVO NORDISK RESEARCH CENTER SEATTLE, INC., and NOVO NORDISK PHARMACEUTICAL INDUSTRIES LP (hereinafter "Defendants" or "Novo"). Upon information and belief, at all times hereinafter mentioned, Plaintiff alleges as follows:

JURISDICTION AND VENUE

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

2. This Court has personal jurisdiction over Defendant Novo Nordisk, Inc., consistent with the United States Constitution and N.J. Court Rule 4:4-4(a)(6), as Defendant's principal place of business is located in New Jersey.

3. This Court has personal jurisdiction over all Defendants, consistent with the United States Constitution and N.J. Court Rule 4:4-4(c) (New Jersey's "long arm" statute) by virtue of Defendants' substantial, continuous, and systematic contacts with the State of New Jersey.

INTRODUCTION

4. Vision is the most dominant of the senses, and plays a critical role in every facet and stage of our lives. Without vision, a person will struggle to learn, walk, read and work.

5. Vision loss can lead to worsened mental health, loss of or limited employment,

social isolation, and the need for a caregiver.

6. Non-arteritic Anterior Ischemic Optic Neuropathy ("NAION") is an irreversible condition that causes sudden and permanent vision loss.

7. Vision loss with NAION is untreatable and can result in permanent blindness.[1]

8. Vision loss with NAION is sudden, and usually discovered when a person wakes up in the morning and notices a loss of their vision in one eye.

9. Patients with NAION suffer from blurred or darkened vision obstructing their field of view, as well as loss of color vision and loss of contrast in vision.[2]

10. About 15% of patients who have NAION in one eye eventually develop it in their other eye too. [3]

11. For most patients with NAION, the vision loss *will not improve with time*. Some will experience progressive worsening of their vision after the initial vision loss.[4]

12. This is an action for damages suffered by Plaintiff, Jeanne Sea, who was severely injured, by developing NAION as a result of Plaintiff's use of Wegovy, an injectable prescription medication that is used chronic weight management in adults with an initial Body Mass index (BMI) of 30 kg/m2 or greater, or with a BMI of 27 kg/m2 or greater and at least one weight-related comorbid condition.

13. Wegovy (semaglutide) belongs to a class of drugs called glucagon-like peptide 1 receptor agonists ("GLP-1 RAs"). GLP-1 RAs are indicated for the treatment of type 2 diabetes,

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[1] *Ischemic Optic Neuropathy*, Cleveland Clinic, (last reviewed 6/30/2024), available at https://my.clevelandclinic.org/health/diseases/ischemic-optic-neuropathy (last visited 12/17/2024).

[2] *Id.*

[3] *Id.*

[4] *Id.*

to aid in chronic weight management, and reduce cardiac risk in some patient populations.

14. Defendants knew, or should have known, based on preclinical trials, premarket clinical trials, post-market surveillance, and adverse event reports of NAION injuries with Wegovy or semaglutide drugs that there was reasonable evidence of a causal association between the use of Wegovy and NAION.

15. Despite this, Defendants failed to warn about the risk of NAION with Wegovy.

16. Instead, Defendants created and expanded the market for weight-loss medication by, among other things, spending hundreds of millions of dollars on marketing to doctors and patients, advocating for obesity to be classified as a disease and thereby expanding the market for their drugs, changing the medical consensus on how to treat that disease, implementing cutting-edge invasive, unprecedented and multifaceted marketing campaigns that were so effective they ingrained 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 and use.

17. Defendants intentionally targeted the American population for the sale of their weight-loss drugs. Defendants understood the vast financial potential of marketing a weight-loss medication in the United States where obesity rates were on the rise despite the culture's obsession with losing weight and being thin.

18. Defendants also sought to make the GLP-1 RAs, including Wegovy, 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.

19. Defendants' efforts to conceal (or minimize) the risks associated with taking their

drugs, including the risk of developing NAION, were intended to create the impression that these were "magic pills" to help a person 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), the drugs do not result in meaningful weight loss for up to 15% of people,[5] the average weight loss for someone taking the drugs is a modest 10.09% of the person's body weight,[6] and that a person will need to stay on these drugs for the rest of their lives to maintain the weight loss.[7] What is worse is that 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.

20. The efforts to ingrain GLP-1 RAs 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 among diabetics and people seeking to lose weight, whether they were using the drug as prescribed or off-label. Plaintiff would not have taken Wegovy if he had been provided a full and clear warning of the true risks of taking this drug, like the risk of developing NAION and its sequelae.

21. Defendants' efforts to expand and grow the market both for treatment of diabetes

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[5] Carbajal, *Up to 15% of patients on weight loss drugs may be 'non-responders'*, Becker's Hospital Review (April 1, 2024) available at https://www.beckershospitalreview.com/glp-1s/up-to-15-of-patients-on-weight-loss-drugs-non-responders.html.

[6] 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).

[7] 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 ….").

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.[8] 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 be 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.[9]

22. 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, such as Wegovy, would guarantee results and be efficacious and safe. Plaintiff injected Wegovy believing that he was doing something to promote his health when, in fact, it had the opposite effect.

23. As a result of the foregoing, Plaintiff took Wegovy, which caused him to develop NAION. Plaintiff is now suffering from the devastating consequences of vision loss and will continue to suffer from the loss of vision for the rest of his life.

PARTY PLAINTIFF

24. Plaintiff, Jeanne Shea, is a citizen of the United States and a resident of the State of

[8] J.P. Morgan Research, *The increase in appetite for obesity drugs* (Nov. 29, 2023), https://www.jpmorgan.com/insights/global-research/current-events/obesity-drugs.

[9] Baig et al., *Medicare Part D Coverage of Antiobesity Medications — Challenges and Uncertainty Ahead*, 388 NEJM 961 (2023).

Massachusetts.

25. Plaintiff used Saxenda from on or about December of 2022 to on or about May of 2023.

26. Plaintiff used Wegovy from on or about June of 2023 to on or about January of 2024.

27. As a result of using Saxenda and Wegovy, Plaintiff was caused to suffer from NAION and its sequelae and, as a result, sustained severe and permanent personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

28. As a result of using Saxenda and Wegovy, Plaintiff was caused to suffer from NAION and its sequelae, which resulted in vision loss and blurred vision in his right eye.

29. On or about May 2, 2025, Plaintiff, through counsel, notified Defendants of their breach of express and implied warranties, pursuant to Massachusetts General Laws, Chapter 106, Section 2-607.

PARTY DEFENDANTS

30. 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.

31. 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.

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

33. Upon information and belief, Defendant Novo Nordisk US Commercial Holdings Inc. is a Delaware corporation with a principal place of business at 103 Foulk Road, Wilmington,

Delaware.

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

35. Upon information and belief, Defendant Novo Nordisk US Holdings Inc. is a Delaware corporation with a principal place of business at 103 Foulk Road, Wilmington, Delaware.

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

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

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

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

40. Defendants Novo Nordisk Inc., Novo Nordisk US Commercial Holdings Inc., Novo Nordisk US Holdings Inc., Novo Nordisk A/S, Novo Nordisk North America Operations A/S, Novo Nordisk Research Center Seattle, Inc., and Novo Nordisk Pharmaceutical Industries LP are referred to collectively herein as "Novo Nordisk," or "Novo," or "the Novo Nordisk Defendants."

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

42. 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 RA drugs, including Ozempic, Rybelsus, Wegovy, Victoza, and Saxenda.

FACTUAL ALLEGATIONS

A. INTRODUCTION TO GLP-1 AND GLP-1 RA PRODUCTS, INCLUDING WEGOVY

43. Researchers first discovered GLP-1 in hamsters in 1983.[10] 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.

44. In 1993, researchers discovered that a peptide from the venom of gila monsters activated GLP-1 receptors.[11] 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.

45. 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, Byetta, with the active ingredient exenatide, which came to market in 2005. Byetta was initially brought to market as a collaboration between the Eli Lilly Company ("Lilly") and Amylin.[12] Whereas naturally-occurring GLP-1 has a short half-life of just a few minutes, Byetta's half-life was 2.4

[10] Bell et al., *Hamster preproglucagon contains the sequence of glucagon and two related peptides*, 302 Nature 716 (1983).

[11] Thorens et al., *Cloning and functional expression of the human islet glp-1 receptor*, 42 Diabetes 1678 (1993).

[12] 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-release-details/amylin-and-lilly-announce-fda-approval-byettatm-exenatide (last visited Nov. 8, 2023) (describing the drug as a "collaboration" between Amylin and Lilly).

hours.[13]

46. At the same time, 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.[14] Liraglutide came to market in 2010, marketed initially as Victoza, for the treatment of diabetes, and later as Saxenda, for weight loss. Liraglutide has a half-life of 13-15 hours.[15]

47. 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 Eli Lilly as Mounjaro and Zepbound), dulaglutide (marketed by Eli Lilly as Trulicity), exenatide (marketed by various companies as Byetta, Bydureon, and Bydureon BCise), albiglutide (formerly marketed by GlaxoSmithKline as Tanzeum), and lixisenatide (marketed by Sanofi as Adlyxin and in combination with insulin as Soliqua 100/33).

48. GLP-1 RAs are recognized by the U.S. Food & Drug Administration ("FDA") to constitute a "class" of drugs based on similarities in their mechanisms of action, physiologic effects, and chemical structure.[16] Defendants likewise recognize that their GLP-1 RAs are

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[13] Cai, et al., *Long-acting preparations of exenatide,* Drug Des. Devel. Ther. (Sept. 2013).

[14] 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.

[15] 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).

[16] *See* FDA Ozempic Summary Review, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000SumR.pdf (including liraglutide, dulaglutide, and semaglutide in the GLP-1 RA class) (last visited Dec. 28, 2023); *see also* https://www.fda.gov/industry/structured-productlabeling-resources/pharmacologic-class (last visited Dec. 28, 2023).

members of the same class.[17]

49. Medications within the GLP-1 RA class of drugs mimic the activities of physiologic GLP-1 in numerous ways,[18] 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),[19] acting on the pancreas to stimulate the release of insulin, suppressing the release of glucagon, and slowing or inhibiting gastric emptying and intestinal motility.[20]

50. 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.GLP-1 RAs such as semaglutide and tirzepatide 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.

51. Most GLP-1 RAs are approved to treat type 2 diabetes,[21] but some (like Wegovy and Saxenda) are approved to treat obesity or to reduce cardiovascular risks.

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[17] SURMOUNT-1 Clinical Trial Protocol at 45, available at https://cdn.clinicaltrials.gov/large-docs/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.").

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

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

[20] Deane, *et al*., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia*, 95 J Clinical Endo Metabolism, 225 (2010).

[21] 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* (March 9, 2022), available at https://my.clevelandclinic.org/health/diseases/21500-type-1-diabetes (last visited 10/3/24) *with* Cleveland Clinic, *Type 2 Diabetes* (Nov. 8, 2023), available at https://my.clevelandclinic.org/health/diseases/21501-type-2-diabetes.

52. Most GLP-1 RAs are administered by injection, with the exception of Rybelsus, which is in tablet form.[22]

53. Most of the GLP-1 RAs are weekly injectable drugs, except that liraglutide (the active ingredient in Saxenda and Victoza) is a daily injectable drug.[23]

54. 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.

B. GLP-1 RAS ARE INEFFECTIVE IN MANY PATIENTS BECAUSE OF HIGH DISCONTINUATION RATES, MINIMAL TO NO WEIGHT LOSS FOR A SIGNIFICANT PERCENTAGE OF PATIENTS AND SUBSEQUENT REBOUND WEIGHT GAIN

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

56. 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 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.[24] 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

[22] Cleveland Clinic, *GLP-1 Agonists* (July 3, 2023), https://my.clevelandclinic.org/health/treatments/13901-glp-1-agonists.
[23] *Id*.
[24] BLUE HEALTH INTELLIGENCE, REAL-WORLD TRENDS IN GLP-1 TREATMENT PERSISTENCE AND PRESCRIBING FOR WEIGHT MANAGEMENT, (May 2024), https://www.bcbs.com/media/pdf/BHI_Issue_Brief_GLP1_Trends.pdf.

prescriptions, citing concerns about efficacy and safety.[25]

57. 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."[26]

58. 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."[27]

59. 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."[28]

60. 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

[25] Blue Cross Blue Shield of Michigan, *Changes coming for select weight loss drugs for some commercial members* (July 2024) https://www.bcbsm.com/content/dam/microsites/corpcomm/provider/the_record/2024/jul/Record_0724h.html.

[26] Patrick 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. (June 2024).

[27] 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 (March 2021).

[28] Wilding, *et al*., *Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension*, Diabetes Obes. Metab. (Feb. 2022).

"potential limitations of GLP-1 RAs for sustained long term weight loss efforts."[29]

61. Additionally, many people do not respond to GLP-1 RAs for weight-loss at all. Research suggests that approximately 14% of patients taking lost less than 5% of their body weight and one-third lost less than 10% of their body weight.[30]

62. 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.[31] Not only is bariatric surgery far more effective, it is also safer[32] and more cost-effective[33] than GLP-1 RAs.

63. 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.

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[29] 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).

[30] Carbajal, *Up to 15% of patients on weight loss drugs may be 'non-responders*, Becker's Hospital Review (April 1, 2024) available at https://www.beckershospitalreview.com/glp-1s/up-to-15-of-patients-on-weight-loss-drugs-non-responders.html.

[31] *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."); 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.") .

[32] *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").

[33] *See, e.g.*, Reed, *Bariatric surgery found more cost-effective than GLP-1s*, Axios, available at https://www.axios.com/2024/10/21/bariatric-surgery-more-cost-effective-glp1 (last visited 10/21/24); Sanchez, *et al*., *Comparative Cost-Effectiveness Analysis of Bariatric Surgery and GLP-1 Receptor Agonists for the Management of Obesity*, Northwestern University Feinberg School of Medicine, available at https://www.surgery.northwestern.edu/docs/edelstone-bendix-research-poster/2024-posters/Sanchez-Joseph.pdf (last visited 10/21/24).

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.[34] 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.[35]

64. 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." This guide describes metformin as "very effective at controlling blood glucose and lowers A1C as much as 15%." The listed side effects include diarrhea and rare lactic acidosis.[36] 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%"[37]

65. 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

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

[35] Lei XG, *et al*., *Efficacy and Safety of Phentermine/Topiramate in Adults with Overweight or Obesity: A Systematic Review and Meta-Analysis.* OBESITY (SILVER SPRING). 2021 June;29(6):985-994.

[36] Johns Hopkins University, The Johns Hopkins Patient Guide to Diabetes, https://hopkinsdiabetesinfo.org/medications-for-type-2-diabetes-metformin/ (last accessed November 10, 2024).

[37] Deborah Hinnen, *Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes*, 30 DIABETES SPECTR 202–210 (2017).

study found "GLP-1 RA and acarbose were ranked as having the highest incidence of GI AEs."[38] Therefore, GLP-1 RAs, including Wegovy, offer minimal increased benefit as it relates to diabetes, while increasing the risk of gastrointestinal adverse injuries, as well as the risk NAION and its sequelae.

C. THE REGULATORY HISTORY OF WEGOVY

66. On December 4, 2020, Novo announced submission of NDA 215256 to the FDA for regulatory approval of subcutaneous semaglutide 2.4 mg, a once-weekly glucagon-like peptide-1 (GLP-1) medication for chronic weight management. In the announcement, Novo represented that "once-weekly semaglutide 2.4 appeared to have a safe and well-tolerated profile" and "[t]he most common side effects were gastrointestinal and were transient, and mild or moderate in severity."[39]

67. On December 4, 2020, Novo submitted NDA 215256, requesting that the FDA grant it approval to market and sell Wegovy (semaglutide) injection in the United States as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of either 30/kg/m^2 or greater (obese), or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition. On June 4, 2021, the FDA approved NDA 215256.[40]

68. On June 29, 2022, Novo submitted supplemental new drug application (sNDA)

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[38] 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*, FRONT ENDOCRINOL (Sept. 14 2022).

[39] Novo Nordisk, *Novo Nordisk files for regulatory approval of once-weekly semaglutide 2.4 mg for weight management,* (Dec. 4, 2020), available at https://www.globenewswire.com/news-release/2020/12/04/2139776/0/en/Novo-Nordisk-files-for-US-FDA-regulatory-approval-of-once-weekly-semaglutide-2-4-mg-for-weight-management.html.

[40] FDA Approval Letter for NDA 215256 (Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/215256Orig1s000ltr.pdf.

215256/S-005 for Wegovy (semaglutide) injection, requesting approval for the addition of an indication for use in adolescents 12 years and older with an initial BMI at or above the 95th percentile for age and sex. On December 23, 2022, the FDA approved sNDA 215256/S-005.[41]

69. On December 23, 2022, Novo announced the FDA's approval of sNDA 215256/S-005 for a new indication of Wegovy to treat obesity in teens aged 12 years and older. In the press release, Novo touted the "safety and efficacy of Wegovy as a treatment for adolescents with obesity[.]"[42] As with its prior press releases, Novo disclosed Important Safety Information and provided links to the Medication Guide and Prescribing Information, but NAION was not warned of as a side effect or risk.

