

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

IN RE GLUCAGON-LIKE PEPTIDE-1
RECEPTOR AGONISTS (GLP-1 RAS)
NON-ARTERITIC ISCHEMIC
OPTIC NEUROPATHY
PRODUCTS LIABILITY LITIGATION

MDL NO. 3163

THIS DOCUMENT RELATES TO ALL
CASES

JUDGE KAREN SPENCER MARSTON

JOHN CARDEN,

Plaintiff,

v.

NOVO NORDISK INC. and NOVO
NORDISK A/S,

Defendants.

COMPLAINT AND JURY DEMAND

CIVIL ACTION NO.: _____

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff files this Complaint pursuant to the Direct Filing Order and is to be bound by the rights, protections and privileges, and obligations of that Direct Filing Order and other Orders of the Court. Further, in accordance with the Direct Filing Order, Plaintiff hereby designates the United States District Court for the Middle District of North Carolina as Plaintiff's designated venue ("Original Venue"). Plaintiff makes this selection based upon one (or more) of the following factors (check the appropriate box(es)):

☒ Plaintiff currently resides in Mocksville, NC (City/State).

☒ Plaintiff purchased and used Defendant(s)' products in Mocksville, NC (City/State).

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

☒ The Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, specifically (28 USC § 1391(b)(2)): Plaintiff purchased and used Defendant(s) products in Mocksville, NC.

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

__Other (please explain): _____.

Plaintiff, John Carden, by Plaintiff’s attorney, Bradley D. Honnold of Goza & Honnold LLC, hereby brings this action against Defendants NOVO NORDISK INC. and NOVO NORDISK A/S, (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 North Carolina.

2. This Court has personal jurisdiction over all Defendants, consistent with the United States Constitution and N.C. Gen. Stat. § 1-75.4 (North Carolina’s “long arm” statute) by virtue of Defendants’ substantial, continuous, and systematic contacts with the State of North Carolina.

INTRODUCTION

3. 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.

4. Vision loss can lead to worsened mental health, loss of or limited employment, social isolation, and the need for a caregiver.

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

6. Vision loss with NAION is untreatable and can result in permanent blindness.¹

7. 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.

8. 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

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

10. 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

11. This is an action for damages suffered by Plaintiff, John Carden, who was severely injured, by developing NAION as a result of Plaintiff's use of Ozempic, injectable prescription medications that is used to control blood sugar in adults with type 2 diabetes.

12. Ozempic (semaglutide) belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs"). GLP-1 RAs are prescribed, for certain patient populations, to treat type 2 diabetes, aid in chronic weight management, and reduce cardiac risk.

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

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.*

14. Despite this, Defendants failed to warn about the risk of NAION with Ozempic.

15. Instead, Defendants created and expanded the market for weight-loss medication by, among other things, by 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, change 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.

16. 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.

17. By undertaking that effort, Defendants also were systematically and intentionally targeting users of other diabetes medications. Defendants' promise of weight loss wrongfully enticed users of other diabetes medications to switch to a GLP-1 RA, such as Ozempic, who never would have done so had it not been for the off-label promotion of those drugs.

18. Defendants also sought to make the GLP-1 RAs, including Ozempic, 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 for people who were diabetics, and for people seeking to lose weight, whether they were using the drug as prescribed or off-label. Plaintiff would not have taken Ozempic 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 and weight-loss, whether off-label or not, worked. The U.S. GLP-1 RA market is expected to

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”).

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 get added to prescription drug coverage under Medicare Part D in the coming years. Some analysts project that this will add \$13.6 to \$26.8 Billion to Medicare Part D expenses even if only 10% of people with obesity use them, causing a significant shift in premiums and coverage in other areas.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 Ozempic, would guarantee results and be efficacious and safe. Plaintiff injected Ozempic 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 Ozempic, 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 their life.

PARTY PLAINTIFF

24. Plaintiff, John Carden, is a citizen of the United States, and is a resident of the State of North Carolina.

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).

25. Plaintiff used Ozempic from on or about August 2022 to on or about September 2023.

26. Plaintiff used Ozempic, at all times, strictly according to the express dosage and administration instructions provided by their licensed healthcare provider.

27. The risks suffered by the Plaintiff were not open, obvious, or common knowledge at the time of ingestion.

28. As a result of using Ozempic, Plaintiff was caused to suffer from NAION and its sequelae and, as a result, sustained severe and permanent personal injuries, pain, suffering, emotional distress, and lost wages.

29. As a result of using Ozempic, Plaintiff is suffering from a loss of vision in both eyes.

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

33. 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.

34. 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 OZEMPIC

35. 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.

36. 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.

37. Following the discovery that exendin-4 is similar in structure to GLP-1, a synthetic version of exendin-4 was developed to treat diabetes. This became the first GLP-1 drug, known as Byetta, with the active ingredient exenatide, which came to market in 2005. Byetta was initially brought to market as a collaboration between 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 noted to be 2.4 hours.¹³

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).