70. On September 23, 2022, Novo submitted sNDA 215256/S-007, requesting approval for an update to the Prescribing Information and Medication Guide to include Wegovy (semaglutide) 1.7 mg subcutaneous weekly as an additional maintenance dose. On July 21, 2023, the FDA approved sNDA 215256/S-007.[43]

71. On September 8, 2023, Novo submitted sNDA 215256/S-011, requesting approval for the addition of an indication for use "in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight." On March 8, 2024, the FDA approved sNDA 215256/S-

[41] FDA Supplement Approval Letter for NDA 215256/S-005(Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/215256Orig1s005ltr.pdf.

[42] Novo Nordisk, *FDA approves once-weekly Wegovy injection for the treatment of obesity in teens aged 12 years and older* (Dec. 23, 2022), available at https://www.novonordisk-us.com/media/news-archive/news-details.html?id=151389.

[43] FDA Supplement Approval Letter for NDA 215256/S-007(Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/215256Orig1s007ltr.pdf.

011.[44]

72. On January 29, 2024, Novo submitted sNDA 215256/S-015, requesting approval for an update to the Prescribing Information and Medication Guide to include Wegovy (semaglutide) 1.7 mg subcutaneous weekly as an additional maintenance dose for pediatric patients ages 12 to less than 18 years with obesity, add subsection 5.6 *Severe Gastrointestinal Adverse Reactions* to the Warnings and Precautions section, revise subsection 5.2 *Acute Pancreatitis* to improve clarity, and "[a]dditional edits made throughout the Prescribing Informaiton to modernize with current labeling guidances, clarify language, and improve readability and organization of information." On November 27, 2024, the FDA approved sNDA 215256/S-015.[45]

73. No version of the Wegovy label has warned patients or their doctors that taking Wegovy may cause NAION or result in permanent vision loss.

D. REGULATORY HISTORY OF SAXENDA

74. On December 20, 2013, Novo submitted NDA 206321, requesting that the FDA grant it approval to market and sell Saxenda (liraglutide 3 mg) in the United States as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of either 30/kg/m2 or greater (obese), or 27 kg/m2 or greater (overweight) combined with at least one weight-related comorbid condition.

75. Following the receipt of several amendments, the FDA approved NDA 206321 on December 23, 2014.[46]

76. At the same time, Novo was seeking approval for Saxenda from health

[44] FDA Supplement Approval Letter for NDA 215256/S-011 (Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/215256Orig1s011ltr.pdf
[45] FDA Supplement Approval Letter for NDA 215256/S-015 (Wegovy), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/215256Orig1s015ltr.pdf
[46] U.S. FOOD & DRUG ADMIN., APPROVAL LETTER FOR NDA 20632, (Dec. 12, 2014) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206321Orig1s000Approv.pdf.

organizations worldwide. Health Canada approved Saxenda for chronic weight management in February 2015. The European Commission authorized Saxenda for marketing throughout the European Union (EU) to help manage weight in adults in March 2015.[47]

77. On April 26, 2017, the FDA approved an updated Saxenda injectable 3 mg label, based on the findings of the SCALE Obesity and Pre-diabetes 3-year trial.[48]

78. On December 4, 2020, the FDA approved Novo's supplemental NDA for Saxenda for chronic weight management in pediatric patients aged 12 years and older who are obese, as defined by specific BMI cut-offs for age and sex that correspond to BMI 30 kg/m2 or higher for adults, and who weigh more than 60 kg (132 pounds).[49] In the press release, Novo touted the "safety and efficacy of Saxenda as a treatment for adolescents with obesity[.]"[50] As with its prior press releases, Novo disclosed Important Safety Information and provided links to the Medication Guide and Prescribing Information, but NAION and its sequelae were not warned of as a side effect or risk.

79. No version of the Saxenda label has warned that patients taking Saxenda may develop NAION or experience permanent vision loss.

E. DEFENDANTS WERE ON NOTICE THAT WEGOVY IS ASSOCIATED WITH NAION AND ITS SEQUELAE

[47] Clinical Trials Arena, *Saxenda (liraglutide) for the treatment of obesity, US* (Aug. 4, 2023), available at https://www.clinicaltrialsarena.com/projects/saxenda-liraglutide-obesity.
[48] U.S. FOOD & DRUG ADMINS, SUPPLEMENTAL APPROVAL LETTER FOR NDA 206321/S-004 (April 26, 2016) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/206321Orig1s004,s006ltr.pdf.
[49] U.S. FOOD & DRUG ADMIN., SUPPLEMENTAL APPROVAL FOR NDA 206321/S-012, -013, -014, (Dec. 4, 2020), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/206321Orig1s012,%20s013,%20s014ltr.pdf
[50] NOVO NORDISK, *FDA approves Saxenda for the treatment of obesity in adolescents aged 12-17* (Dec. 4, 2020), https://www.prnewswire.com/news-releases/fda-approves-saxenda-for-the-treatment-of-obesity-in-adolescents-aged-12-17-301186800.html..

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

81. Defendants knew or should have known of the causal association between the use of semaglutide and the risk of developing NAION and its sequelae, but they ignored it. Defendants' actual and constructive knowledge derived from their clinical studies, adverse events reports made to them, and medical literature, including the epidemiological studies, and case reports referenced in this Complaint.

82. It has been known since at least 2016 that the human eye contains GLP-1 receptors.[51] This finding has been confirmed by Novo's own scientists.[52]

83. On July 3, 2024, *JAMA Ophthalmology* published a study suggesting an association between semaglutide and NAION. The study, which evaluated data from December of 2017 through November of 2023, showed that patients with type 2 diabetes taking semaglutide had a more than three times greater risk of developing NAION than those taking non-GLP-1 RA medications. For patients taking semaglutide for overweight/obesity indications, the risk of developing NAION was nearly seven times greater than non-GLP-1 RA medications.[53]

84. The *JAMA* study referenced a potential causal mechanism, proposing that

[51] Hernández C et al, *Topical Administration of GLP-1 Receptor Agonists Prevents Retinal Neurodegeneration in Experimental Diabetes,* 65 DIABETES 172 (2016).

[52] Hebsgaard JB, et al, *Glucagon-like peptide-1 receptor expression in the human eye* 20 DIABETES OBES METAB. 2304 (2018).

[53] Specifically, the study showed a cumulative incidence of NAION of 8.9% in type 2 diabetes patients taking semaglutide, compared to only 1.8% for patients not taking GLP-1RA medications, with a hazard ratio of 4.28. For overweight/obese patients, the cumulative incidence of NAION was 6.7% for patients taking semaglutide, compared to only 0.8% for those not taking GLP-1RAs, with a hazard ratio of 7.64. Hathaway, et al., *Risk of Nonarteritic Anterior Ischemic Optic Neuropathy in Patients Prescribed Semaglutide*, 142 JAMA OPHTHALMOLOGY 732 (2024).

"expression of the GLP-1 receptor in the human optic nerve and GLP-1 RA induced enhanced sympathetic nervous system activity might influence optic nerve head perfusion and potentially increase the risk of NAION."[54]

85. The FDA's Adverse Events Reporting System (FAERS) shows multiple reports of "Optic Ischemic Neuropathy" reported in connection with use of GLP-1 RAs. The earliest reported Optic Ischemic Neuropathy event associated with any GLP-1 RA occurred in 2012, and the earliest associated with semaglutide specifically was in 2019.[55] Analysis of this data shows that patients taking GLP-1 RA drugs report injuries associated with NAION at a statistically-significantly greater rate than patients taking other diabetes or weight-loss drugs.[56]

86. A Novo spokesperson acknowledged that cases of NAION, which leads to severe

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[54] *Id.*

[55] The FAERS database is accessible online at https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard. See also Castellana E, *Potential risk of non-arteritic anterior ischaemic optic neuropathy in semaglutide users: pharmacovigilance insights*, EUR. J. HOSP. PHARM. (2024) (online ahead of print). Note that FAERS does not contain a code for NAION itself, only "optic ischemic neuropathy," a condition that encompasses NAION.

[56] *See* Kim et al., *Adverse drug reaction patterns of GLP-1 receptor agonists approved for obesity treatment: Disproportionality analysis from global pharmacovigilance database*, DIABETES OBES. METAB. (2025) (online ahead of print) (finding 80% increased risk of reporting vision loss compared to other weight-loss drugs); Massey et al., *Increased vision impairment reports linked to semaglutide: analysis of FDA adverse event data*, BMC MEDICINE (2025) (finding increased reporting rates of vision impairment for Semaglutide ranging from 57% to 289% in comparison to various weight-loss and diabetes drugs); Azab et al., *Semaglutide: Nonarteritic Anterior Ischemic Optic Neuropathy in the FDA adverse event reporting system*, OBESITY RESEARCH & CLINICAL PRACTICE (2025) (online ahead of print) (finding increased risk of reporting of optic ischaemic neuropathy of over 1000%); Procacci et al., *Disproportionality analysis on semaglutide and nonarteritic anterior ischemic optic neuropathy in the FDA adverse event reporting system: An emerging pharmacovigilance signal?*, OBESITY RESEARCH & CLINICAL PRACTICE (2025) (online ahead of print) (finding increased risk of reporting of optic ischaemic neuropathy of over 1000%)

and irreversible vision loss, were identified in Novo's clinical trials.[57]

87. Fourteen cases of NAION suspected to be causally associated with use of GLP-1 RA drugs have been reported in published, peer-reviewed case reports.[58] Notably in one of these cases the patient experienced re-challenge when her NAION worsened after re-starting her GLP-1 RA drug.[59]

88. A study of diabetic patients in Denmark between 2018 and 2024 showed that use of semaglutide "more than doubles the risk of NAION, even when multiple other factors have been taken into account." The study observed that "after the introduction of once-weekly semaglutide in Denmark in November 2018, the annual number of first-time NAION episodes reached an all-time high for the years 2019-2023."[60]

89. A 2024 cohort study conducted in Denmark and Norway showed that users of semaglutide were almost twice as likely to develop NAION than those taking sodium-glucose co-transporter 2 inhibitors, another class of prescription medications used to treat type 2 diabetes.[61]

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[57] Kevin Dunleavey, *After studies flag possible link between Novo's Ozempic and rare eye disorder, Danish agency calls for probe*, FIERCE PHARMA, (December 17, 2024), https://www.fiercepharma.com/pharma/novo-nordisk-faces-new-reports-suggesting-link-between-ozempic-and-blindness.

[58] Maceroni et al., *Non arteritic ischemic optic neuropathy in a patient taking semaglutide: Is there a relation? A case report and a review of the literature*, EUROPEAN JOURNAL OF OPHTHALMOLOGY (2025) (reporting one case); Ahmadi et al., *Anterior ischemic optic neuropathy in patients treated with semaglutide: report of four cases with a possible association*, BMC OPHTHALMOLOGY (2025) (reporting four cases); Katz et al., *Ophthalmic Complications Associated With the Antidiabetic Drugs Semaglutide and Tirzepatide*, JAMA OPHTHALMOLOGY (2025) (online ahead of print) (reporting nine cases).

[59] *See* Katz et al.

[60] Jakob Grauslund, et al., *Once-weekly semaglutide doubles the five-year risk of nonarteritic anterior ischemic optic neuropathy in a Danish cohort of 424,152 persons with type 2 diabetes*, INT. J. RETINA AND VITREOUS, 10, 97 (2024), available at https://journalretinavitreous.biomedcentral.com/articles/10.1186/s40942-024-00620-x

[61] Simonsen et al., *Use of semaglutide and risk of non-arteritic anterior ischemic optic neuropathy: A Danish–Norwegian cohort study*, DIABETES OBES METAB. (2025) (online ahead of print).

90. In response to these studies, the Danish Medicines Agency has requested that the European Pharmacovigilance Risk Assessment Committee (PRAC) further investigate the link between semaglutide and NAION.[62]

91. Subsequent studies lend further support for the causal association between NAION and GLP-1 RA drugs. The paper by Hsu et al. published in JAMA Ophthalmology analyzing hundreds of thousands of patients from a large national database found "an increased NAION risk was also observed among patients with diabetes who had a history of Ozempic (Novo Nordisk) use or stand-alone Ozempic (Novo Nordisk) prescription history," particularly in patients taking GLP-1RA drugs for multiple years.[63] Likewise a paper by Cai et al, also published in JAMA Ophthalmology and using data from a large national database, found an increased risk of NAION among patients taking semaglutide using a self-controlled case series analysis, which effectively compares the risk for individual patients developing NAION while taking or not taking semaglutide.[64]

92. A meta-analysis of all clinical trials of GLP-1RA drugs, including Novo's own clinical trials, found a non-statistically significant increased risk of optic ischemic neuropathy. The authors note that optic ischemic neuropathy is rare and may have been underreported in the clinical trials, leading a lower estimated risk. The overall rate of optic ischemic neuropathy was higher in the treatment group than the control group: 5.6 and 3.0 cases per 100,000 patient-years, respectively. The authors also note that "inappropriate use of drugs for inducing weight loss in

[62] *Suspicion of rare eye condition from Ozempic use to be investigated further*, Danish Medicines Agency, (December 16, 2024), https://laegemiddelstyrelsen.dk/en/news/2024/suspicion-of-rare-eye-condition-from-ozempic-use-to-be-investigated-further/.

[63] Hsu et al., *Semaglutide and Nonarteritic Anterior Ischemic Optic Neuropathy Risk Among Patients With Diabetes*, JAMA OPHTHALMOLOGY (2025) (online ahead of print).

[64] Cai et al., Semaglutide and Nonarteritic Anterior Ischemic Optic Neuropathy, JAMA OPHTHALMOLOGY (2025) (online ahead of print).

moderately overweight patients with low cardiovascular risk could be associated with rare, but severe, adverse effects, possibly including NAION."[65]

93. Defendants knew or should have known that there was reasonable evidence of a causal association between the use of Wegovy and the risk of developing NAION and its sequelae, but they ignored it. Defendants' actual and constructive knowledge derived from their clinical studies and adverse event reports as well as publicly available medical literature, including the medical literature and case reports referenced in this Complaint. Defendants' failure to advise Plaintiff and his doctors of this risk has caused permanent damage to his eyesight.

F. BACKGROUND ON PHARMACEUTICAL MARKETING

1. Regulatory Framework for Pharmaceutical Advertising

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

95. By statute, "labeling" is defined 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."[66] The FDA's implementing regulation specifies 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, 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

[65] Silverii et al., *Glucagon-like peptide 1 (GLP1) receptor agonists and risk for ischemic optic neuropathy: A meta-analysis of randomised controlled trials, 27* DIABETES OBES METAB 1005, (2025).

[66] 21 U.S.C. § 321(m).

determined to be labeling as defined in section 201(m) of the act."[67]

96. The FDA recognizes a difference between direct-to-consumer ("DTC") advertisements and promotional labeling.[68] 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." 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."[69]

97. 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."[70] Importantly, "[p]romotional labeling about a drug is said to 'accompany' that drug, even if the promotional labeling is not physically attached to a drug container. Promotional labeling must be accompanied by the drug's prescribing information.'"[71]

98. Under the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations, drug promotional labeling and prescription drug advertising must be truthful and non-

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[67] 21 CFR § 202.1(k)(2).

[68] U.S. FOOD AND DRUG ADMIN., *Drug Advertising: A Glossary of Terms*, (Jan. 19, 2020) https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms.

[69] *Id*. (emphasis added).

[70] *Id.*

[71] *Id*.

misleading, convey information about the drug's efficacy and its risks in a balanced manner, and reveal material facts about the drug.[72]

99. 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."[73] 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."[74]

100. 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."[75] In other words, federal 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 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.[76]

101. 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.

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[72] U.S. FOOD AND DRUG ADMIN, PRESENTING QUANTITATIVE EFFICACY AND RISK INFORMATION IN DIRECT-TO-CONSUMER (DTC) PROMOTIONAL LABELING AND ADVERTISEMENTS GUIDANCE FOR INDUSTRY (Dec. 2023), https://www.fda.gov/media/169803/download.

[73] *Id*. (emphasis added).

[74] *Id*.

[75] U.S. FOOD AND DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: PRESENTING RISK INFORMATION IN PRESCRIPTION DRUG AND MEDICAL DEVICE PROMOTION (May 2009) https://www.fda.gov/media/76269/download (emphasis in original).

[76] U.S. FOOD AND DRUG ADMIN., *Drug Advertising: A Glossary of Terms*, (Jan. 19, 2020) https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms.

For example, in the FDA Evidence Based User 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."[77]

102. 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."[78]

103. 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 prescriber to prescribe an FDA-approved drug for an off-label use but it is illegal to market those

[77] BARUCH FISCHOFF ET AL, U.S. FOOD AND DRUG ADMIN., COMMUNICATING RISK AND BENEFITS: AN EVIDENCE BASED USER'S GUIDE, (Aug. 2011), https://www.fda.gov/files/about%20fda/published/Communicating-Risk-and-Benefits---An-Evidence-Based-User%27s-Guide-%28Printer-Friendly%29.pdf.

[78] U.S. FOOD AND DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: COMMUNICATIONS FROM FIRMS TO HEALTH CARE PROVIDERS REGARDING SCIENTIFIC INFORMATION ON UNAPPROVED USES OF APPROVED/CLEARED MEDICAL PRODUCTS, (Oct. 2023), https://www.fda.gov/media/173172/download.

drugs for such off-label use. Promoting or advertising a drug for anything other than its FDA-approved use, is illegal "misbranding."[79] 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.

104. It is recognized that off-label marketing can harm patients, third-party payors, competitor manufacturers, and researchers and clinicians in multiple ways.[80] This includes the exposure to adverse side effects from drugs that have not been adequately tested for safety and effectiveness in treatment of a particular condition.[81] This can occur when the off-label promotion taps a market demand without spending the time or money to fully study the safety and efficacy in that population.[82]

2. Methods of Pharmaceutical Marketing

105. Pharmaceutical marketing is a sophisticated industry that follows well-established practices. It is typically a well-integrated process, where both patients and physicians 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.

106. "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

[79] Van Norman GA, *Off-Label Use vs Off-Label Marketing: Part 2: Off-Label Marketing-Consequences for Patients, Clinicians, and Researchers*, 8 JACC BASIC TRANSL SCI. 359-370, (2023).
[80] *Id*.
[81] *Id*.
[82] *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.[83]

107. "Unbranded" campaigns typically contain "help-seeking" advertisements or "disease-state awareness" materials. Unlike branded promotion, it is not regulated by the FDA.[84] Consumer-facing unbranded materials generally 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. 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.[85] Physician-facing unbranded materials provide ostensibly neutral scientific information about diseases and various approaches to treating them without specifically calling for the use of a manufacturers drug.

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

109. 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.

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[83] U.S. FOOD AND DRUG ADMIN., *The Bad Ad Program* (Dec. 12, 2024) https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program.

[84] U.S. FOOD AND DRUG ADMIN., *Basics of Drug Ads*, (June 19, 2015) https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads.

[85] Beth Snyder Bulik, *Unbranded pharma ads—what are they good for? Actually quite a bit, marketing panelists say,* FIERCE PHARMA (Mar. 11, 2018), https://www.fiercepharma.com/marketing/unbranded-pharma-ad-what-are-they-good-for-actually-quite-a-bit-marketer-panelists-say.

110. Defendants utilize an "omnichannel" marketing scheme, which collects and collates data across promotional "channels" to optimally target health care providers and potential customers.

111. 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."[86]

112. Novo continues their use of big data and machine learning to create highly effective, targeted marketing campaigns today.[87] This includes 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.[88]

G. DEFENDANTS' EXTENSIVE AND MULTIFACETED MARKETING AND PROMOTION OF GLP-1 RAs, INCLUDING WEGOVY

113. After Novo saw the 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 the weight loss effects of their diabetes drug, Novo sought to fundamentally change the paradigm that doctors and insurers applied to weight-loss treatments.

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[86] Matthew Arnold, *Patient Marketing Report: From A1C to Z*, MED. MARKETING AND MEDIA (Aug. 31, 2012), https://www.mmm-online.com/home/channel/features/patient-marketing-report-from-a1c-to-z/.

[87] *Hyperright AB*, Utilizing Advanced Marketing Analytics for Sales Optimization – Peter Vester, Novo Nordisk, YOUTUBE (Dec. 22, 2022), https://www.youtube.com/watch?v=nCZR6wK7MlU.

[88] *Id.*

114. Before Novo's weight loss drugs hit the market and it began to intervene in the practice of medicine, lifestyle modification (i.e. diet and exercise) and bariatric surgery were considered the standard of care treatments for weight loss and no insurance provider, including Medicare, would reimburse for weight-loss drugs. Obesity itself was generally not understood to be a disease.

115. In 2013 however, the American Medical Association ("AMA"), with the support of various advocacy organizations funded by Defendants, voted to recognize obesity as a disease state requiring treatment and prevention. This reclassification as a disease opened medical professionals up to considering pharmaceuticals as a possible treatment and opened insurers up to the possibility of reimbursing for that treatment.

116. Novo began re-orienting its business around weight-loss drugs in 2012, with its annual investment report listing "establish presence in obesity" as a strategic focus area. [89] It has continued to re-affirm this commitment through subsequent years, stating its intention to change the perception and treatment of obesity.[90] In 2019, Novo wrote that its mission was to "change how the world sees people with obesity and make obesity a healthcare priority"[91] and projected

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[89] NOVO NORDISK, NOVO NORDISK ANNUAL REPORT, (2012) https://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2012.pdf.

[90] NOVO NORDISK, NOVO NORDISK ANNUAL REPORT, (2019), https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2020/Novo-Nordisk-Annual-Report-2019.pdf; *see also* NOVO NORDISK, NOVO NORDISK ANNUAL REPORT 28-29 (2015) 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 ensure obesity is recognized as a disease); NOVO NORDISK, NOVO NORDISK ANNUAL REPORT 26-27 (2018), https://www.novonordisk.com/content/dam/nncorp/global/en/about-us/pdfs/corporate-governance/annual-general-meetings/agm2019/uk/annual-report-2018.pdf (Novo committed to "making obesity a healthcare priority").

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

growth of the weight-loss drug market from approximately 15 million to 24 million patients.[92]

117. The company has positioned itself as leader in the weight management space. One analysis found that "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, [Novo] became the most influential spokespeople in the whole obesity debate. . . ."[93]

118. 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.[94] Saxenda, however, required daily injections and its effects on weight loss were modest.

119. In an effort to find ways to make a longer-lasting, more convenient, and thus marketable, weight loss drug, Novo experimented with related molecules. It ultimately brought a related compound, semaglutide, to market in 2017 under the brand name Ozempic. This medicine only needed to be injected once a week, making it much more appealing to consumers.

120. Even though it was only approved for diabetes, Novo sought to maximize its profits from Ozempic by turning it into an obesity drug. If Novo could firmly associate its drug with weight loss, and obtain regulatory approval for that indication, it 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 as a diabetes medication.

121. 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

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[92] *Id.*

[93] Maya Koleva, *Novo Nordisk changed the obesity debate. But its reputation is on the line*, COMETRIC (Mar. 13, 2024), https://commetric.com/2024/03/13/novo-nordisk-changed-the-obesity-debate-but-its-reputation-is-on-the-line/.

[94] Gina Kolata, *We Know Where New Weight Loss Drugs Came From, but Not Why They Work*, NY TIMES (Aug. 17, 2023), https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.

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.

122. 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 pushing in its place a pharmaceutical intervention as the primary treatment option.

123. Novo invested billions in marketing Ozempic and its other GLP-1 RAs to push them into the cultural zeitgeist and position them as wonder drugs for weight loss. Although Wegovy was approved for weight loss in 2021, much of Defendants' marketing of their GLP-1RA drugs included off-label marketing, pushing drugs for weight loss when it was never approved for such an indication.

124. 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 drugs. Therefore, Novo invested millions to ensure that potential customers had easy access to its drugs. For example, Novo first partnered with and then directly invested in well-known telemedicine company Noom, ensuring that consumers could purchase Ozempic and other GLP-1 RAs 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.

125. Sales of Novo's GLP-1 RAs Ozempic and Wegovy grew exponentially in 2022 and 2023, resulting in shortages. 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.[95] The number of prescriptions 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.[96] In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.[97] The latest data shows that between January 2021 and December 2023 prescriptions for semaglutide soared over 442%.[98] A 2024 study found that 1 in 8 adults in the United states has taken Ozempic or another GLP-1RA drug.[99]

126. 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) to 42 billion DKK ($6.1 billion) 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

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[95] Bob Woods, *Big pharma's blockbuster obesity drug battle is just getting started, and it's headed for $100 billion*, CNBC (Sept. 9, 2023), https://www.cnbc.com/2023/09/09/big-pharma-blockbuster-obesity-drug-battle-is-headed-for-100-billion.html.

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

[97] 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*, WASH. POST (June 12, 2023), https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance.

[98] Sara Chernikoff, *Who gets Ozempic? People with private insurance and generous health plans, study shows*, USA TODAY (Aug. 7, 2024), https://www.usatoday.com/story/news/health/2024/08/07/ozempic-semaglutide-access-insurance-study/74692296007/.

[99] Diedre McPhillips, *1 in 8 adults in the US has taken Ozempic or another GLP-1 drug, KFF survey finds*, CNN (May 10, 2024), https://www.cnn.com/2024/05/10/health/ozempic-glp-1-survey-kff/index.html.

establish obesity as a serious chronic disease."[100]

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

127. Obesity and overweight are conditions related to excessive body fat. Both of these conditions are defined by convention by a measurement known as Body Mass Index ("BMI"), a calculation of weight as a factor of height that is reduced to a single number. The cutoffs for obesity and overweight are 30 and 25, respectively.[101] These specific numbers are largely arbitrary, and as recently as 1997 the cutoff for overweight was moved from 27 to 25 following the vote of a panel convened by the National Institutes of Health, making millions of people overweight overnight.[102]

128. The single-number definition of obesity is itself controversial, as BMI fails to account for the variables in fat kind and distribution that are of particular importance in characterizing an individual person's health risks.[103]

129. As discussed above, prior to 2013 obesity was not widely thought to be a disease. When the AMA took up the issue, it commissioned a report from its Committee on Science and Public Health. The committee concluded that labeling obesity a disease would "hurt patients, creating even more stigma around weight and pushing people into unnecessary—and ultimately

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[100] *See* NOVO NORDISK, OBESITY CARE, NOVO NORDISK CAPITAL MARKETS DAY PRESENTATION at 8 (Mar. 7, 2024), https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/cmd/2024/P5-Obesity-Care.pdf.

[101] CDC, ADULT BMI CATEGORIES (March 19, 2024), https://www.cdc.gov/bmi/adult-calculator/bmi-categories.html.

[102] Harriet Brown, *How Obesity Became a Disease: And, as a consequence, how weight loss became an industry*, THE ATLANTIC (Mar. 24, 2014), https://www.theatlantic.com/health/archive/2015/03/how-obesity-became-a-disease/388300/.

[103] Rachel Pray & Suzanne Riskin, *The History and Faults of the Body Mass Index and Where to Look Next: A Literature Review*, CUREUS (Nov. 3, 2023).

useless—'treatments.'" It also correctly predicted that medicalizing obesity would lead to a growth in expensive pharmaceutical treatments for obesity and the pursuit of a single number determinant of health, i.e. body weight and BMI.[104]

130. Nonetheless, the AMA voted to characterize obesity as a disease.[105]

131. 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.'"[106]

132. Traditionally, obesity treatment involved lifestyle interventions including improving diet, increasing exercise, improving sleep, and addressing the underlying factors contributing to over-eating. Bariatric surgeries also have decades of evidence for their efficacy and the risks are correspondingly well understood.

133. 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 and surgical approaches to obesity.

134. For example, one unbranded DTC video created by Novo 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."[107]

135. Another unbranded Novo DTC campaign – "Truth about Weight" – features a

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[104] AMERICAN MEDICAL ASSOCIATION COMMITTEE ON SCIENCE AND PUBLIC HEALTH, *Is Obesity a Disease?*, CSAPH Report 3-A-13 (2013), https://web.archive.org/web/20150612122934/https://www.ama-assn.org/assets/meeting/2013a/a13-addendum-refcomm-d.pdf.

[105] Harriet Brown, *How Obesity Became a Disease: And, as a consequence, how weight loss became an industry*, THE ATLANTIC (Mar. 24, 2014), https://www.theatlantic.com/health/archive/2015/03/how-obesity-became-a-disease/388300/

[106] Julia Belluz, *Are We Thinking About Obesity All Wrong?*, NY TIMES (Sept. 19, 2024), https://www.nytimes.com/2024/09/19/opinion/obesity-disease-ozempic-weight-loss.html.

[107] Novo Nordisk, *WOD 2022 Time for a new approach*, YOUTUBE (Mar. 4, 2024), https://www.youtube.com/watch?v=sPrhwdl-xE8.

series of videos portraying overweight individuals eating health foods and exercising while expressing their disappointment as they fail to lose weight, while explicitly stating that "long term health goes beyond dieting" and "exercise alone may not be enough for you," before concluding with the individuals visiting doctors for help. [108]

136. Obtaining acceptance from insurance payors, particularly Medicare, was necessary to grow the obesity medication market and a key driver in Novo's large expenditures on lobbying. Novo recognized that they needed to lobby to expand Medicare coverage.[109] Novo's 2019 Capital Days presentation called for "engaging with a broad range of coalition partners" to advocate for obesity care and Medicare coverage.[110]

137. In sum, Defendants took the public debate about "obesity as a disease" and expanded that to advocate for the best treatment for that disease being a pharmaceutical intervention because traditional treatments, i.e. lifestyle improvement and exercise, are simply insufficient for most people.

138. 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 as contributing to weight loss even though the drug was not approved for that indication. They targeted marketing in various forums, including social media, to vulnerable groups who would be prone to weight loss messages

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[108] Novo Nordisk, *Truth About Weight - NYE22 – Diet*, YOUTUBE (Jan. 19, 2023), https://youtu.be/7UYDWmaQmV4?si=7QAlsBrba4igXoCK; Novo Nordisk, *Truth About Weight - NYE22 – Exercise*, YOUTUBE (Jan. 19, 2023), https://www.youtube.com/watch?v=kcc4VFV_2gw&list=PL3xIWWD6Vj9oba3TRoYtNUoznFH6E83iL&index=2.

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

[110] *Id*.

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 regained some or all of the weight, they would actually be less healthy than they were when they started.

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

139. Defendants engaged in a multipronged approach to control and manipulate the universe of knowledge around GLP-1 RAs and obesity treatment including 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

140. There is strong evidence that doctors prescribe more of a drug when they receive money from a pharmaceutical company linked to that drug.[111] Defendants made voluminous direct payments to physicians, which are recorded in the Open Payments database maintained by the U.S.

[111] Hannah Fresques, *Doctors Prescribe More of a Drug If They Receive Money from a Pharma Company Tied to It*, PROPUBLICA (Dec. 20, 2019), https://www.propublica.org/article/doctors-prescribe-more-of-a-drug-if-they-receive-money-from-a-pharma-company-tied-to-it (including quotes from Novo Nordisk).

Centers for Medicare and Medicaid Services.[112]

141. Between 2018 and 2023, Novo made approximately $153 million in general payments to doctors, including marketing, consulting, travel and meals. Payments totaled $27.9 million in 2018, $26.8 million in 2019, $15.2 million in 2020, $27.3 million in 2021, $33.9 million in 2022 and $21.9 million in 2023. [113] In 2022 alone, Novo purchased over 450,000 meals for doctors.[114]

142. Over the past decade, at least 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.[115]

143. Critically, Reuters examined payments to experts involved in crafting five prominent sets of clinical guidelines for obesity treatment. Among the 109 authors and reviewers credited in the guidelines, 53 had accepted cash or in-kind payments between 2013 and 2022 from

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

[113] U.S. CENTERS FOR MEDICARE & MEDICAID SERVICES, *Novo Nordisk, Inc.*, OPENPAYMENTSDATA, https://openpaymentsdata.cms.gov/company/100000000144 (accessed Jan. 16 2025).

[114] John LaMattina, *Fattening Doctors To Promote Weight Loss Drugs*, FORBES (July 20, 2023) https://www.forbes.com/sites/johnlamattina/2023/07/20/fattening-doctors-to-promote-weight-loss-drugs/; Nicholas Florko, *Novo Nordisk bought prescribers over 450,000 meals and snacks to promote drugs like Ozempic*, STAT (July 5, 2023) https://www.statnews.com/2023/07/05/ozempic-rybelsus-novo-nordisk-meals-for-doctors.

[115] Chad Terhune & Robin Respaut, *Maker of Wegovy, Ozempic showers money on U.S. obesity doctors*, REUTERS (Dec. 1, 2023), https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/.

companies that were selling or developing obesity drugs.[116]

144. Novo was responsible for almost three quarters of all pharmaceutical industry payments (excluding those related directly to research) received by this influential group of physicians.[117]

b. Key Opinion Leaders ("KOLs")

145. A key opinion leader ("KOL") is a trusted 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 KOLs a centerpiece of their influence strategy.

146. For instance, Dr. Fatima Cody Stanford is an obesity specialist that frequently speaks on behalf of Novo, is featured on Novo's website, and has received payments directly from Novo.[118] Upon information and belief, Dr. Stanford is one of Novo's highest paid KOLs.[119]

147. Dr. Stanford promoted the safety and efficacy of GLP-1 RAs when she was interviewed by 60 Minutes in 2023.[120] She also stated that obesity is a "brain disease" and that diet and exercise are insufficient for most people to lose weight.[121] Physicians Committee for

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[116] *Id*.

[117] *Id*.

[118] U.S. CENTERS FOR MEDICARE & MEDICAID SERVICES, *Fatima C. Stanford*, OPENPAYMENTSDATA, https://openpaymentsdata.cms.gov/physician/807348 (last accessed on Sept. 18, 2023); Mark Materacky, *Changing the mindset around obesity*, NOVO NORDISK https://web.archive.org/web/20231025171334/https://www.novonordisk-us.com/about/perspectives/changing-the-mindset-around-obesity.html (last accessed Jan. 16, 2025).

[119] Melissa Suran, *As Ozempic's Popularity Soars, Here's What to Know About Semaglutide and Weight Loss*, 329 JAMA 1627-1629 (2023).