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*,

38. Simultaneously with the development of exenatide, Novo was developing another GLP-1 drug called liraglutide. In the early 1990s, Novo researchers discovered that when they injected liraglutide into rats, it caused them to stop eating almost entirely.¹⁴ Liraglutide came to market in 2010, marketed initially as Victoza and later as Saxenda. Liraglutide has a half-life of 13-15 hours.¹⁵

39. Various active ingredients fall within the GLP-1 RA class of drugs, including semaglutide (marketed by Novo as Ozempic, Wegovy, and Rybelsus), liraglutide (marketed by Novo as Saxenda, Victoza, and in combination with insulin as Xultophy 100/3.6), tirzepatide (marketed by Lilly as Mounjaro and Zepbound), dulaglutide (marketed by Lilly as Trulicity), exenatide (marketed by various companies as Byetta, Bydureon, and Bydureon BCise), albiglutide (marketed by GlaxoSmithKline as Tanzeum), and lixisenatide (marketed by Sanofi as Adlyxin and in combination with insulin as Soliqua 100/33).

40. 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 members of the same class.¹⁷

41. Medications within the GLP-1 RA class of drugs mimic the activities of physiologic

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).

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.”).

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

42. In contrast to naturally-occurring GLP-1, which has a short life and is quickly metabolized by enzymes, GLP-1 RAs are engineered to last longer, as previously noted. The chemical structure of GLP-1 RAs includes a fatty chain that inhibits such quick dissolution. GLP-1 RAs such as semaglutide 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.

43. 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.

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

45. Most of the GLP-1 RAs are weekly injectable drugs, except that liraglutide (the

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>.

²² Cleveland Clinic, *GLP-1 Agonists* (July 3, 2023), <https://my.clevelandclinic.org/health/treatments/13901-glp-1-agonists>.

active ingredient in Saxenda and Victoza) is a daily injectable drug.²³

46. 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

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

48. 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 prescriptions, citing concerns about efficacy and safety.²⁵

49. 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

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.

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.

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

50. 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

51. 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

52. A systematic review and network meta-analysis published in January 2024 reported that the effects of GLP-1 RAs on body weight gradually decline during long term use, indicating “potential limitations of GLP-1 RAs for sustained long term weight loss efforts.”²⁹

53. 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

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).

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

54. 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 safer³² and more cost-effective³³ than GLP-1 RAs.

55. Likewise, other, well-established, prescription and over-the-counter medications with FDA approval for weight loss are available and offer significantly lower risk profiles than GLP-1 RAs. For example, Orlistat, an over-the-counter medication, was FDA-approved for weight loss in 1999 and has been shown to reduce fat absorption by up to 30%. While associated with some gastrointestinal adverse effects, they are much less severe than those seen with GLP-1 RAs and include fatty stools, fecal urgency, incontinence, and increased defecation.³⁴ Similarly, a prescription appetite suppressant combining phentermine and topiramate has been approved since

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).

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

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

56. 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

57. A meta-analysis of Metformin found "there is no significant risk of GI AEs associated neither with the dose size of metformin nor metformin treatment duration." This same study found "GLP-1 RA and acarbose were ranked as having the highest incidence of GI AEs."³⁸ Therefore, GLP-1 RAs, including Ozempic, 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.

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).

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 (Lausanne) (Sept. 14 2022) 13:975912. doi: 10.3389/fendo.2022.975912. PMID: 36187122; PMCID: PMC9524196.

C. THE REGULATORY HISTORY OF OZEMPIC

58. On October 19, 2008, Novo filed an Investigational New Drug (“IND”) application for Ozempic (semaglutide).³⁹

59. On December 5, 2016, Novo announced submission of a New Drug Application (“NDA”) 209637 to the FDA for regulatory approval of once-weekly injectable semaglutide, a new glucagon-like peptide-1 (GLP-1) medication for treatment of type 2 diabetes. In the announcement, Novo represented that in clinical trials “once-weekly semaglutide had a safe and well tolerated profile with the most common adverse event being nausea.”⁴⁰

60. On December 5, 2016, Novo submitted NDA 209637, requesting that the FDA grant it approval to market and sell Ozempic (semaglutide) 0.5 mg or 1 mg injection in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On December 5, 2017, the FDA approved NDA 209637.⁴¹

61. On March 20, 2019, Novo submitted supplemental new drug application (sNDA) 209637/S-003 for Ozempic (semaglutide) 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.⁴² On

³⁹ Determination of Regulatory Review Period for Purposes of Patent Extension; OZEMPIC, 84 Fed. Reg. 65826 (Nov. 29, 2019).

⁴⁰ Novo Nordisk, *Novo Nordisk files for regulatory approval of once-weekly semaglutide in the US and EU for the treatment of type 2 diabetes* (Dec. 5, 2016), available at <https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183>.

⁴¹ FDA Approval Letter for NDA 209637 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf.

⁴² *Novo Nordisk files for US FDA approval of oral semaglutide for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes*, Cision PR Newswire (March 20, 2019), available at <https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html>.