[120] 60 Minutes, *Promising new weight loss medication in short supply and often not covered by insurance*, YOUTUBE (Jan. 2, 2023), https://www.youtube.com/watch?v=DMRnDNhPwqM.

[121] *Id*.

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 had received significant payments from Novo.[122] Dr. Stanford also appeared on Oprah discussing obesity and promoting obesity drugs in September of 2023.[123] Her financial ties to Novo were not fully disclosed during these appearances and not mentioned at all with respect to her appearance on Oprah.

148. 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 is included on Novo's website where she argues that access to Novo's weight-loss drugs is an issue of equity and disparity for communities of color.[124] Again, the full financial relationship between Dr. Stanford and Novo is not disclosed on Novo's website.

149. Similarly, Novo has 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 was previously the head of the Obesity, Metabolism and Nutrition Institute at Massachusetts General Hospital and a professor at Harvard Medical School. This makes him an influential KOL for Novo, which paid him approximately $1.4 million between 2013 and 2022.[125]

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[122] PHYSICIAN'S COMMITTEE FOR RESPONSIBLE MEDICINE, *CBS's 60 Minutes News Segment Was an Unlawful Weight Loss Drug Ad, Physicians' Complaint Alleges* (Jan. 19, 2023), https://www.pcrm.org/news/news-releases/cbs-60-minutes-news-segment-was-unlawful-weight-loss-drug-ad-physicians.

[123] Melissa Suran, As Ozempic's Popularity Soars, Here's What to Know About Semaglutide and Weight Loss, 329 JAMA 1627-1629 (2023).

[124] Mark Materacky, *Changing the mindset around obesity*, NOVO NORDISK https://web.archive.org/web/20231025171334/https://www.novonordisk-us.com/about/perspectives/changing-the-mindset-around-obesity.html (last accessed Jan. 16, 2025).

[125] Chad Terhune & Robin Respaut, *Maker of Wegovy, Ozempic showers money on U.S. obesity doctors* (Dec. 1, 2023), https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/.

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

150. Defendants contribute to numerous influential advocacy groups, either directly or through payments to their members, to influence medical and public opinion regarding obesity as a "disease," the treatment for obesity, and the safety and efficacy of GLP-1 RAs. These include The Obesity Society, The Obesity Action Coalition, Obesity in Action Coalition, American Board of Obesity Medicine, and Stop Obesity Alliance.

151. The Obesity Society bills itself as "the leading professional society focused on obesity science, treatment and prevention" and has over 2,800 members worldwide.

152. Dr. Donna Ryan, former President of the Obesity Society, was instrumental in persuading the U.S. Office of Personnel Management to cover Wegovy and similar drugs for millions of federal workers.[126] She accepted more than $1 million from Novo over the last decade, including $600,691 in payments related to Wegovy and Saxenda.[127]

153. The current President, Dr. Jamy Ard, is overseeing the group's effort to write new practice guides for primary care doctors that cover Wegovy and similar therapies.[128] Dr. Ard has accepted more than $200,000 from Novo.[129]

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

155. 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.[130]

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[126] *Id.*
[127] *Id.*
[128] *Id.*
[129] *Id.*
[130] NOVO NORDISK, NOVO NORDISK ANNUAL REPORT at 28(2015),

156. Novo contributes more than $100,000 to the OAC annually.[131] It is "a long-time supporter" of OAC and routinely renews their support of OAC's Chairman's Council at the Platinum level.[132]

157. Novo provided financial backing to the OAC "Your Weight Matters" campaign that provided potential patients with information about weigh loss drugs.

158. In 2012, Robert Kushner served on the Board of Directors for the OAC.[133] The same year, ahead of the vote by the AMA to classify obesity as a disease, Dr. Kushner published an influential article in the American Heart Association's medical journal arguing that obesity should be classified as a disease.[134] Dr. Kushner received funding from Novo for his research between 2008 and 2012[135] and has served as a member of Novo's Medical Advisory Board since 2016.[136]

159. Dr. Kushner was also the lead author on the Guidelines for the Management of Overweight and Obesity in Adults published in 2013 and backed by American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic and Bariatric

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https://www.novonordisk.com/content/dam/Denmark/HQ/Commons/documents/Novo-Nordisk-Annual-Report-2015.PDF.

[131] *Corporate Council*, OBESITY ACTION COALITION, https://www.obesityaction.org/corporate-partners/ (last accessed Sept. 18, 2023).

[132] *Novo Nordisk Renews Support for OAC Chairman's Council at Platinum Level*, OBESITY ACTION COALITION (April 1, 2023), https://www.obesityaction.org/novo-nordisk-renews-support-for-oac-chairmans-council-at-platinum-level/.

[133] Robert F. Kushner, *Clinical assessment and management of adult obesity*, 126 CIRCULATION 2870 (2012).

[134] *Id*.

[135] Michael D. Jensen, *Executive Summary: Guidelines (2013) for the Management of Overweight and Obesity in Adults*, 22, Suppl. 2 OBESITY S5 (2014).

[136] *Faculty Profile: Robert F. Kushner, M.D.*, NORTHWESTERN MEDICINE, https://www.feinberg.northwestern.edu/faculty-profiles/az/profile.html?xid=11686 (last accessed Jan. 17, 2025).

Surgery.[137] Both committee co-chairs responsible for the guidelines and five additional committee members had received funding from Novo.[138]

160. Since 2017, Novo has paid Dr. Kushner at least $423,000 for this work, including nearly $170,000 for his STEP study.[139] Lilly reported paying him $2,500 for consulting work in 2023, the last year the data is publicly available.[140] That number is likely to increase given the company's more recent expansion within the anti-obesity medication industry. He also consults for WeightWatchers and serves as part of its scientific advisory board, which has overseen the company's transition to offering GLP-1s to its members.[141] He has also offered comments for WeightWatchers materials on using GLP-1RAs intended for members and prospective patients.[142]

161. The American Board of Obesity Medicine is a professional credentialing organization for the practice of obesity medicine. Its purpose 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."

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[137] 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, Suppl. 1 OBESITY S1 (2013).

[138] Michael D. Jensen, *Executive Summary: Guidelines (2013) for the Management of Overweight and Obesity in Adults*, 22, Suppl. 2 OBESITY S5 (2014).

[139] U.S. Centers for Medicare & Medicaid Services, *Robert Kushner*, OPENPAYMENTSDATA, https://openpaymentsdata.cms.gov/physician/61175 (last accessed Jan. 17, 2024).

[140] *Id.*

[141] *WeightWatchers® Scientific Advisory Board*, WEIGHTWATCHERS (Nov. 16, 2016) https://www.weightwatchers.com/us/science-center/scientific-advisory-board;

Robert Kushner, ICMJE Form for Disclosure of Potential Conflicts of Interest (Dec. 12, 2015), https://www.nejm.org/doi/suppl/10.1056/NEJMclde1515935/suppl_file/nejmclde1515935_disclosures.pdf.

[142] Deanna Pai, *GLP-1 agonists: Overview, how they work, and more*, WEIGHTWATCHERS (February 8, 2023), https://www.weightwatchers.com/us/blog/weight-loss/glp-1-for-weight-loss.

162. Rekha Babu Kumar, former Director of ABOM, received payments totally tens of thousands of dollars from Novo during her tenure.[143] She has also promoted GLP-1 RAs for weight loss as part of a telehealth company and continues to receive payments.[144]

163. At least one member of the ABOM Guidelines committee received payments directly from Novo during his tenure.[145]

164. ABOM lists public health "partners" on their website.[146] Novo is itself financially involved with many of these groups: (1) OAC (discussed above); (2) American Society for Metabolic and Bariatric Surgery;[147] and (3) Stop Obesity Alliance.[148]

165. Stop Obesity Alliance operates out of George Washington University's Milken Institute School of Public Health and advocates for insurance coverage and expanded pharmaceutical obesity treatment.

166. Novo is a corporate sponsor of Stop Obesity Alliance.

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[143] *Weight loss medication isn't cheating. It's science.*, FOUND, https://joinfound.com/pages/medication-biology (last accessed Sept. 18, 2023); U.S. Centers for Medicare & Medicaid Services, *Rekha Kumar*, OPENPAYMENTSDATA, https://openpaymentsdata.cms.gov/physician/1294300 (last accessed Sept. 18, 2023); *Rekha Kumar, M.D, M.S.*, LINKEDIN, https://www.linkedin.com/in/rekha-kumar-m-d-m-s-70b481237/ (last accessed Sept. 18, 2023).

[144] *5 Things to know about personalized weight loss from a goop podcast with Found's Dr. Rekha Kumar*, FOUND (Dec. 31, 2024), https://joinfound.com/blog/5-things-to-know-about-weight-loss-from-a-goop-podcast-with-found?srsltid.

[145] U.S. Centers for Medicare & Medicaid Services, *Karl Zahlmann Nadolsky*, OPENPAYMENTSDATA, https://openpaymentsdata.cms.gov/physician/1379381 (last accessed Sept. 18, 2023); *see also Meet the Diplomate: Karl Nadolsky, DO*, AMERICAN BOARD OF OBESITY MEDICINE https://www.abom.org/karl-nadolsky/ (last accessed Jan. 17, 2025).

[146] *American Board of Obesity Medicine*, AMERICAN BOARD OF OBESITY MEDICINE, https://www.abom.org/ (last accessed Sept. 18, 2023).

[147] *Corporate Council*, AMERICAN SOCIETY FOR METABOLIC AND BARIATRIC SURGERY, https://asmbs.org/corporate-council (last accessed Sept. 18, 2023).

[148] *Membership*, STOP OBESITY ALLIANCE, https://stop.publichealth.gwu.edu/membership (last accessed Sept. 18, 2023).

167. All About Obesity is another advocacy group pushing for treatment services for those living with obesity.[149]

168. Both board members receive funding for grants, consulting, or speaking from Novo.[150] Novo went on and partly funded the creation of the website in 2021.

169. In addition, Novo is financially involved with the American Association of Clinical Endocrinologists,[151] the Endocrine Society,[152] and the American College of Cardiology.[153]

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

170. Defendants recognized that, historically, physicians were reluctant to prescribe weight loss medication. 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.[154] Novo concluded that their 10-year plan to establish a leading position within treatment for obesity "starts by educating doctors."[155]

171. Defendants operate comprehensive, integrated education for health care providers that consistently reinforces the idea that obesity is a disease and advocates for pharmaceutical interventions.

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[149] *About Us*, ALL ABOUT OBESITY, https://allaboutobesity.org/about-us/ (last accessed Jan. 17, 2025).

[150] *Declaration of Interests*, ALL ABOUT OBESITY, https://allaboutobesity.org/declaration-of-interests/ (last accessed Jan. 17, 2025).

[151] *Corporate AACE Partnership*, AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGY, https://pro.aace.com/about/corporate-aace-partnership-cap (last accessed Oct. 17, 2024).

[152] *Partner With Us*, ENDOCRINE SOCIETY (Feb. 13, 2024), https://www.endocrine.org/partnerships.

[153] *Industry Advisory Forum*, AMERICAN COLLEGE OF CARDIOLOGY, (Nov. 2024), https://www.acc.org/About-ACC/Industry-Relations/corporate-advisory

[154] NOVO NORDISK, NOVO NORDISK ANNUAL REPORT at 28 (2015), https://www.novonordisk.com/content/dam/Denmark/HQ/Commons/documents/Novo-Nordisk-Annual-Report-2015.PDF.

[155] *Id*.

172. Novo offers robust continuing medical education through its website "Rethinking Obesity." One of the first training modules available is one entitled "Virtual Obesity Clinics Programme," which promises that physicians will learn "how to introduce virtual patient consultations and best practices into an existing obesity clinic model."[156]

173. In addition to the educational materials available directly from Defendants, they also fund education produced by other organizations. For instance, Novo provides "independent" educational grants to Medscape to subsidize free electronic CME on obesity and weight management to U.S. physicians.[157]

174. Defendants also sponsor presentations at industry and academic conferences on the topic of obesity. Recently, Novo also held an "unbranded" symposium discussing the need for increased care and insurance coverage in obesity.[158] Novo is a sponsor of the "Obesity Care Week" Conference in the United States[159] that advocates for "clinically-based care" for obesity, which primarily consists of GLP-1 RAs.

e. Defendants Influence Medical Research and Literature

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

176. Novo has sponsored many publications related to weight management since 2013:

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[156] *Obesity eCME and medical education – A comprehensive collection*, RETHINK OBESITY, https://www.rethinkobesity.global/global/en/resources/ecme-and-medical-education.html (last accessed Jan. 17, 2025).

[157] *Id.*

[158] NOVO NORDISK, DRIVING CHANGE IN OBESITY CARE: A MULTI-STAKEHOLDER PERSPECTIVE ON THE VALUE OF NON-INVASIVE INTERVENTIONS (May 9, 2023), https://www.ispor.org/docs/default-source/intl2023/novo-nordisk-presentation.pdf?sfvrsn=3179cf91_0.

[159] *Partners*, OBESITY CARE WEEK, https://www.obesitycareweek.org/partners/ (last accessed Jan. 17, 2025).

- On April 1, 2013, Holly R. Wyatt published an "update on Treatment Strategies for Obesity" in the Endocrine Society Journal and disclosed a financial grant from Novo.[160]

- On October 24, 2017, University of Leeds researchers called semaglutide an "anti-obesity drug" after Novo funded their research on appetite control.[161]

- In 2021, Novo funded research regarding the genetics of obesity.[162]

- Novo has also funded research regarding the pervasiveness, impact, and implications of weight stigma.[163]

- 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.[164]

- 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."[165] This academic steering committee had received over $7.5 Million dollars in payments from Novo between 2015-2022.[166]

- In May of 2013, American Association of Clinical Endocrinologists released Consensus Statement on "Comprehensive Diabetes Management Algorithm" that mentions obesity fifty (50) times; 12 of 19 authors had ties to Novo or to Eli Lilly, another GLP-1RA manufacturer.[167]

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[160] Holly R. Wyatt, *Update on Treatment Strategies for Obesity*, 98 J. CLINICAL ENDOCRINOLOGY & METABOLISM 1299 (2013).

[161] *Anti-obesity drug acts on brain's appetite control system,* UNIV. OF LEEDS (Oct. 24, 2017), https://www.leeds.ac.uk/news-health/news/article/4122/anti-obesity-drug-acts-on-brain-s-appetite-control-system.

[162] Ruth J. F. Loos & Giles S. H. Yeo, *The genetics of obesity: from discovery to biology*, 23 NATURE REVIEWS GENETICS 120 (2022).

[163] Adrian Brown, *Pervasiveness, impact and implications of weight stigma*, ECLINICALMEDICINE (Apr. 21, 2022).

[164] *Obesity resources for physicians and patients*, RETHINK OBESITY, https://www.rethinkobesity.global/content/rthkobesity/global/en/resources/obesity-resources-for-physicians-and-patients.html (last accessed Jan. 17, 2025).

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

[166] *Id*.

[167] Alan J. Garber, *American Association of Clinical Endocrinologists' comprehensive diabetes management algorithm 2013 consensus statement*, 19, Suppl. 2 ENDOCR PRACT. 1 (2013).

- In May of 2013, Novo, among others, provided grants to a working group that published an important clinical guideline with the American Diabetes Association and Endocrine Society.[168]

- Novo paid personal fees to the author of the study "Influence and effects of weight stigmatization in the media."[169] Novo has separately funded the Joint International Consensus Statement for ending the Stigma of Obesity.[170]

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

177. The cost of Defendants' GLP-1RA drugs – Wegovy for instance costs approximately $1,350/month – presents a significant barrier to widespread adoption of the drugs.

178. In order to achieve mass adoption of GLP-1RA drugs and maximize their profit potential, Novo sought to have them added to the Medicare formulary. 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 provide similar coverage.[171]

179. Unfortunately for Defendants, drugs used for weight loss were excluded by Congress when it established Medicare's Part D prescription drug benefit in 2003.[172]

180. Defendants therefore spent millions of lobbying for changes in the law. A primary focus of that lobbying is the proposed Treat and Reduce Obesity Act, which would require

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[168] Elizabeth R. Seaquist, et al., *Hypoglycemia and diabetes: a report of a workgroup of the American Diabetes Association and the Endocrine Society*, 98 J. CLIN. ENDOCRINOL METAB. 1845 (2013).

[169] James Kite et al, *Influence and effects of weight stigmatisation in media: A systematic*, ECLINICALMEDICINE. (May 20, 2022).

[170] Francesco Rubino et al, *Joint international consensus statement for ending stigma of obesity*, 26 NATURE MEDICINE 485 (2020).

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

[172] *Id.*

Medicare to cover, among other treatments, chronic-weight-management drugs.[173]

181. From 2012 to 2023, Novo spent over $35 million on lobbying for obesity drug coverage:[174]

182. In 2021 Novo gave hundreds of thousands of dollars to the Congressional Black Caucus Foundation and has also contributed to the Congressional Hispanic Caucus and Congressional Asian Pacific American Caucus.[175] The Congressional Black Caucus, Congressional Hispanic Caucus and Congressional Asian Pacific American Caucus have all backed a bill on health disparities that would remove Medicare's prohibition on covering prescriptions for weight loss similar to the Treat and Reduce Obesity Act.[176]

183. 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,[177] and direct

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[173] Jia Tolentino, *Will the Ozempic Era Change How We Think About Being Fat and Being Thin?*, NEW YORKER (March 20, 2023), 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 (July 20, 2023), https://www.fiercepharma.com/pharma/novo-nordisk-eli-lilly-and-boehringer-get-behind-lawmakers-bill-enable-obesity-drug-coverage.

[174] *See, e.g.*, OPEN SECRETS, *Novo Nordisk*, https://www.opensecrets.org/orgs/novo-nordisk/lobbying (last accessed Jan. 17, 2025).

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

[176] *Id*.

[177] OBESITY CARE ADVOCACY NETWORK, TREAT AND REDUCE OBESITY ACT OF 2021 (TROA) FACT SHEET, https://assets.obesitycareadvocacynetwork.com/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0.pdf (last visited on Sept. 18, 2023).

contributions to political campaigns of various politicians.[178]

184. 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 boon 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."[179]

3. Defendants' Extensive Branded Advertising Has Changed Prescriber Behavior and Driven Up Demand by Ingraining Their Drugs in the Popular Culture

185. Once Novo recognized the significant potential of Ozempic, it employed an aggressive marketing approach to make its GLP-1 RAs household names.

186. 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."[180]

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

[179] *Cost of covering antiobesity drugs could be billions to Medicare despite, a new analysis finds*, VANDERBUILT UNIVERSITY MEDICAL CENTER (March 15, 2023), https://www.vumc.org/health-policy/medicare-antiobesity-medications-nejm.

[180] Phoebe Bain, *Ozempic was 2023's buzziest drug*, AD AGE (July 10, 2023),

187. The advertising blitz began on July 30, 2018 when Novo launched its first Ozempic television advertisement – "Magic" – that repeated the catchy phrase "Oh, oh, oh, Ozempic!" to the tune of the 1970s song "Magic." The jingle helped Ozempic become widely recognized. The ad also noted that "you may lose weight" and that "adults lost on average up to 12 pounds" even though Ozempic has never been approved for weight loss.[181]

188. From 2018 through 2023, Novo spent approximately $884 million on television advertising in the United States to promote Ozempic and later, its other semaglutide drugs Wegovy and Rybelsus.[182]

189. This massive spending ingrained Ozempic in pop culture. In 2022, Novo's "earned media coverage" (i.e. coverage it 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.[183]

190. Ozempic is ubiquitous in the culture. Jimmy Kimmel joked about Ozempic at the Oscars;[184] Howard Stern discussed it, noting that the "catchy" theme song "distracts" the listener,

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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 surge*, MEDICAL MARKETING AND MEDIA (September 29, 2023), https://www.mmm-online.com/home/channel/spending-on-ozempic-wegovy-surges/.

[181] *See Ozempic TV Spot, 'Oh!'*, ISPOT (July 30, 2018), https://www.ispot.tv/ad/d6Xz/ozempic-oh.

[182] *See* Ritzau, *Novo Nordisk runs TV ads in US for multimillion-dollar sum*, MEDWATCH (Apr. 26, 2023), https://medwatch.com/News/Pharma___Biotech/article15680727.ece.

[183] 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.

[184] Hannah Yasharoff, *Jimmy Kimmel joked about Ozempic at the Oscars. We need to actually talk about it*, USA TODAY (Mar. 13, 2023), https://www.usatoday.com/story/life/health-wellness/2023/03/13/ozempic-sweeping-hollywood-celebrities-weight-loss/11428801002/ (last

preventing them from actually hearing any of the listed side effects;[185] 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.[186]

191. This extensive marketing caused 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 indication. 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.

192. Defendants also created numerous marketing campaigns and online platforms designed to promote obesity as a disease and advocate for pharmaceutical treatment of obesity.[187]

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

194. Novo collected extensive data through quizzes and questionnaires taken by users of the websites. 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.

195. These websites were purportedly created to educate the general public about the

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accessed Sept. 17, 2023).

[185] The Howard Stern Show, *Howard Goofs on the Ozempic Commercial*, YOUTUBE (April 5, 2023), https://www.youtube.com/watch?v=QD-nCQn1Ads.

[186] Rachel Hosie & Amber Middleton, *Celebrities Can't Lose Weight Without People Speculating They're on Ozempic*, BUSINESS INSIDER (Aug. 14, 2024), https://www.insider.com/ozempic-celebrities-denied-semaglutide-wegovy-weight-loss-drugs-khloe-kardashian-2023-3#chelsea-handler-said-she-was-on-semaglutide-without-realizing-it-7.

[187] NOVO NORDISK, NOVO NORDISK ANNUAL REPORT at 28 (2018), https://www.novonordisk.com/content/dam/nncorp/global/en/about-us/pdfs/corporate-governance/annual-general-meetings/agm2019/uk/annual-report-2018.pdf.

science of obesity and change in how obesity is understood and treated,[188] including by suggesting that obesity is a chronic health condition that requires pharmaceutical drugs to manage.[189]

196. The "The Truth about Weight" website is specifically intended to target minority communities that have heightened rates of obesity. It has 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 members of these communities toward believing that pharmaceutical interventions are the only answer. The website also suggests pushing back against doctors: "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.[190]

197. 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.[191]

198. Novo had long been a proponent of using analytics to target and maximize sales.[192]

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[188] *Truth About Weight*, TRUTH ABOUT WEIGHT, https://www.truthaboutweight.com/ (last visited on Sept. 18, 2023).

[189] *It's Bigger than Me*, IT'S BIGGER THAN ME, https://www.itsbiggerthan.com (last accessed Sept. 18, 2023).

[190] *I'm Ready to Know the Science Behind Weight and the Impact Culture has on it*, TRUTH ABOUT WEIGHT (May 2024), https://www.truthaboutweight.com/understanding-excess-weight/my-weight-my-culture.html.

[191] Gina Kolata, *We Know Where New Weight Loss Drugs Came From, but Not Why They Work*, NY TIMES (Aug. 17, 2023), https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.

[192] *Hyperright AB*, Utilizing Advanced Marketing Analytics for Sales Optimization – Peter Vester, Novo Nordisk, YOUTUBE (Dec. 22, 2022), https://www.youtube.com/watch?v=nCZR6wK7MlU.

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.[193]

199. 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 of color who struggle with weight.) and Facebook can push a specifically calibrated advertisement out to that exact audience based on its data analytics and algorithm.[194] Instagram and other social media networks have similar features.

200. 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 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.[195] The organization warns parents that "[c]ompanies 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."[196]

201. It is recognized by the medical community that weight loss drugs may cause or

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

[194] Meta Ads, *Audience ad targeting*, META, https://www.facebook.com/business/ads/ad-targeting (last visiting Jan. 17, 2025).

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

[196] *Id.*

worsen eating disorders.[197] Adolescent girls are particularly susceptible to eating disorders.

202. As noted, Novo partnered directly with Meta to run marketing campaigns on Facebook and Instagram. One diabetes marketing campaign achieved 28% direct engagement rate, an unusually high rate for online advertising.[198]

203. Marketing on social media, including Instagram and TikTok, often uses hashtags, which are words or phrases preceded by the hash symbol ("#") that categorize and track content. Hashtags can be appended to posts to make them more searchable and help users find related content. It can also help brands reach their target audience and optimize the brand's reach.

204. Novo's hashtags and campaigns such as #Ozempic, #wegovyweightloss, #ozempicjourney all had hundreds of millions of views across multiple platforms.

205. Novo sponsored an "Ask Me Anything" session on Reddit, a popular forum akin to a digital town hall where users can ask questions and receive responses directly through the web forum. The AMA was hosted by medical doctor with a specialty in weight management. She offered dozens of responses to users, including the suggestion that "eating and physical activity are essential for many people, they may not be enough to keep weight off," which implies that some people may need medication in order to lose weight.[199]

206. These social media campaigns can also be used to facilitate engagement with the Defendants' website. For example, the hashtag #ItsBiggerThan, was an advertising campaign on

[197] Liz Szabo, Marina Kopf & Akshay Syal, *Weight loss drugs like Wegovy may trigger eating disorders in some patients, doctors warn*, NBC NEWS (July 31, 2024), https://www.nbcnews.com/health/mental-health/eating-disorders-increase-weight-loss-drugs-wegovy-zepbound-rcna162124.

[198] *Novo Nordisk*, INSTAGRAM FOR BUSINESS, https://business.instagram.com/success/novo-nordisk (last visited Sept. 17, 2023).

[199] Tiffany Lowe-Clayton (u/itsbiggerthan_me), REDDIT (Dec. 6, 2022), https://www.reddit.com/user/itsbiggerthan_me/comments/xqn6q7/comment/iz5ocg1/.

Instagram ostensibly intended to educate the public about obesity and to change the conversation around weight stigma. This campaign was sponsored by It's Bigger Than Me, which in turn is funded largely by Novo. Paid influencers would use the hashtag, which would link back to Novo's website. #ItsBiggerThan was 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.

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

207. As set forth repeatedly above, Defendants consistently promoted their GLP-1 RAs for weight loss as part of their strategy to grow the market for weight loss drugs even before their GLP-1RA drugs were actually approved for weight loss, in violation of FDA regulations.

208. Ozempic has never been 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.

209. Novo was not permitted to market Ozempic for weight loss without FDA approval for that specific indication,[200] but before Wegovy ever received separate approval for treatment of weight loss, Novo had already begun mentioning weight loss in their Ozempic marketing, advertising, commercials and other promotional materials.[201]

[200] Gina Kolata, *We Know Where New Weight Loss Drugs Came From, but Not Why They Work*, NY TIMES (Aug. 17, 2023), https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.

[201] *Id.*

210. Novo's very first television ad for Ozempic touted that "adults lost on average up to 14 pounds" when taking Ozempic.[202]

211. The Ozempic website has likewise consistently touted weight loss:

- From 2018 to 2020: Novo's Ozempic.com claimed "[w]hile Ozempic is not for weight loss, you may also lose some weight."[203]
- From 2018 to 2019, Novo's OzempicPro.com homepage touted "Superior weight reduction."[204]
- From at least 2020 to 2021, Novo's OzempicPro.com also claimed superior weight reduction vs. Trulicity and Bydureon; plus "more than double the weight reduction for each dose comparison vs. Trulicity."[205]
- In 2020, Novo's OzempicPro.com homepage touted "significant weight

[202] *Ozempic TV Spot, 'Oh!'*, ISPOT (July 30, 2018), https://www.ispot.tv/ad/d6Xz/ozempic-oh.

[203] *Questions About Ozempic*, OZEMPIC, https://web.archive.org/web/20180820075728/https:/www.ozempic.com/FAQ/about-ozempic.html (archived Aug. 20, 2018).

[204] *Ozempic*, OZEMPIC FOR HEALTHCARE PROFESSIONALS, https://web.archive.org/web/20180826124503/https://www.ozempicpro.com/ (archived Aug. 6, 2018).

[205] *Ozempic—significant weight reductions in a once-weekly injectable*, OZEMPIC, https://web.archive.org/web/20201123163450/https://www.ozempicpro.com/a1c-and-weight/ozempic-and-weight.html (archived Nov. 23, 2020).

reduction" with a link to "Examine weight data."[206]

- In 2021, Novo's Ozempic.com said "Ozempic may help you lose some weight" and "Adults taking Ozempic lost on average up to 12 pounds."[207]
- In 2021, Novo's Ozempic.com said "People lost more than double the weight on Ozempic vs Trulicity."[208]
- From 2022 to 2024, Novo's Ozempic.com homepage said: "Discover the Ozempic Tri-Zone," the third zone was "Ozempic may help you lose some weight."[209]
- From 2022 to 2024, Novo's Ozempic.com, under "What is Ozempic?" said "Adults taking Ozempic lost up to 14 pounds."[210]
- From 2022 to 2024, Novo's Ozempic.com said "People lost more than double the weight on Ozempic vs. Trulicity."[211]
- From 2022 to 2024, Novo's Novomedlink.com touted the Ozempic "Tri-Zone" which lead to "compelling weight loss."[212]
- In 2023, Novo's Ozempic.com FAQs page added a new disclaimer: "At this time, Novo Nordisk has not conducted studies to evaluate the effect on weight after discontinuation of Ozempic."

212. Novo has also promoted weight loss in its public statements. For instance, the

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[206] *Ozempic*, OZEMPIC FOR HEALTHCARE PROFESSIONALS, https://web.archive.org/web/20210730195708/https://www.ozempicpro.com/ (archived July 30, 2021).

[207] *Ozempic*, OZEMPIC, https://web.archive.org/web/20211006213958/https:/www.ozempic.com/ (archived Oct. 6, 2021).

[208] *Id*.

[209] *Ozempic*, OZEMPIC, https://web.archive.org/web/20220808142658/https://www.ozempic.com/ (Archived Aug. 8, 2022).

[210] *What Is Ozempic®?*, OZEMPIC https://web.archive.org/web/20220818181119/https://www.ozempic.com/why-ozempic/what-is-ozempic.html (archived Aug. 18 2022).

[211] *Ozempic® vs Other Type 2 Diabetes Medicines*, OZEMPIC https://web.archive.org/web/20221003122256/https://www.ozempic.com/why-ozempic/diabetes-medicines-comparison.html (archived Oct. 3, 2022).

[212] *Ozempic*, NOVOMEDLINK, https://web.archive.org/web/20240919183819/https://www.novomedlink.com/diabetes/products/treatments/ozempic.html (archived Sep. 19, 2024).

March 28, 2022 press release announcing the approval of a higher dose of Ozempic, mentions that "[Ozempic] can help many patients lose some weight."[213]

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

213. On October 1, 2019, Novo announced a partnership with Noom, a leading telehealth platform, for "digital health solutions to help people with obesity lose weight and keep it off."[214]

214. Since 2021, Novo has been an investor in Noom.[215]

215. Noom Med, Noom's specialized weight loss service, provides prescriptions for GLP-1 RAs directly to patients.[216] Noom Med promotes off label usage of GLP-1 RAs on its website.[217] Noom currently has over 45 million users.[218]

216. Other telehealth providers mirrored Noom's approach offering prescriptions directly to consumers for GLP-1 RAs, including Weight Watchers, which currently has over 3.5

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[213] *See* 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), 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.

[214] *See* Novo Nordisk, *Novo Nordisk and Noom to partner around digital health solutions to help people with obesity lose weight and keep it off*, PR NEWSWIRE (Oct. 1, 2019), https://www.prnewswire.com/in/news-releases/novo-nordisk-and-noom-to-partner-around-digital-health-solutions-to-help-people-with-obesity-lose-weight-and-keep-it-off-811725389.html.

[215] *Noom*, NOVO HOLDINGS, https://novoholdings.dk/investments/noom/ (last accessed Jan. 16, 2025).

[216] Noom joins Weight Watchers in offering medications like Wegovy for weight loss: What to know, ABC News (June 5, 2023) https://abcnews.go.com/GMA/Wellness/noom-joins-weight-watchers-offering-medications-wegovy-weight/story?id=99841160.

[217] *Weight loss medication, the right way, with Noom*, NOOM, https://www.noom.com/med/ (last accessed Sept. 18, 2023).

[218] *Noom's big number moat: 45 million*, Exits & Outcomes (Nov. 15, 2021), https://exitsandoutcomes.com/free-excerpt-from-the-noom-report-a-45-million-moat/.

million subscribers[219] and Calibrate, which raised $100 million in capital funding from investors in 2021.

217. Collectively, telehealth providers accounted for approximately half of all weight loss prescriptions in 2022.[220]

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

219. 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."[221]

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

220. 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."[222]

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[219] WW International Inc., *WW International, Inc. Announces First Quarter 2023 Results*, (May 4, 2023), https://finance.yahoo.com/news/ww-international-inc-announces-first-200100340.html.

[220] Katie Palmer, Where are patients getting their prescriptions for GLP-1 drugs like Wegovy and Ozempic? (Aug. 10, 2023), https://www.statnews.com/2023/08/10/wegovy-ozempic-weight-loss-telehealth-prescriptions/.

[221] Omar 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.

[222] *See* Novo Nordisk, *Novo Nordisk Launches Ozempic and Fiasp, Expanding Treatment Options for Adults With Diabetes*, PR NEWSWIRE (Feb. 5, 2018),

221. Novo Nordisk has from time to time offered similar rebate programs for Wegovy, including a $300 discount coupon available on their website.[223]

222. These programs allowed patients to get on 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 GLP1-RA DRUGS AND DOWNPLAYED THESE RISKS IN THEIR UNPRECEDENTED MARKETING TO HEALTHCARE PROVIDERS AND PATIENTS

223. 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 reports, that there was reasonable evidence of a causal association between the use of GLP-1 RAs and the risk of developing NAION and its sequelae.

224. 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.

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

226. 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.

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https://www.prnewswire.com/news-releases/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment-options-for-adults-with-diabetes-300592808.html.

[223] NOVO NORDISK, *Ways to Save on Wegovy* (April 2025), https://www.wegovy.com/coverage-and-savings/save-on-wegovy.html.

227. 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.

228. 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 NAION and its sequelae.

229. Defendants were also obligated under 21 CFR §§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.

230. Defendants likewise violated 21 CFR § 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.

231. 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.