January 16, 2020, the FDA approved sNDA 209637/S-003 for cardiovascular risk reduction in adults with Type 2 diabetes and known heart disease.⁴³

62. On May 28, 2021, Novo submitted sNDA 209637/S-009, requesting approval for a higher 2 mg dose of Ozempic (semaglutide) injection. On March 28, 2022, the FDA approved sNDA 209637/S-009 for a higher-dose Ozempic 2 mg injection for increased glycemic control in adults with type 2 diabetes.⁴⁴

63. On September 22, 2023, Novo added “ileus” under Section 6-3 Postmarketing Experience of the Prescribing Information (“PI” or “label”) in a revised Ozempic label. The new label listed ileus as an adverse reaction reported during post-approval use of semaglutide, the active ingredient of Ozempic.⁴⁵

64. On September 6, 2024, the FDA notified Novo of new safety information that it determined should be included in the labeling for GLP-1 RAs pertaining to the risk of pulmonary aspiration during general anesthesia or deep sedation. On October 4, 2024, Novo submitted a supplemental new drug application (sNDA 209637/S-032) and amendments for Ozempic incorporating the FDA’s required safety modifications to the label. On November 1, 2024, the FDA provided supplemental approval for sNDA 209637/S-032.⁴⁶

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

D. DEFENDANTS WERE ON NOTICE THAT GLP1-RAS ARE ASSOCIATED WITH

⁴³ FDA Supplement Approval Letter for NDA 209637/A-003 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf.

⁴⁴ FDA Supplement Approval Letter for NDA 209637/S-009 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209637Orig1s009ltr.pdf.

⁴⁵ Ozempic Label (dated 9/22/23), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf.

⁴⁶ FDA Supplement Approval Letter for NDA 209637/S-032 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/209637Orig1s032ltr.pdf

NAION AND ITS SEQUELAE

66. 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.

67. Defendants knew or should have known of the causal association between the use of Ozempic 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.

68. It has been known since at least 2016 that the human eye contains GLP-1 receptors.⁴⁷ This finding has been confirmed by Novo's own scientists.⁴⁸

69. Defendants' own pre-approval clinical trial data gave Defendants an early signal of an ocular vascular safety risk associated with semaglutide, which Defendants failed to adequately investigate, differentiate, or disclose.

70. In the SUSTAIN-6 cardiovascular outcomes trial completed in 2016 - a randomized, double-blind, placebo-controlled trial conducted by Novo Nordisk prior to Ozempic's FDA approval - diabetic retinopathy complications (defined in the trial as vitreous hemorrhage, blindness, or conditions requiring treatment with an intravitreal agent or photocoagulation) occurred in 50 of 1,648 patients (3.0%) in the semaglutide group, compared to 29 of 1,649 patients (1.8%) in the placebo group.

71. This ocular safety signal was known to Defendants prior to Ozempic's December 2017 FDA approval, was generated by Defendants' own trial, and gave Defendants actual notice that semaglutide was associated with an increased rate of serious ocular vascular complications in a controlled clinical setting.

72. Defendants did not conduct diagnostic follow-up, and as a result, did not differentiate the SUSTAIN-6 ocular signal into its component conditions, including NAION, before bringing Ozempic to market.

73. Rather than disclosing this ocular vascular signal as a distinct risk warranting investigation, Defendants' FDA-approved labeling minimized it as an extension of a previously described and unrelated phenomenon.

74. Following Ozempic's approval, independent post-marketing evidence specifically identifying NAION as a semaglutide-associated risk continued to accumulate, providing Defendants further and increasingly specific notice.

75. On July 3, 2024, the *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.⁴⁹

⁴⁷ Hernández C et al, *Topical Administration of GLP-1 Receptor Agonists Prevents Retinal Neurodegeneration in Experimental Diabetes*, DIABETES 2016 Jan;65(1):172-87. doi: 10.2337/db15-0443. Epub 2015 Sep 17. PMID: 26384381.

⁴⁸ Hebsgaard JB, et al, *Glucagon-like peptide-1 receptor expression in the human eye* DIABETES OBES METAB. 2018 Sep;20(9):2304-2308. doi: 10.1111/dom.13339. Epub 2018 May 24. PMID: 29707863; PMCID: PMC6099507.

⁴⁹ 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

76. The *JAMA* study referenced a potential causal mechanism, proposing that “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.”⁵⁰

77. The FDA’s Adverse Events Reporting System (FAERS) shows multiple reports of “Optic Ischaemic Neuropathy” reported in connection with use of GLP-1RAs. The earliest reported Optic Ischaemic Neuropathy event associated with any GLP-1RA occurred in 2012, and the earliest associated with semaglutide specifically was in 2019.⁵¹ Analysis of this data shows that patients taking GLP-1RA drugs report injuries associated with NAION at a statistically-significantly greater rate than patients taking other diabetes or weight-loss drugs.⁵²

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

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).

⁵⁰ *Id.*

⁵¹ 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.

⁵² 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.⁵³

79. Fourteen cases of NAION suspected to be causally associated with use of GLP-1RA drugs have been reported in published, peer-reviewed case reports.⁵⁴ Notably in one of these cases the patient experienced re-challenge when her NAION worsened after re-starting her GLP-1RA drug.⁵⁵

80. 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.”⁵⁶

81. 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 (“SGLT-2is”), another class of prescription medications used to treat type

⁵³ Kevin Dunleavy, *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>.

⁵⁴ 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).

⁵⁵ See Katz et al.