232. Defendants failed to warn doctors and consumers of these dangers, including the risk of NAION and its sequelae.

233. Defendants intentionally withheld from or misrepresented to the FDA post-approval information concerning their GLP-1 RAs that they were required to submit under the Federal Food, Drug, and Cosmetic Act. Had Defendants not withheld or misrepresented this information, the FDA would have recommended that Defendants add warnings relating to the risks

of the injuries suffered by Plaintiff.

234. Despite developing this knowledge, Defendants did not disclose these risks and intentionally downplayed these risks in their labelling, promotion materials, marketing, advertising, and other public facing communications. Defendants' failure to disclose and 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 physicians, from having the full information necessary to weigh the risks and benefits of taking the Defendants' GLP-1 RAs.

I. The Sponsor of a Drug is Responsible for Ensuring the Safety of Its Drug and for Warning Healthcare Providers and Patients of the Risks

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

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

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

238. The Institute of Medicine wrote in a report entitled *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, that, "[t]he 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."

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

240. At the same time, manufacturers have superior access to information about their drugs, especially in the post-approval phase as new risks emerge, compared to FDA.

241. Risks that are uncommon, are mistaken for common conditions, develop after long periods of time, or only effect special populations may go undetected in clinical trials.

242. 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 to healthcare providers. FDA standards govern a manufacturer's duty to warn.

243. 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."[224]

244. In addition, 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."[225]

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

[224] 21 C.F.R. § 201.57(c)(6).
[225] *Id.*

246. 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.

247. FDA's 2011 Guidance on Warnings in labeling advises that"[t]he WARNINGS AND PRECAUTION section is intended to identify and describe a discrete set of adverse reactions and other potential safety hazards that are serious or otherwise clinically significant because they have implications for prescribing decisions or for patient management."

248. FDA's Guidance also states that "[a]dverse 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."

II. The Labels for Wegovy and Saxenda Were Inadequate at All Relevant Times From Launch to Present

249. At all relevant times, the "Warnings and Precautions" sections of the Prescribing Information for Wegovy and Saxenda omitted and continue to omit any "Warnings and Precautions" concerning NAION, the potential need for emergent care, hospitalization, long term treatment or permanent vision loss.

250. As discussed above, peer-reviewed medical literature and FDA Adverse Event Reports demonstrate the risk of NAION and its sequelae with GLP1-RA drugs, including Wegovy and Saxenda.

251. 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.

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

253. At all relevant times, Defendants failed to disclose information regarding the serious risks of NAION with Wegovy and Saxenda.

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

255. Had Defendants affirmatively and specifically presented such safety information regarding the risk of NAION with Wegovy and Saxenda to FDA, FDA would have permitted Defendants to add the risk of NAION to the labels of Wegovy and Saxenda.

256. This failure to adequately warn patients and healthcare providers has caused or substantially contributed to Plaintiff's physical injury and emotional suffering, and permanent vision loss.

257. This failure to adequately warn patients and healthcare providers also made Defendants' GLP-1RA drugs, including those taken by Plaintiff, unreasonably dangerous.

258. Upon information and belief, as a result of Defendants' inadequate warnings, the medical community at large, and Plaintiff's prescribing healthcare providers in particular, were not aware that Wegovy and Saxenda.can cause NAION and its sequelae.

259. Upon information and belief, had Defendants adequately warned Plaintiff's prescribing healthcare providers that Wegovy and Saxenda. is causally associated with NAION and its sequelae, then their prescribing decisions would have changed.

260. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from NAION and its sequelae, which resulted in severe and debilitating personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences and/or dying.

I. DEFENDANTS' MARKETING OF GLP-1 RAS WAS INTENTIONALLY DECEPTIVE AND MISLEADING AND LACKED FAIR BALANCE

261. 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 in weighing the risks and benefits of taking a GLP-1 RA, including Wegovy and Saxenda.

262. Defendants did not disclose and/or minimize the risks of developing NAION and its sequelae.

263. 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 include the fact that: (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 to maintain the benefits); (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.

264. ***Average Weight Loss Is Modest***. Novo touts weight loss of 15% of a person's body weight or a total of 35 lbs. while using Wegovy.

265. Meanwhile, studies show that the real number are much lower. On July 8, 2024, a JAMA Internal Medicine article suggested that Novo overstated the weight loss benefits of their drug in advertisements. Over a year's time, those on semaglutide (Ozempic/Wegovy) lost an

average of 9.3% of their body weight. Only 18% of those on semaglutide reported a weight loss of at least 15% of their body weight after one year of treatment.[226] 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.[227]

266. ***Non-responders***. 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%."[228] Notably, the article discussing the research states that "Wegovy and Zepbound have been approved by the FDA for weight loss, while Ozempic and Mounjaro have been prescribed for that purpose in an off-label fashion."

267. ***Patients Must Remain on the Drug to Sustain Weight Loss***. For those who lose weight, they typically need to stay on the drug forever to maintain the weight loss.[229] 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."[230]

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[226] *See* Patricia J. Rodriguez et al., *Semaglutide vs Tirzepatide for Weight Loss in Adults With Overweight or Obesity*, 184 JAMA INTERN MED., 1056 (2024).

[227] NOVO NORDISK, OBESITY CARE, NOVO NORDISK CAPITAL MARKETS DAY PRESENTATION at 8 (Mar. 7, 2024), https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/cmd/2024/P5-Obesity-Care.pdf.

[228] Erica Carbajal, *Up to 15% of patients on weight loss drugs may be 'non-responders*, BECKER'S HOSPITAL REVIEW (April 1, 2024), https://www.beckershospitalreview.com/glp-1s/up-to-15-of-patients-on-weight-loss-drugs-non-responders.html.

[229] Melinda Karth, *Is Semaglutide a Miracle Weight-Loss Drug?*, PSYCHOLOGY TODAY (April 1, 2023), https://www.psychologytoday.com/ie/blog/the-neuroscience-of-eating-disorders/202303/ozempic-and-wegovy-is-semaglutide-a-miracle-weight.

[230] Julie Stewart, *Help Patients Prevent Weight Gain After Stopping GLP-1s*, Medscape Med. News (Mar. 18, 2024), https://www.medscape.com/viewarticle/help-patients-prevent-weight-gain-after-stopping-glp-1s-2024a10004z9?form=fpf; *see also* https://www.medscape.com/viewarticle/help-patients-prevent-weight-gain-after-stopping-glp-1s-2024a10004z9?form=fpf.

268. Novo has publicly recognized that most individuals will regain all the weight within five years of stopping Ozempic or Wegovy.[231] A trial published by Novo showed that after a year participants who stopped taking semaglutide gained back two-thirds of the weight lost while taking the drug.[232] Indeed, Novo has acknowledged that some individuals will regain even more weight after stopping Ozempic or Wegovy than they initially lost.[233]

269. 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***."[234]

270. Wegovy and Ozempic are often marketed as part of a "metabolic reset"[235] even though it knows that the weight will be regained upon cessation and even though it has recognized that GLP-1 RAs do not rewire "your neural networks to really define a new body weight setpoint."[236] Not only is it not a "reset," some patients will actually regain even more weight after stopping the drug.[237]

271. A meta-analysis of GLP-1 RA clinical trials found that "several GLP-1 RAs

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[231] Annika Kim Constantino, *People taking obesity drugs Ozempic and Wegovy gain weight once they stop medication,* CNBC (Mar 29 2023), https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html

[232] John P. H. Wilding et al, *Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension*, 24 DIABETES, OBESITY AND METABOLISM 1553 (2022).

[233] Annika Kim Constantino, *People taking obesity drugs Ozempic and Wegovy gain weight once they stop medication,* CNBC (Mar 29 2023), https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html

[234] Katie Kindelan, *New study focuses on what happens if you stay on weight loss drug Wegovy for years*, ABC (May 20, 2024) https://abcnews.go.com/GMA/Wellness/new-study-focuses-stay-weight-loss-drug-wegovy/story?id=110401021 (emphasis added).

[235] *How Long Does it Take to Lose Weight with Ozempic?*, CALIBRATE (June 6, 2022), https://www.joincalibrate.com/resources/how-long-does-it-take-to-lose-weight-on-ozempic.

[236] Annika Kim Constantino, *People taking obesity drugs Ozempic and Wegovy gain weight once they stop medication,* CNBC (Mar 29 2023), https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html

[237] *Id.*

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."[238]

272. ***Not a Healthy Weight Loss***. Patients taking GLP-1RAs for weight loss may become 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 the extent that BMI is less than 30, whether they also have a weight-related health condition (*i.e.,* cardiovascular disease, etc.).

273. 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 lbs., putting his BMI at 29.4 and making him extremely overweight and borderline obese. This does not account for the fact that he is an elite athlete with a body fat percentage under 10 percent, a true measure of obesity and overall health. Nonetheless, if he had an additional health condition or gained five pounds (or simply claims to weight five pounds more during a telehealth visit), this NFL quarterback would qualify for one of Defendants' weight loss drugs.

274. Because of the obvious shortcomings of BMI, the AMA has urged doctors to deemphasize their use of BMI in determining healthy weights for patients.[239] On June 14, 2023,

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[238] 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)

[239] *Id*.

the AMA adopted a new policy clarifying how BMI should be used as a measure in medicine.[240] 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.[241]

275. The *Lancet* Journal similarly established a commission to evaluate the proper role of BMI in clinical treatment. The Commission ultimately recommended that "that BMI should be used only as a surrogate measure of health risk at a population level, for epidemiological studies, or for screening purposes, rather than as an individual measure of health" because "BMI-based metrics of obesity can misclassify excess adiposity and could both underdiagnose and overdiagnose disease."[242]

276. 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 assessing the whole health of an individual.[243] These clinicians have cautioned that "a lower body weight does not always mean a person is healthier."[244] In many instances, when someone loses weight, they lose fat (a good result) and also lose muscle mass (a bad result).

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[240] AMERICAN MEDICAL ASSOCIATION, AMA ADOPTS NEW POLICY CLARIFYING ROLE OF BMI AS A MEASURE IN MEDICINE (June 14, 2023), https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measure-medicine.

[241] *Id.*

[242] Francesca Rubino et al, The Lancet Diabetes & Endocrinology Commission, *Definition and Diagnostic Criteria of Clinical Obesity*, 13 LANCET DIABETES & ENDOCRINOLOGY 221 (2025).

[243] Scott Hagan & Karin Nelson, *Are Current Guidelines Perpetuating Weight Stigma? A Weight-Skeptical Approach to the Care of Patients with Obesity*, 38 J. GEN. INTERN. MED. 793 (2022); *Why body mass index doesn't give the whole health picture*, UNIVERSITY OF WASHINGTON (June 20, 2023), https://newsroom.uw.edu/video-library/why-body-mass-index-doesnt-give-the-whole-health-picture.

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

277. The medical community recognizes that weight loss achieved by Ozempic and Wegovy is often comes with a significant loss of muscle mass.[245] As a result, individuals may be lighter but have a higher percentage of body fat.[246]

278. Further exacerbating this problem, if patients stop taking a GLP-1 RA and gain the weight back, that weight gain is typically fat rather than muscle. Therefore, the resulting "new you" is less healthy—weighing the same but having a higher percentage of body fat.

279. The loss of too much muscle mass can lead to sarcopenia, a condition 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.[247]

280. Defendants do not warn about the dangers of the type of unhealthy weight loss occurring with GLP-1 RAs. In fact, Novo personnel continue to represent the opposite in public, referring to weight loss resulting from Wegovy as a "healthy" weight loss.[248] 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

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

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

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

[248] A. Pawlowski, *Is it safe to take the anti-obesity drug Wegovy long-term? Doctors weigh in*, TODAY (Jan. 31, 2024), https://www.today.com/health/diet-fitness/is-wegovy-safe-for-weight-loss-rcna67277.

loss could potentially be healthier than a very dramatic fast weight loss."[249] A representative for Novo also admitted that reasonable preservation of lean body mass "has to be a focus area, and you will probably see [it] in our pipeline."[250]

281. 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.[251]

282. ***Many Patients Do Not Stay on the Drugs Long Enough to See Benefits.*** Approximately 58% of patients stop taking a GLP-1 RA by 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 statistics.[252] This means that "[the] value [GLP-1 RA treatment] is not likely to be realized" in most patients.[253]

283. 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. Physicians recognize that adverse

[249] *See Novo Nordisk A/S (NVO) Q3 2022 Investor Call Transcript*, SEEKING ALPHA (Nov. 3, 2022) https://seekingalpha.com/article/4552694-novo-nordisk-a-s-nvo-q3-2022-investor-call-transcript.

[250] *Id*.

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

[252] BLUE HEALTH INTELLIGENCE, REAL-WORLD TRENDS IN GLP-1 TREATMENT PERSISTENCE AND PRESCRIBING FOR WEIGHT MANAGEMENT, (May 2024), https://www.bcbs.com/media/pdf/BHI_Issue_Brief_GLP1_Trends.pdf.

[253] Patrick 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).

events are more likely to occur during dose escalation with Ozempic and Wegovy.[254]

284. Novo does not warn or highlight that most people are unable to tolerate the drug and stay on it long enough for it to make a meaningful difference. These facts could impact a patient's decision to take a GLP-1 RA.

EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

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

286. Defendants are and were under a continuing duty to disclose the true character, quality and nature of risks and dangers associated with Wegovy. Because of Defendants' purposeful and fraudulent concealment of material information concerning the true character, quality and nature of risks of such products, Defendants are estopped from relying on any statute of limitations defense.

CAUSES OF ACTION

COUNT I
FAILURE TO WARN - NEGLIGENCE
(AGAINST ALL DEFENDANTS)

287. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

288. Defendants had a duty to exercise reasonable care in designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, labeling, selling and/or

[254] *See, e.g.,* Natasha Chidekel Bergmann et al, *Semaglutide for the treatment of overweight and obesity: A review*, 25 DIABETES, OBESITY AND METABOLISM 1, 29 (2023).

distributing Wegovy and Saxenda into the stream of commerce, including a duty to assure Wegovy and Saxenda would not cause users to suffer unreasonable, dangerous side effects.

289. At all relevant times, Defendants failed to exercise ordinary care in the design, research, testing, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or distribution of Wegovy and Saxenda in that Defendants knew or should have known that the drug could proximately cause Plaintiff's injuries and/or presented an unreasonably high risk of injuries.

290. Defendants' Wegovy and Saxenda were expected to and did reach the usual users and/or consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendants.

291. At all relevant times, and at the times Wegovy and Saxenda left Defendants' control, Defendants knew or should have known that Wegovy and Saxenda was unreasonably dangerous because it did not adequately warn of the increased risks of NAION and its sequelae.

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

293. Despite the fact that Defendants knew or should have known that Wegovy and Saxenda caused unreasonably dangerous injuries, Defendants continued to market Wegovy and Saxenda to prescribing physicians and healthcare providers, including Plaintiff's prescribing healthcare providers, without adequate warnings.

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

295. At all relevant times, given its increased safety risks, Wegovy and Saxenda were not fit for the ordinary purposes for which it was intended.

296. At all relevant times, given its increased safety risks, Wegovy and Saxenda did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

297. Defendants had a duty to exercise reasonable care in designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, labeling, selling and/or distributing Wegovy and Saxenda into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as NAION and its sequelae.

298. At all relevant times, Plaintiff was using Wegovy and Saxenda for the purposes and in a manner normally intended.

299. The Wegovy and Saxenda 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 this product created a risk of serious and dangerous injuries, including the increased risk of NAION and its sequelae, as well as other severe and debilitating personal injuries which are permanent and lasting in nature, and Defendants failed to adequately warn of said risks.

300. The Wegovy and Saxenda designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of

the risks of serious side effects, including the increased risks of NAION and its sequelae, as well as other severe, debilitating and permanent health consequences from Wegovy and Saxenda, they failed to provide adequate warnings to users and/or prescribers of this product, and continued to improperly advertise, market and/or promote the product.

301. At all relevant times, the labels for Wegovy and Saxenda were inadequate because they did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Wegovy, including the increased risk of NAION and its sequelae.

302. At all relevant times, the labels for Wegovy and Saxenda were inadequate because they did not warn and/or adequately warn that Wegovy and Saxenda had not been sufficiently and/or adequately tested for safety risks, including the increased risk of NAION and its sequelae.

303. At all relevant times, the labels for Wegovy and Saxenda were inadequate because they did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Wegovy.

304. At all relevant times, the labels for Wegovy and Saxenda 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.

305. Communications made by Defendants to Plaintiff and Plaintiff's prescribing healthcare providers were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Wegovy and Saxenda, including the increased risk of NAION and its sequelae.

306. Communications made by Defendants to Plaintiff and Plaintiff's prescribing healthcare providers were inadequate because Defendants failed to warn and/or adequately warn

that their Wegovy and Saxenda had not been sufficiently and/or adequately tested for safety risks, including the increased risks of NAION and its sequelae.

307. 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.

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

309. Upon information and belief, had Plaintiff's prescribing healthcare providers been warned of the increased risk of NAION and its sequelae, which has reasonable evidence of a causal association with Wegovy and Saxenda, then the prescribing healthcare providers would not have prescribed Wegovy or Saxenda and/or would have provided Plaintiff with adequate warnings regarding the dangers of Wegovy and Saxenda so as to allow Plaintiff to make an informed decision regarding her use of Wegovy and Saxenda.