⁵⁶ 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>

2 diabetes.⁵⁷

82. In response to these studies, the Danish Medicines Agency has requested that the European Pharmacovigilance Risk Assessment Committee (PRAC) further investigate the link between Ozempic and NAION.⁵⁸

83. Subsequent studies lend further support for the causal association between NAION and GLP-1RA 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.⁵⁹ 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.⁶⁰

84. 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

⁵⁷ 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).

⁵⁸ *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/>.

⁵⁹ Hsu et al., *Semaglutide and Nonarteritic Anterior Ischemic Optic Neuropathy Risk Among Patients With Diabetes*, JAMA OPHTHALMOLOGY (2025) (online ahead of print).

⁶⁰ Cai et al., *Semaglutide and Nonarteritic Anterior Ischemic Optic Neuropathy*, JAMA OPHTHALMOLOGY (2025) (online ahead of print).

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 moderately overweight patients with low cardiovascular risk could be associated with rare, but severe, adverse effects, possibly including NAION.”⁶¹

85. Defendants, as sophisticated pharmaceutical manufacturers with dedicated pharmacovigilance functions, monitored or should have monitored this accumulating medical and scientific literature concerning NAION and semaglutide as part of their ongoing obligation to evaluate the safety of their marketed products.

86. Defendants knew or should have known that there was reasonable evidence of a causal association between the use of Ozempic 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 him to permanently lose his ability to see.

E. BACKGROUND ON PHARMACEUTICAL MARKETING

1. Regulatory Framework for Pharmaceutical Advertising

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

88. By statute, the FDA defines the term “labeling” as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”⁶² The statute contemplates that certain marketing materials are part of the product’s labeling: “brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips,

lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published . . . for use by medical practitioners, pharmacists or nurses containing drug information supplied by the manufacturer, . . . of the drug and which are disseminated by or on behalf of its manufacturer . . . are hereby determined to be labeling as defined in section 201(m) of the act.”⁶³

89. The FDA recognizes a difference between direct-to-consumer (“DTC”) advertisements and promotional labeling.⁶⁴ 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.”⁶⁵

90. 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. . . .”⁶⁶

⁶¹ 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).

⁶² 21 U.S.C. § 321(m).

⁶³ 21 CFR § 202.1(k)(2).

⁶⁴ 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>.

⁶⁵ *Id.* (emphasis added).

⁶⁶ *Id.*

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.”⁶⁷

91. Under the Federal Food, Drug, and Cosmetic Act (“FD&C Act”) and FDA’s implementing regulations, drug promotional labeling and prescription drug advertising must be truthful and non-misleading, convey information about the drug’s efficacy and its risks in a balanced manner, and reveal material facts about the drug.⁶⁸

92. 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.”⁶⁹ 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.”⁷⁰

93. 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.”⁷¹ In other words, the FDA recognizes that pharmaceutical marketing must have fair balance defined as:

⁶⁷ *Id.*

⁶⁸ 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>.

⁶⁹ *Id.* (emphasis added).

⁷⁰ *Id.*

⁷¹ 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).

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.⁷²

94. The definition of “fair balance” is not black and white. Indeed, the FDA recognizes the impact emotion can have on an individual’s ability to understand risks or benefits of a drug. For example, in 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.”⁷³

95. 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.”⁷⁴

⁷² 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>.

⁷³ 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->

⁷⁴ U.S. FOOD AND DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: COMMUNICATIONS FROM FIRMS TO HEALTH CARE PROVIDERS REGARDING SCIENTIFIC INFORMATION ON UNAPPROVED

96. 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 drugs for such off-label use. Promoting or advertising a drug for anything other than its FDA-approved use, the manufacturer is described as illegal “misbranding.”⁷⁵ 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.

97. It is recognized that off-label marketing can harm patients, third-party payors, competitor manufacturers, and researchers and clinicians in multiple ways.⁷⁶ 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.⁷⁷ This can occur when the off-label promotion taps a market demand without spending the time or money to get full safety clearance by the FDA.⁷⁸

2. Methods of Pharmaceutical Marketing

98. 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

USES OF APPROVED/CLEARED MEDICAL PRODUCTS, (Oct. 2023), <https://www.fda.gov/media/173172/download>.

⁷⁵ 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).

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

advertising, personal selling, sales promotions, public relations, and branded and unbranded marketing.

99. “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 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.⁷⁹

100. “Unbranded” campaigns typically contain “help-seeking” advertisements or “disease-state awareness” materials. Unlike branded promotion, it is not regulated by the FDA.⁸⁰ 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.⁸¹ 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.

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

⁷⁹ 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>.

⁸⁰ U.S. FOOD AND DRUG ADMIN., *Basics of Drug Ads*, (June 19, 2015) <https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads>.

⁸¹ 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>.

102. 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.

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

104. 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.”⁸²

105. Novo continues their use of big data and machine learning to create highly effective, targeted marketing campaigns today.⁸³ 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.⁸⁴

F. DEFENDANTS’ EXTENSIVE AND MULTIFACETED MARKETING AND

⁸² 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/>.

⁸³ *Hyperright AB*, Utilizing Advanced Marketing Analytics for Sales Optimization – Peter Vester, Novo Nordisk, YOUTUBE (Dec. 22, 2022), <https://www.youtube.com/watch?v=nCZR6wK7MIU>.