310. Upon information and belief, had Plaintiff's prescribing healthcare providers been warned that Wegovy and Saxenda had not been sufficiently and/or adequately tested for safety risks, including the increased risks of NAION and its sequelae, the prescribing healthcare providers would not have prescribed Wegovy or Saxenda and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Wegovy so as to allow Plaintiff to make an informed decision regarding her use of Wegovy and Saxenda.

311. If Plaintiff had been warned of the increased risk of NAION and its sequelae, which has reasonable evidence of a causal association with Wegovy and Saxenda, then Plaintiff would not have used Wegovy and Saxenda and/or suffered from NAION and its sequelae.

312. If Plaintiff had been warned that Wegovy and Saxenda had not been sufficiently and/or adequately tested for safety risks, including the increased risks of NAION and its sequelae, then Plaintiff would not have used Wegovy and Saxenda and/or suffered from NAION and its sequelae.

313. If Plaintiff had been warned of the increased risk of NAION and its sequelae, which has reasonable evidence of a causal association with Wegovy and Saxenda, then Plaintiff would have informed his prescribers that he did not want to take Wegovy and Saxenda.

314. Upon information and belief, if Plaintiff had informed his prescribing physicians that he did not want to take Wegovy and Saxenda due to the increased risks of NAION and its sequelae, or the lack of adequate testing for safety risks, then Plaintiff's prescribing healthcare providers would not have prescribed Wegovy and Saxenda.

315. By reason of the foregoing, Defendants have become liable to Plaintiff for designing, marketing, promoting, distribution and/or selling their unreasonably dangerous Wegovy and Saxenda.

316. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore liable for the injuries sustained by Plaintiff.

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

318. Said inadequate warnings for Wegovy and Saxenda were a substantial factor in causing Plaintiff's injuries.

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

320. As a direct and proximate result of one or more of the foregoing acts and omissions, Plaintiff also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiff is informed and believes and further alleges that he will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
FAILURE TO WARN – STRICT LIABILITY
(AGAINST ALL DEFENDANTS)

321. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

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

323. At all relevant times, Defendants designed, researched, manufactured, produced, tested, advertised, promoted, marketed, sold, and/or distributed the Wegovy and Saxenda that Plaintiff used.

324. Wegovy and Saxenda 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 it was produced, manufactured, sold, distributed, and marketed by Defendants.

325. At all relevant times, and at the times Wegovy and Saxenda left Defendants' control, Defendants knew or should have known that Wegovy and Saxenda were unreasonably dangerous because it did not adequately warn of the risks of NAION and its sequelae, especially when used in the form and manner as provided by Defendants.

326. Despite the fact that Defendants knew or should have known that there was reasonable evidence of a causal association with unreasonably dangerous injuries, including NAION and its sequelae, Defendants continued to market, distribute, and/or sell Wegovy and Saxenda to consumers, including Plaintiff, without adequate warnings.

327. Despite the fact that Defendants knew or should have known that there was reasonable evidence of a causal association with unreasonably dangerous injuries, including NAION and its sequelae, Defendants continued to market Wegovy and Saxenda to prescribing healthcare providers, including Plaintiff's prescribing healthcare providers, without adequate warnings.

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

329. At all relevant times, given its increased safety risks, Wegovy and Saxenda were not fit for the ordinary purposes for which it was intended.

330. At all relevant times, given its increased safety risks, Wegovy and Saxenda did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

331. Defendants had a duty to exercise reasonable care in designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, labeling, selling, and/or distributing Wegovy and Saxenda into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as NAION and its sequelae.

332. At all relevant times, Plaintiff was using Wegovy and Saxenda for the purposes and in a manner normally intended.

333. The Wegovy and Saxenda designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings or instructions, as Defendants knew or should have known that this product created a risk of serious and dangerous injuries, including NAION and its sequelae, as well as other severe and debilitating personal injuries which are permanent and lasting in nature, and Defendants failed to adequately warn of said risks.

334. At all relevant times, the labels for Wegovy and Saxenda were inadequate because they did not warn and/or adequately warn of all possible adverse side effects for which there is reasonable evidence of a causal association with the use of Wegovy and Saxenda, including the increased risk of NAION and its sequelae.

335. At all relevant times, the labels for Wegovy and Saxenda were inadequate because they did not warn and/or adequately warn that Wegovy and Saxenda had not been sufficiently and/or adequately tested for safety risks, including the increased risk of NAION and its sequelae.

336. At all relevant times, the labels for Wegovy and Saxenda were inadequate because they did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of the Wegovy and Saxenda.

337. At all relevant times, the labels for Wegovy and Saxenda 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.

338. Communications made by Defendants to Plaintiff and Plaintiff's prescribing healthcare providers were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects with reasonable evidence of a causal association with the use of Wegovy and Saxenda, including the increased risk of NAION and its sequelae.

339. Communications made by Defendants to Plaintiff and Plaintiff's prescribing healthcare providers were inadequate because Defendants failed to warn and/or adequately warn that Wegovy and Saxenda had not been sufficiently and/or adequately tested for safety risks, including the increased risk of NAION and its sequelae.

340. 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.

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

342. Upon information and belief, had Plaintiff's prescribing healthcare providers been warned of the increased risk of NAION and its sequelae, for which there is reasonable evidence of a causal association with Wegovy and Saxenda, then the prescribing healthcare providers would not have prescribed Wegovy or Saxenda, and/or would have provided Plaintiff with adequate warnings regarding the dangers of Wegovy and Saxenda, so as to allow Plaintiff to make an informed decision regarding her use of Wegovy and Saxenda.

343. Upon information and belief, had Plaintiff's prescribing healthcare providers been warned that Wegovy and Saxenda had not been sufficiently and/or adequately tested for safety risks, including the increased risk of NAION and its sequelae, the prescribing healthcare providers would not have prescribed Wegovy and Saxenda, and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Wegovy and Saxenda, so as to allow Plaintiff to make an informed decision regarding her use of Wegovy and Saxenda.

344. If Plaintiff had been warned of the increased risks of NAION and its sequelae, for which there is reasonable evidence of a causal association with Wegovy and Saxenda, then Plaintiff would not have used Wegovy and Saxenda, and/or suffered from NAION and its sequelae.

345. If Plaintiff had been warned that Wegovy and Saxenda had not been sufficiently and/or adequately tested for safety risks, including the increased risks of NAION and its sequelae, then Plaintiff would not have used Wegovy and Saxenda and/or suffered from NAION and its sequelae

346. If Plaintiff had been warned of the increased risk of NAION and its sequelae, for which there is reasonable evidence of a causal association with Wegovy and Saxenda, then Plaintiff would have informed Plaintiff's prescribing healthcare providers that he did not want to use Wegovy and Saxenda.

347. Upon information and belief, if Plaintiff had informed his prescribing healthcare providers that he did not want to use Wegovy and Saxenda due to the risk of NAION and its sequelae, or the lack of adequate testing for safety risks, then Plaintiff's prescribing healthcare providers would not have prescribed Wegovy and Saxenda.

348. By reason of the foregoing, Defendants have become liable to Plaintiff for designing, marketing, promoting, distributing and/or selling Defendants' unreasonably dangerous Wegovy and Saxenda.

349. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore liable for the injuries sustained by Plaintiff.

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

351. Said inadequate warnings for Wegovy and Saxenda were a substantial factor in causing Plaintiff's injuries.

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

353. As a direct and proximate result of one or more of the foregoing acts and omissions, Plaintiff also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiff is informed and believes and further alleges that he will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
BREACH OF EXPRESS WARRANTY /
FAILURE TO CONFORM TO REPRESENTATIONS
(AGAINST ALL DEFENDANTS)

354. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

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

356. At all relevant times, Defendants expressly represented to Plaintiff and Plaintiff's prescribing healthcare providers that Wegovy and Saxenda was safe for chronic weight management in adults with an initial Body Mass index (BMI) of 30 kg/m2 or greater, or with a BMI of 27 kg/m2 or greater and at least one weight-related comorbid condition.

357. The aforementioned express representations were made to Plaintiff and Plaintiff's prescribing healthcare providers by way of thelabels, websites, advertisements, promotional materials for Wegovy and Saxenda and through other statements.

358. As a result of Defendants' express representations, Plaintiff's prescribing healthcare providers were induced to prescribe Wegovy and Saxenda to Plaintiff, and Plaintiff was induced to use Wegovy.

359. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Wegovy and Saxenda based upon their express representations.

360. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as Plaintiff's prescribing healthcare providers, would recommend, prescribe and/or dispense Wegovy and Saxenda based upon their express representations.

361. At all relevant times, Defendants knew or should have known that Wegovy and Saxenda were unreasonably dangerous because of the increased risks of NAION and its sequelae, especially when the drug was used in the form and manner as provided by Defendants.

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

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

364. The unreasonably dangerous characteristics of Wegovy and Saxenda were beyond that which would be contemplated by Plaintiff's prescribing healthcare providers, with the ordinary knowledge common to prescribing healthcare providers as to the drug's characteristics.

365. At the time Wegovy and Saxenda left Defendants' control, Wegovy and Saxenda did not conform to Defendants' express representations because Wegovy and Saxenda was not safe for FDA-approved indications of the drugs, in that they was causally associated with increased risks of NAION and its sequelae.

366. The express representations made by Defendants regarding the safety of Wegovy and Saxenda were made with the intent to induce Plaintiff to use the products and/or Plaintiff's prescribing healthcare providers to prescribe the products.

367. Defendants knew and/or should have known that by making the express representations to Plaintiff and/or Plaintiff's prescribing healthcare providers, it would be the

natural tendency of Plaintiff to use Wegovy and Saxenda and/or the natural tendency of Plaintiff's prescribing healthcare providers to prescribe Wegovy and Saxenda.

368. Plaintiff and Plaintiff's prescribing healthcare providers, as well as members of the medical community, relied on the express representations of Defendants identified herein.

369. Had Defendants not made these express representations, Plaintiff would not have used Wegovy and/or, upon information and belief, Plaintiff's prescribing healthcare providers would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Wegovy and Saxenda so as to allow Plaintiff to make an informed decision regarding his use of Wegovy and Saxenda.

370. Had Plaintiff been warned of the increased risk of NAION and its sequelae causally associated with Wegovy and Saxenda, Plaintiff would not have used Wegovy and Saxenda and and/or suffered from NAION and its sequelae.

371. Had Plaintiff been warned that Wegovy and Saxenda had not been sufficiently and/or adequately tested for safety risks, including NAION and its sequelae, Plaintiff would not have used Wegovy and Saxenda and/or suffered from NAION and its sequelae.

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

373. Defendants' breaches of express warranties were a substantial factor in causing Plaintiff's injuries.

374. Plaintiff's injuries and damages arose from a reasonably anticipated use of Wegovy by Plaintiff.

375. As a direct and proximate result of one or more of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including NAION and its sequelae, as well as

other severe and debilitating personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

376. As a direct and proximate result of one or more of the foregoing acts and omissions, Plaintiff also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiff is informed and believes and further alleges that he will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
BREACH OF IMPLIED WARRANTY
(AGAINST ALL DEFENDANTS)

377. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein

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

379. Wegovy and Saxenda were expected to and did reach the usual consumers, handlers, and persons encountering said products without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

380. At all relevant times, Defendants impliedly warranted to Plaintiff, Plaintiff's prescribing healthcare providers, and the medical community that Wegovy and Saxenda were of merchantable quality and safe and fit for its ordinary purpose.

381. At all relevant times, Defendants knew or should have known that Wegovy and Saxenda were unreasonably dangerous because of the increased risks of NAION and its sequelae, especially when the drug was used in the form and manner as provided by Defendants.

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

383. At the time Wegovy and Saxenda left Defendants' control, Wegovy and Saxenda did not conform to Defendants' implied warranties and was unfit for its ordinary purposes because Defendants failed to provide adequate warnings of the drug's causal association with increased risks of NAION and its sequelae.

384. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as Plaintiff's prescribing healthcare providers, would recommend, prescribe and/or dispense Wegovy and Saxenda for for their FDA approved indications.

385. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Wegovy and Saxenda for their ordinary purposes.

386. Despite the fact that Defendants knew or should have known that there was reasonable evidence of a causal association between Wegovy and Saxenda and unreasonably dangerous injuries, such as NAION and its sequelae, Defendants continued to market, distribute, and/or sell Wegovy and Saxenda to consumers, including Plaintiff, without adequate warnings.

387. The unreasonably dangerous characteristics of Wegovy and Saxenda 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.

388. The unreasonably dangerous characteristics of Wegovy and Saxenda were beyond that which would be contemplated by Plaintiff's prescribing healthcare providers, with the ordinary knowledge common to prescribing healthcare provider as to the drug's characteristics.

389. Plaintiff reasonably relied on Defendants' implied warranties of merchantability relating tothe safety and efficacy of Wegovy and Saxenda.

390. Plaintiff reasonably relied upon Defendants' skill and judgment as to whether Wegovy and Saxenda were of merchantable quality and safe and fit for their intended uses.

391. Upon information and belief, Plaintiff's prescribing healthcare providers relied on Defendants' implied warranties of merchantability and fitness for the ordinary uses and purposes relating to Wegovy and Saxenda.

392. Upon information and belief, Plaintiff's prescribing healthcare providers, reasonably relied upon the skill and judgment of Defendants as to whether Wegovy and Saxenda was of merchantable quality and safe and fit for their intended uses.

393. Had Defendants not made these implied warranties, Plaintiff would not have used Wegovy and Saxenda, and/or, upon information and belief, Plaintiff's prescribing healthcare providers would not have prescribed Wegovy and Saxenda, and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Wegovy and Saxenda, to allow Plaintiff to make an informed decision regarding her use of Wegovy and Saxenda.

394. Defendants herein breached the aforesaid implied warranties of merchantability because Wegovy and Saxenda were not fit for their intended purposes.

395. Defendants' breaches of implied warranties of merchantability were a substantial factor in causing Plaintiff's injuries.

396. As a direct and proximate result of one or more of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries, including NAION and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

397. As a direct and proximate result of one or more of the foregoing breaches, Plaintiff also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiff is informed and believes and further alleges that he will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
FRAUDULENT CONCEALMENT/FRAUD BY OMISSION
(AGAINST ALL DEFENDANTS)

398. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

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

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

401. At all relevant times, Defendants knew or should have known that Wegovy and Saxenda was unreasonably dangerous because of the increased risk of NAION and its sequelae, especially when the drug was used in the form and manner as provided by Defendants.

402. Defendants had a duty to disclose material information about Wegovy and Saxenda to Plaintiff and Plaintiff's prescribing healthcare providers, namely that Wegovy and Saxenda are causally associated with increased risk of NAION and its sequelae, because Defendants have superior knowledge of the drug and its dangerous side effects, this material information was not readily available to Plaintiff or Plaintiff's prescribing healthcare providers by reasonable inquiry, and Defendants knew or should have known that Plaintiff and Plaintiff's healthcare providers would act on the basis of mistaken knowledge.

403. Nonetheless, Defendants consciously and deliberately withheld and concealed this material information from Plaintiff's prescribing physicians, Plaintiff, the medical and healthcare community, and the general public.

404. Defendants' promotional websites for Wegovy and Saxenda do not disclose that there is reasonable evidence of a causal association between Wegovy and Saxenda and increased risk of NAION and its sequelae.

405. Defendants' omissions and concealment of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce healthcare providers, such as

Plaintiff's prescribing healthcare providers, and patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Wegovy or Saxenda for their FDA-approved indications.

406. Defendants knew or should have known that Plaintiff's prescribing healthcare providers would prescribe and Plaintiff would use Wegovy and Saxenda without the awareness of the risks of serious side effects, including NAION and its sequelae.

407. Defendants knew that Plaintiff and Plaintiff's prescribing healthcare providers had no way to uncover the concealed information and determine the truth surrounding Wegovy and Saxenda, as set forth herein.

408. Upon information and belief, Plaintiff's prescribing healthcare providers justifiably relied on Defendants' material omissions when making the decision to dispense, provide, and prescribe Wegovy and Saxenda.

409. Upon information and belief, had Plaintiff's prescribing healthcare providers been warned of the increased risk of NAION and its sequelae causally associated with Wegovy and Saxenda, they would not have prescribed Wegovy and Saxenda and/or would have provided Plaintiff with adequate information regarding the increased risk of NAION and its sequelae causally associated with Wegovy and Saxenda to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy.

410. Upon information and belief, had Plaintiff's prescribing healthcare providers been told that Wegovy had not been sufficiently and/or adequately tested for safety risks, including NAION and its sequelae, they would not have prescribed Wegovy and Saxenda and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing

of Wegovy and Saxenda to allow Plaintiff to make an informed decision regarding Plaintiff's use of Wegovy and Saxenda.

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

412. Had Plaintiff been informed of the increased risks causally associated with Wegovy and Saxenda, Plaintiff would not have used Wegovy and Saxenda and/or suffered NAION and its sequelae.