⁸⁴ *Id.*

PROMOTION OF GLP-1 RAs, INCLUDING OZEMPIC

106. 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.

107. 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.

108. 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.

109. 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.⁸⁵ It has continued to re-affirm this commitment through subsequent years, stating its intention to change the perception and treatment of obesity.⁸⁶ In 2019, Novo wrote that its mission was to "change

⁸⁵ NOVO NORDISK, NOVO NORDISK ANNUAL REPORT, (2012)
https://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2012.pdf.

⁸⁶ 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)

how the world sees people with obesity and make obesity a healthcare priority”⁸⁷ and projected growth of the weight-loss drug market from approximately 15 million to 24 million patients.⁸⁸

110. 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, became the most influential spokespeople in the whole obesity debate”⁸⁹

111. 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.⁹⁰ Saxenda, however, required daily injections and its effects on weight loss were modest.

112. 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.

113. Even though it was only approved for diabetes, Novo sought to maximize its profits

<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”).

⁸⁷ 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>.

⁸⁸ *Id.*

⁸⁹ 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/>.

⁹⁰ 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>.

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 solely as a diabetes medication.

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

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

116. 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.

117. 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.

118. Sales of Novo's GLP-1 RAs Ozempic 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.⁹¹ The number of prescriptions filled reached what was, at that time, an all-time high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.⁹² In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.⁹³ The latest data shows that between January 2021 and December 2023 prescriptions for semaglutide soared over 442%.⁹⁴ A 2024 study found that 1 in 8 adults in the United states has taken Ozempic or another GLP-1RA drug.⁹⁵

⁹¹ 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>.

⁹² 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/>.

⁹³ 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>.

⁹⁴ 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/>.

⁹⁵ 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>.

119. At its Capital Markets Day held on March 7, 2024, where the company provides a progress update on its Strategic Aspirations for 2025, Novo admitted that it had “unlocked the market with Wegovy” noting that sales for “obesity care” had grown from 8 billion Danish Krone (“DKK”) in 2021 (approximately 1.16 Billion USD) to 42 billion DKK (\$6.1 billion USD) in 2023. Over 75% of those sales were Wegovy with Saxenda making up the remainder. Novo admitted that its current aspiration is to “[c]ontinue efforts to expand the market by reaching more patients and establish obesity as a serious chronic disease.”⁹⁶

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

120. 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” 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.⁹⁷ 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.⁹⁸

121. 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

⁹⁶ 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>.

⁹⁷ CDC, ADULT BMI CATEGORIES (March 19, 2024), <https://www.cdc.gov/bmi/adult-calculator/bmi-categories.html>.

⁹⁸ 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/>.

characterizing an individual patient's health risks.⁹⁹

122. 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 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.¹⁰⁰

123. Nonetheless, the AMA voted to characterize obesity as a disease.¹⁰¹

124. 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.’”¹⁰²

125. 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.

126. 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

⁹⁹ 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).

¹⁰⁰ 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>.

¹⁰¹ 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/>

¹⁰² 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>.

conventional, evidence-based lifestyle and surgical approaches to obesity.

127. 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.”¹⁰³

128. Another unbranded Novo DTC campaign – “Truth about Weight” – features a series of videos showing overweight individuals eating health foods and exercising while showing their disappointment as they don’t lose weight, and conveying messages such as “long term health goes beyond dieting” and “exercise alone may not be enough for you” before concluding with the individuals visiting a doctor for help.¹⁰⁴

129. 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.¹⁰⁵ Novo’s 2019 Capital Days presentation called for “engaging with a broad range of coalition partners” to advocate for obesity care and Medicare coverage.¹⁰⁶

130. 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 such as diet, exercise, and improved sleep were simply

¹⁰³ Novo Nordisk, *WOD 2022 Time for a new approach*, YOUTUBE (Mar. 4, 2024), <https://www.youtube.com/watch?v=sPrhwdl-xE8>.

¹⁰⁴ 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.

¹⁰⁵ 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>.

¹⁰⁶ *Id.*

insufficient for most people.

131. 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 regardless of their BMI or other health conditions. Defendants partnered with telemedicine companies to get widespread distribution of their drugs with as little supervision as possible. Defendants failed to disclose the risks of these drugs and failed to disclose that patients would likely have to be on these drugs for the rest of their lives to maintain the weight loss and that if they came off the drugs and gained some or all of the weight back, they would actually be less healthy than they were when they started.

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

132. Defendants engaged in a multipronged approach to control and manipulate the universe of knowledge around GLP-1 RAs and obesity treatment including, but not limited to making direct payments to doctors, many of whom were influential in the relevant disciplines, so that they would promote the use of GLP-1 RAs; writing, promoting or funding articles regarding the safety and efficacy of the GLP-1 RAs; speaking at conferences regarding the safety and efficacy of GLP-1 RAs; participating in and influencing health care advocacy groups focused on obesity and obesity treatment; conducting continuing medical education seminars related to GLP-1 RAs; and spending millions of dollars lobbying for prescription drug coverage of GLP-1 RAs.

a. Direct Payments to Physicians

133. There is strong evidence that doctors prescribe more of a drug when they receive

money from a pharmaceutical company linked to that drug.¹⁰⁷ Defendants made voluminous direct payments to physicians, which are recorded in the Open Payments database maintained by the U.S. Centers for Medicare and Medicaid Services.¹⁰⁸

134. 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 2023.¹⁰⁹ In 2022 alone, Novo purchased over 450,000 meals for doctors.¹¹⁰
135. 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.¹¹¹

¹⁰⁷ 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).

¹⁰⁸ 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

¹⁰⁹ U.S. CENTERS FOR MEDICARE & MEDICAID SERVICES, *Novo Nordisk, Inc.*, OPENPAYMENTS DATA, <https://openpaymentsdata.cms.gov/company/100000000144> (accessed Jan. 16 2025).

¹¹⁰ 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>.

¹¹¹ Chad Terhune & Robin Respaut, *Maker of Wegovy, Ozempic showers money on U.S. obesity*

136. Critically, Reuters examined Novo’s spending among 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 companies that were selling or developing obesity drugs.¹¹²
137. 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.¹¹³

b. Key Opinion Leaders (“KOLs”)

138. 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.
139. 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.¹¹⁴ Upon information and belief, Dr. Stanford is one of Novo’s highest paid KOLs.¹¹⁵
140. Dr. Stanford promoted the safety and efficacy of GLP-1 RAs when she was

doctors, REUTERS (Dec. 1, 2023), <https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/>.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ U.S. CENTERS FOR MEDICARE & MEDICAID SERVICES, *Fatima C. Stanford*, OPENPAYMENTS DATA, <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).

¹¹⁵ Melissa Suran, *As Ozempic’s Popularity Soars, Here’s What to Know About Semaglutide and Weight Loss*, 329 JAMA 1627-1629 (2023).

interviewed by 60 Minutes in 2023.¹¹⁶ She also stated that obesity is a “brain disease” and that diet and exercise are insufficient for most people to lose weight.¹¹⁷ Physicians Committee for Responsible Medicine later filed a complaint, alleging the 60 Minutes segment was an “unlawful weight loss drug ad” and that Dr. Stanford had not disclosed she had received significant payments from Novo.¹¹⁸ Dr. Stanford also appeared on Oprah discussing obesity and promoting obesity drugs in September of 2023.¹¹⁹ Her financial ties to Novo were not fully disclosed during these appearances and not mentioned at all with respect to her appearance on Oprah.

141. 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.¹²⁰ Again, the full financial relationship between Dr. Stanford and Novo is not disclosed on Novo’s website.
142. 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

¹¹⁶ 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>.

¹¹⁷ *Id.*

¹¹⁸ 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>.

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

¹²⁰ 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).

Institute at Massachusetts General Hospital and a professor at Harvard Medical School. He is a powerful messenger for Novo, which paid him approximately \$1.4 million by between 2013 and 2022.¹²¹

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

143. Defendants directly or indirectly pay or influence numerous influential advocacy groups to influence medical and public opinion regarding obesity, the treatment for obesity, and the safety and efficacy of GLP-1 RAs. These include The Obesity Society, The Obesity Action Coalition, Obesity in Action Coalition, American Board of Obesity Medicine, and Stop Obesity Alliance.
144. The Obesity Society bills itself as “the leading professional society focused on obesity science, treatment and prevention” and has over 2,800 members worldwide.
145. 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.¹²² One analysis found that she accepted more than \$1 million from Novo over the last decade, including \$600,691 in payments related to Wegovy and Saxenda.¹²³
146. The current President, Dr. Jamy Ard of Wake Forest University, is overseeing the group’s effort to write new practice guides for primary care doctors that cover Wegovy and similar therapies.¹²⁴ Dr. Ard has accepted more than \$200,000 from Novo.¹²⁵

¹²¹ 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/>.

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

147. The Obesity Action Coalition (“OAC”) claims to be “the nation’s leading voice on obesity” with “more than 85,000” members.
148. 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.¹²⁶
149. Novo contributes more than \$100,000 to the OAC annually.¹²⁷ It is “a long-time supporter” of OAC, and routinely renews their support of OAC’s Chairman’s Council at the Platinum level.¹²⁸
150. In 2012, Robert Kushner served on the Board of Directors for the OAC.¹²⁹ 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 *Circulation* journal arguing that obesity should be classified as a disease.¹³⁰ Dr. Kushner received funding from Novo for his research between 2008 and 2012¹³¹ and has served as a member of Novo’s Medical Advisory Board since 2016.¹³²
151. Dr. Kushner was also the lead author on the Guidelines for the Management of

¹²⁶ 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>.

¹²⁷ *Corporate Council*, OBESITY ACTION COALITION, <https://www.obesityaction.org/corporate-partners/> (last accessed Sept. 18, 2023).

¹²⁸ *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/>.

¹²⁹ Robert F. Kushner, *Clinical assessment and management of adult obesity*, 126 CIRCULATION 2870 (2012).

¹³⁰ *Id.*

¹³¹ Michael D. Jensen, *Executive Summary: Guidelines (2013) for the Management of Overweight and Obesity in Adults*, 22, Suppl. 2 OBESITY S5 (2014).

¹³² *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).