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

414. Plaintiff intends to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

415. As a direct and proximate result of the above stated omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries, including NAION and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

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

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI
FRAUDULENT / INTENTIONAL MISREPRESENTATION
(AGAINST ALL DEFENDANTS)

417. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

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

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

420. At all relevant times, Defendants knew or should have known of the serious side effects of Wegovy and Saxenda, including NAION and its sequelae.

421. At all relevant times, Defendants knew or should have known that Wegovy and Saxenda was not safe for their FDA-approved indications, given its increased risk of NAION and its sequelae.

422. Nonetheless, Defendants made material misrepresentations to Plaintiff, Plaintiff's prescribing healthcare providers, the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Wegovy and Saxenda.

423. Defendants represented affirmatively and by omission on television advertisements, social media and other online advertisements, and on the labels of Wegovy and Saxenda that the drugs were safe and effective for their FDA-approved indications, despite being aware of increased risks of NAION and its sequelae causally associated with using Wegovy and

Saxenda.

424. Defendants were aware or should have been aware that their representations were false or misleading, and knew that they were concealing and/or omitting material information from Plaintiff, Plaintiff's prescribing healthcare providers, the medical and healthcare community, and the general public.

425. Defendants' misrepresentations of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing healthcare providers, and patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Wegovy and Saxenda for their FDA-approved indications.

426. Upon information and belief, Plaintiff's prescribing healthcare providers had no way to determine the truth behind Defendants' false and/or misleading statements, concealments and omissions surrounding Wegovy and Saxenda and reasonably relied on false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts which Plaintiff's prescribing healthcare providers had no way to know were omitted.

427. Upon information and belief, Plaintiff's prescribing healthcare providers justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to prescribe Wegovy and Saxendato Plaintiff.

428. Upon information and belief, had Plaintiff's prescribing healthcare providers been informed of the increased risk of NAION and its sequelae causally associated with Wegovy and Saxenda, Plaintiff's prescribing healthcare providers would not have prescribed Wegovy and Saxenda and/or would have provided Plaintiff with adequate information regarding safety of Wegovy and Saxenda to allow Plaintiff to make an informed decision regarding Plaintiff's use of

Wegovy and Saxenda.

COUNT VII
NEGLIGENT MISREPRESENTATION / MARKETING
(AGAINST ALL DEFENDANTS)

429. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

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

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

432. The information distributed by Defendants to the public, the medical community, Plaintiff and Plaintiff's prescribing healthcare providers, including advertising campaigns, labeling materials, print advertisements, commercial media, and marketing was false and misleading and contained omissions and concealment of truth about the dangers of Wegovy and Saxenda.

433. Defendants' conduct had the capacity to deceive and/or its purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiff's health care providers; to falsely assure them of the quality of Wegovy and

Saxendaand induce the public and medical community, including Plaintiff and Plaintiff's healthcare providers to request, recommend, purchase, and prescribe Wegovy and Saxenda.

434. Defendants had a duty to accurately and truthfully represent and market to the medical and healthcare community, medical pharmaceutical manufacturers, Plaintiff, Plaintiff's healthcare providers and the public, the known risks of Wegovy and Saxenda, including their propensity to cause NAION and its sequelae.

435. Defendants made continued omissions in the labeling of Wegovy and Saxenda, including promoting them as safe and effective while failing to warn of their propensity to cause NAION and its sequelae.

436. Defendants made additional misrepresentations beyond the product labeling by representing Wegovy and and Saxenda assafe and effective for their FDA-approved indications.

437. Defendants misrepresented and overstated the benefits of Wegovy and Saxenda to Plaintiff, Plaintiff's prescribing healthcare providers, and the medical community without properly advising of the known risks to patients.

438. Defendants made the misrepresentations alleged herein with the intent to induce consumers, like Plaintiff, to use their drug.

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

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

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

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

443. Plaintiff would not have used Wegovy and Saxendaand her healthcare providers would not have prescribed Wegovy and Saxenda had the true facts not been concealed by Defendants.

444. Defendants had sole access to many of the material facts concerning the defective nature of Wegovy and Saxenda and their propensity to cause serious and dangerous side effects.

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

446. Defendants failed to exercise ordinary care in making representations concerning Wegovy and Saxenda while they were involved in the manufacture, design, sale, testing, quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate commerce, because Defendants negligently misrepresented thehigh risk of unreasonable and dangerous adverse side effects associated with Wegovy and and Saxenda.

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

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

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII
STRICT PRODUCT LIABILITY MISREPRESENTATION / MARKETING (AGAINST ALL DEFENDANTS)

449. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

450. State law imposes a duty on producers, manufacturers, distributors, lessors, and sellers of a product to exercise all reasonable care when marketing, promoting, distributing, and selling their products.

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

452. Defendants made material misrepresentations to Plaintiff, Plaintiff's prescribing healthcare providers, the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Wegovy and Saxenda.

453. Defendants represented affirmatively and by omission on advertisements and on the labels of Wegovy and Saxenda that they were a safe and effective for their FDA-approved indications, despite the increased risks of NAION and its sequelae causally associated with using Wegovy.

454. Defendants' representations were false or misleading and/or concealing and/or omitting material information from Plaintiff, Plaintiff's prescribing healthcare providers, the medical and healthcare community, and the general public.

455. Plaintiff and Plaintiff's prescribing healthcare providers had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding Wegovy and Saxenda, as set forth herein.

456. Upon information and belief, Plaintiff's prescribing healthcare providers justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to prescribe Defendants' Wegovy and Saxenda to Plaintiff.

457. Upon information and belief, had Plaintiff's prescribing healthcare providers been warned of the increased risks of NAION and its sequelae causally associated with Wegovy and Saxenda, Plaintiff's prescribing healthcare providers would not have prescribed Wegovy and Saxenda and/or would have provided Plaintiff with adequate information regarding safety of Wegovy and Saxenda to allow Plaintiff to make an informed decision regarding her use of Wegovy and Saxenda.

458. Upon information and belief, had Plaintiff's prescribing healthcare providers been told that Wegovy and Saxenda had not been sufficiently and/or adequately tested for safety risks, including NAION and its sequelae, they would not have prescribed Wegovy and Saxenda and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Wegovy and Saxenda so that Plaintiff could make an informed decision regarding her use of Wegovy and Saxenda.

459. Plaintiff reasonably relied on the false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts which Plaintiff had no way to know were omitted.

460. Had Plaintiff been told of the increased risks of NAION and its sequelae causally associated with Wegovy and Saxenda, Plaintiff would not have used Wegovy and Saxenda and/or suffered from NAION and its sequelae.

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

462. As a direct and proximate result of one or more of the foregoing false representations and/or omissions, Plaintiff had also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiff is informed and believes and further alleges that he will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IX
NEGLIGENT DESIGN
(AGAINST ALL DEFENDANTS)

463. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

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

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

466. Defendants negligently and carelessly breached the above-described duties to Plaintiff by, among other acts and omissions, negligently and carelessly:

a. Failing to use ordinary care in designing, testing, and manufacturing Wegovy and Saxenda;

b. Failing to design Wegovy and Saxenda to properly minimize the adverse effects to the eyes and optic nerve;

c. Failing to counteract in the design the known adverse effects on the eyes and optic nerve;

d. Designing a product where the benefits was greatly outweighed by the risks, including NAION and its sequelae; and

e. Designing a product without taking into consideration the proper dosage that could avoid NAION and its sequelae.

467. Wegovy and Saxenda were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

468. At all relevant times, given their lack of efficacy and increased safety risks, Wegovy and Saxenda did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff, or in the alternative, Plaintiff's medical providers.

469. Wegovy and Saxenda were defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous,

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

470. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of Wegovy and Saxenda, at all relevant times, Defendants designed and brought the products to market and continued to market the drugs when there were safer alternatives available, including but not limited to alternate dosing and reduced exposure.

471. Plaintiff intends to plead all claims of product liability that are supported by his factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

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

473. As a direct and proximate result of one or more of the foregoing negligent acts and omissions by Defendants, Plaintiff has also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiff is informed and believes and further alleges that she will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT X
STRICT LIABILITY DESIGN DEFECT
(AGAINST ALL DEFENDANTS)

474. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

475. Plaintiff is in the class of persons that Defendants should have reasonably foreseen as being subject to the harm caused by defectively designed Wegovy and Saxenda insofar as Plaintiff was the type of persons for whom Wegovy and Saxenda were intended to be used.

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

477. Defendants, which are engaged in the business of designing, researching, manufacturing, testing, advertising, promoting, marketing, selling and/or distributing the Wegovy and Saxenda that was used by Plaintiff, placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of Wegovy and Saxenda.

478. The Wegovy and Saxenda supplied to Plaintiff was defective in design or formulation and unreasonably dangerous when it left the hands of Defendants, and it reached the users and consumers of the products, including Plaintiff, without substantial alteration in the condition in which it was sold.

479. Wegovy and Saxenda was defective in design or formulation in that:

a. Defendants knew or should have known of the dangers associated with Wegovy and Saxenda, but failed to use ordinary care in designing, researching, manufacturing, testing, advertising, promoting, marketing, selling and/or distributing Wegovy and Saxenda;

b. The benefits of Wegovy and Saxenda were greatly outweighed by the foreseeable risks associated with the design or formulation of Wegovy and Saxenda, including NAION and its sequelae;

c. There was a safer, economically feasible alternative design or formulation for Wegovy and Saxenda that Defendants could have used;

d. The design or formulation of Wegovy failed to properly minimize the known adverse effects to the ocular system;

e. The design or formulation of Wegovy and Saxenda failed to counteract the known adverse effects on the ocular system; and

f. The design or formulation of Wegovy and Saxenda failed to take into consideration the proper dosage that could avoid NAION and its sequelae.

480. At all relevant times, given its lack of efficacy and increased safety risks, Wegovy and Saxenda did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff, or in the alternative, Plaintiff's medical providers.

481. Wegovy and Saxenda were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers and/or distributors, they were unreasonably dangerous, more dangerous than an ordinary consumer would expect, and more dangerous than other similar drugs.

482. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of Wegovy and Saxenda, at all relevant times, Defendants designed and brought the products to market and continued to market the drugs when there were safer alternatives available, including but not limited to alternate dosing and reduced exposure.

483. Plaintiff intends to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.

484. As a direct and proximate result of one or more of the foregoing acts and omissions by Defendants, Plaintiff was caused to suffer serious and dangerous injuries including NAION and

its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

485. As a direct and proximate result of one or more of the foregoing acts and omissions by Defendants, Plaintiff has also suffered consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages. Plaintiff is informed and believes and further alleges that he will require future medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XI
NEGLIGENCE
(AGAINST ALL DEFENDANTS)

486. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

487. Defendants, directly or indirectly, caused Wegovy and Saxenda to be sold, distributed, packaged, labeled, marketed, promoted, and used by Plaintiff. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, overpromoted, and sold Wegovy and Saxenda throughout the United States.

488. At all relevant times, Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, labeling, sale and/or distribution of Wegovy and Saxenda, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that did not cause

users to suffer from unreasonable, dangerous side effects without an adequate warning—when used alone or in foreseeable combination with other drugs.

489. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known of the hazards and dangers associated with Wegovy and Saxenda, and specifically that use of this drug could cause NAION and its sequelae.

490. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known that there was reasonable evidence of a causal association with NAION and its sequelae, and that the use of Wegovy and Saxenda could cause Plaintiff's injuries, and thus, created a dangerous and unreasonable risk of injury to the users of this product that Defendants did not warn of.

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

492. Defendants breached their duty of care to Plaintiff and Plaintiff's prescribing healthcare providers, in the warning, testing, monitoring, and pharmacovigilance of Wegovy and Saxenda.

493. In disregard of their duties, Defendants committed one or more of the following negligent acts or omissions:

a. Manufacturing, producing, overpromoting, marketing, formulating, creating, developing, designing, selling, and distributing Wegovy and Saxenda, without thorough and adequate pre- and post-market testing of the product;

b. Manufacturing, producing, overpromoting, marketing, advertising, formulating, creating, developing, and distributing Wegovy and Saxenda, and upon information and belief, while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risks of serious harm associated with the use of Wegovy and Saxenda;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Wegovy and Saxenda was safe for their intended uses;

d. Upon information and belief, failing to disclose and warn of the products' defects to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Wegovy and Saxenda were indeed unreasonably unsafe and unfit for use by reason of the products' defects and risks of harm to their users;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the risks of harm from Wegovy and Saxenda were unreasonable and that there were safer and effective alternative products available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use Wegovy and Saxenda;

g. Advertising, marketing, and recommending the use of Wegovy and Saxenda, while concealing and failing to disclose or warn of the dangers Defendants knew or should have known to be connected with, and inherent in, the use of Wegovy and Saxenda;

h. Representing that Wegovy and Saxenda were safe for weight management when in fact Defendants knew and/or should have known the product was not safe for those purposes;

i. Continuing to manufacture and sell Wegovy and Saxenda with the knowledge that Wegovy and Saxenda, when used for weight management, were unreasonably unsafe and dangerous;

j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of Wegovy and Saxenda so as to avoid the risks of serious harm associated with the use of Wegovy and Saxenda. Failing to design and manufacture Wegovy and Saxenda so as to ensure the drug was at least as safe and effective as other similar products;

k. Failing to ensure that Wegovy and Saxenda were accompanied by proper and accurate warnings about the increased risks of NAION and its sequelae;

l. Failing to ensure that Wegovy and Saxenda were accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Wegovy and Saxenda and that use of Wegovy and Saxenda created a high risk of severe and debilitating injuries; and

m. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Wegovy and Saxenda.

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

495. As a direct and proximate result of Defendants' negligent testing, monitoring, and pharmacovigilance of Wegovy and Saxenda, Defendants introduced drugs into the State of Massachusetts which they knew or should have known would cause serious, severe and debilitating injuries, including NAION and its sequelae.

496. The aforementioned negligence and wrongs done by Defendants were aggravated by the kind of grossly negligent conduct and disregard for the rights of others, the public, and Plaintiff, for which the law allows the imposition of exemplary or punitive damages, in that Defendants' conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants proceeded with a reckless disregard to the rights, safety, and welfare of others, including Plaintiff.

497. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to applicable state law.

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

499. As a direct and proximate result of one or more of the foregoing negligent acts and omissions by Defendants, Plaintiff suffered bodily injuries and consequent economic and other

losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XII
NEGLIGENT UNDERTAKING
(AGAINST ALL DEFENDANTS)

500. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

501. Numerous state laws recognize liability related to the voluntary assumption of a duty or undertaking. This includes the voluntary undertaking of targeting patients with direct-to-consumer ("DTC") marketing campaigns.

502. Defendants voluntarily undertook the responsibility to market Wegovy and Saxenda directly to the consumer instead of solely to physicians and other health care providers. In choosing to target the ordinary consumer with their DTC marketing campaigns, the Defendants undertook the responsibility to do so in a truthful and non-misleading manner and to adequately warn of the risks of their product. Having undertaken the responsibility, Defendants were required to do so with reasonable care.

503. Courts have recognized that DTC advertising "provides the consumer with a diluted variation of risks associated with the drug product" and "[c]onsumers often interpret such warnings as a 'general reassurance' that their condition can be treated," rather than an awareness of risks. *See Perez v. Wyeth Lab'ys Inc.,* 161 N.J. 1, 14, 734 A.2d 1245, 1253 (1999).

504. The FDA requires pharmaceutical promotional materials to be truthful and non-misleading and that they comply with applicable statutory and regulatory requirements. The FDA looks not just at specific risk-related statements, but at the net impression of promotional materials.

505. Common law requires a company to act with reasonable care when they assume a duty to the consumer.

506. As alleged above, Defendants failed to warn consumers in their DTC advertisements about the true nature and extent of the risks associated with Wegovy and Saxenda. This includes warnings as to the possibility of developing NAION and its sequelae, and the true efficacy of the drugs – primarily that most patients stop taking the drug and regain any weight that was lost. Only a small percentage of patients ever reach and maintain a normal BMI on weight loss drugs.

507. Novo does not disclose the need to remain on its weight loss drugs forever in order to maintain weight loss in its direct-to-consumer marketing campaigns. Nor does Novo disclose that everyone is at risk of regaining all the weight back within five years.

508. If this information had been disclosed to Plaintiff, then he would not have sought a prescription for Wegovy and Saxenda.

509. As a direct and proximate result of Defendant's breach of duty of care, Plaintiff suffered mental and physical injuries from taking Wegovy and Saxenda.

510. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to applicable state law.

511. As a direct and proximate result of these negligent acts and omissions by Defendants, Plaintiff suffered bodily injuries and consequent economic and other losses, including

pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above referenced claims and causes of action, jointly and severally, awarding:

(a) Compensatory damages in excess of $75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, and other noneconomic damages in an amount to be determined at trial of this action;

(b) Economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;

(c) Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

(d) Pre-judgment interest;

(e) Post-judgment interest;

(f) Reasonable attorneys' fees;

(g) The costs of these proceedings; and

(h) Such other and further relief as this Court deems just and proper.

JURY DEMAND

TAKE NOTE that Plaintiff demands trial by jury as to all issues herein.

Dated: June 6, 2025

RESPECTFULLY SUBMITTED,
/s/ Parvin K. Aminolroaya

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