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 Surgery.¹³³ Both committee co-chairs responsible for the guidelines and five additional committee members had received funding from Novo.¹³⁴

152. Since 2017, Novo has paid Dr. Kushner at least \$423,000 for this work, including nearly \$170,000 for his STEP study.¹³⁵ Lilly reported paying him \$2,500 for consulting work in 2023, the last year the data is publicly available.¹³⁶ However, the number is likely set 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.¹³⁷ He has also offered comments for WeightWatchers materials on using GLP-1RAs intended for members and prospective patients.¹³⁸
153. 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

¹³³ 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).

¹³⁴ Michael D. Jensen, *Executive Summary: Guidelines (2013) for the Management of Overweight and Obesity in Adults*, 22, Suppl. 2 OBESITY S5 (2014).

¹³⁵ U.S. Centers for Medicare & Medicaid Services, *Robert Kushner*, OPENPAYMENTS DATA, <https://openpaymentsdata.cms.gov/physician/61175> (last accessed Jan. 17, 2024).

¹³⁶ *Id.*

¹³⁷ *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/NEJMcde1515935/suppl_file/nejmcde1515935_disclosures.pdf.

¹³⁸ 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>.

clinical services for patients with obesity by increasing the number of competent physicians that can treat this complex, chronic disease.”

154. Rekha Babu Kumar, former Director of ABOM, received payments totaling tens of thousands of dollars from Novo during her tenure.¹³⁹ She has also promoted GLP-1 RAs for weight loss as part of a telehealth company and continues to receive payments.¹⁴⁰

155. According to Open Payments Data, at least one member of the ABOM Guidelines committee received payments directly from Novo during his tenure.¹⁴¹

156. ABOM lists public health “partners” on their website.¹⁴² Novo serves on the board and/or provides direct financial contributions to many of these public health advocacy groups: (1) OAC (discussed above); (2) American Society for Metabolic and Bariatric Surgery;¹⁴³ and (3) Stop Obesity Alliance.¹⁴⁴

157. Stop Obesity Alliance operates out of George Washington University’s Milken

¹³⁹ *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*, OPENPAYMENTS DATA, <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).

¹⁴⁰ *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?srsrtid>.

¹⁴¹ U.S. Centers for Medicare & Medicaid Services, *Karl Zahlmann Nadolsky*, OPENPAYMENTS DATA, <https://openpaymentsdata.cms.gov/physician/1379381> (last accessed Sept. 18, 2023); *see also Meet the Diplomat: Karl Nadolsky, DO*, AMERICAN BOARD OF OBESITY MEDICINE <https://www.abom.org/karl-nadolsky/> (last accessed Jan. 17, 2025).

¹⁴² *American Board of Obesity Medicine*, AMERICAN BOARD OF OBESITY MEDICINE, <https://www.abom.org/> (last accessed Sept. 18, 2023).

¹⁴³ *Corporate Council*, AMERICAN SOCIETY FOR METABOLIC AND BARIATRIC SURGERY, <https://asmbs.org/corporate-council> (last accessed Sept. 18, 2023).

¹⁴⁴ *Membership*, STOP OBESITY ALLIANCE, <https://stop.publichealth.gwu.edu/membership> (last accessed Sept. 18, 2023).

Institute School of Public Health and advocates for insurance coverage and expanded pharmaceutical obesity treatment.

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

159. All About Obesity is another advocacy group pushing for treatment services for those living with obesity.¹⁴⁵

160. Both board members receive funding for grants, consulting, or speaking from Novo.¹⁴⁶ Novo went on and partly funded the creation of the website in 2021.

161. In addition, Novo:

- is a Corporate Partner/Gold Sponsor for American Association of Clinical Endocrinologists;¹⁴⁷
- serves on the Endocrine Society “Corporate Liaison Board”;¹⁴⁸
- is a member of American College of Cardiology (“ACC”) “Industry Advisory Forum,” in which it contributes at least \$25,000 annually (the ACC website says the Industry Advisory Forum “organization[s] will have a front-row seat to discussions on topics of mutual interest and importance impacting the cardiovascular healthcare environment.”);
- sits on the “Chairman’s Council” for the Obesity Action Coalition¹⁴⁹ and provided financial backing to the OAC “Your Weight Matters” campaign that provided potential patients with information about weight loss drugs.¹⁵⁰

¹⁴⁵ *About Us*, ALL ABOUT OBESITY, <https://allaboutobesity.org/about-us/> (last accessed Jan. 17, 2025).

¹⁴⁶ *Declaration of Interests*, ALL ABOUT OBESITY, <https://allaboutobesity.org/declaration-of-interests/> (last accessed Jan. 17, 2025).

¹⁴⁷ *Corporate AACE Partnership*, AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGY, <https://pro.aace.com/about/corporate-aace-partnership-cap> (last accessed Oct. 17, 2024).

¹⁴⁸ PARTNER WITH US, ENDOCRINE SOCIETY (Feb. 13, 2024), <https://www.endocrine.org/partnerships> (last accessed July 8, 2024).

¹⁴⁹ *See* OBESITY ACTION COALITION, 2023 ANNUAL REPORT: THE POWER OF CHANGE (2023) <https://www.obesityaction.org/wp-content/uploads/OAC-Annual-Report-2023.pdf>.

¹⁵⁰ *See* Ben Adams, *Eli Lilly, Novo Nordisk and other Big Pharmas back OAC’s ‘Your Weight Matters’ campaign challenge*, FIERCE PHARMA (Sep. 10, 2024), <https://www.fiercepharma.com/marketing/eli-lilly-novo-nordisk-and-other-big-pharmas-back->

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

162. Defendants recognized that there was a historical reluctance among physicians 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.¹⁵¹ Novo concluded that their 10-year plan to establish a leading position within treatment for obesity “starts by educating doctors.”¹⁵²

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

164. 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.”¹⁵³

165. In addition to the educational materials available directly from Defendants, they have also funded 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.¹⁵⁴

oacs-your-weight-matters-campaign.

¹⁵¹ 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>.

¹⁵² *Id.*

¹⁵³ *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).

¹⁵⁴ *Id.*

166. 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.¹⁵⁵ Novo is a sponsor of the “Obesity Care Week” Conference in the United States¹⁵⁶ that advocates for “clinically-based care” for obesity, which primarily consists of GLP-1 RAs.

e. Defendants Influence Medical Research and Literature

167. 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.

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

- On April 1, 2013, Holly R. Wyatt published an “update on Treatment Strategies for Obesity” in the Endocrine Society Journal and disclosed financial grant money from Novo.¹⁵⁷
- On October 24, 2017, University of Leeds researchers called semaglutide an “anti-obesity drug” after Novo funded their research on appetite control.¹⁵⁸
- In 2021, Novo funded research regarding the genetics of obesity.¹⁵⁹
- Novo has also funded research regarding the pervasiveness, impact, and

¹⁵⁵ 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.

¹⁵⁶ *Partners*, OBESITY CARE WEEK, <https://www.obesitycareweek.org/partners/> (last accessed Jan. 17, 2025).

¹⁵⁷ Holly R. Wyatt, *Update on Treatment Strategies for Obesity*, 98 J. CLINICAL ENDOCRINOLOGY & METABOLISM 1299 (2013).

¹⁵⁸ *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>.

¹⁵⁹ Ruth J. F. Loos & Giles S. H. Yeo, *The genetics of obesity: from discovery to biology*, 23 NATURE REVIEWS GENETICS 120 (2022).

implications of weight stigma.¹⁶⁰

- 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.¹⁶¹
- The 2023 Cardiovascular outcomes of the SELECT Trial – which was the basis for FDA approval of a label change for cardiovascular benefits – was conducted by Novo and an “academic steering committee.”¹⁶² This academic steering committee had received over \$7.5 Million dollars in payments from Novo between 2015-2022.¹⁶³
- In May of 2013, American Association of Clinical Endocrinologists releases 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.¹⁶⁴
- 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.¹⁶⁵
- Novo paid personal fees to the author of the study “Influence and effects of weight stigmatization in the media.”¹⁶⁶ Novo has separately funded the Joint International Consensus Statement for ending the Stigma of Obesity.¹⁶⁷

f. Defendants Pay Lobbying Groups to Support Legislation Authorizing

¹⁶⁰ Adrian Brown, *Pervasiveness, impact and implications of weight stigma*, ECLINICAL MEDICINE (Apr. 21, 2022).

¹⁶¹ *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).

¹⁶² 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>.

¹⁶³ *Id.*

¹⁶⁴ Alan J. Garber, *American Association of Clinical Endocrinologists' comprehensive diabetes management algorithm 2013 consensus statement*, 19, Suppl. 2 ENDOCR PRACT. 1 (2013).

¹⁶⁵ 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).

¹⁶⁶ James Kite et al, *Influence and effects of weight stigmatisation in media: A systematic*, ECLINICALMEDICINE. (May 20 2022).

¹⁶⁷ Francesco Rubino et al, *Joint international consensus statement for ending stigma of obesity*, 26 NATURE MEDICINE 485 (2020).

Reimbursements for GLP-1 RAs

169. 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.

170. In order to achieve mass adoption of GLP-1RA drugs and maximizing 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.¹⁶⁸

171. Unfortunately for Defendants, drugs used for weight loss were excluded by Congress when it established Medicare's Part D prescription drug benefit in 2003.¹⁶⁹

172. 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 Medicare to cover, among other treatments, chronic-weight-management drugs.¹⁷⁰

173. From 2012 to 2023, Novo spent over \$35 million on lobbying for obesity drug coverage.¹⁷¹

174. In 2021, Novo also gave hundreds of thousands of dollars to the Congressional

¹⁶⁸ See Rachana Pradhan, *Ozempic 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-medicare-favor>.

¹⁶⁹ *Id.*

¹⁷⁰ 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>.

¹⁷¹ See, e.g., OPEN SECRETS, *Novo Nordisk*, <https://www.opensecrets.org/orgs/novo-nordisk/lobbying> (last accessed Jan. 17, 2025).

Black Caucus Foundation and has also contributed to the Congressional Hispanic Caucus and Congressional Asian Pacific American Caucus.¹⁷² 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.¹⁷³

175. 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,¹⁷⁴ and direct contributions to political campaigns of various politicians.¹⁷⁵

176. 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

¹⁷² See Rachana Pradhan, *Ozempic 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-medicare-favor>.

¹⁷³ *Id.*

¹⁷⁴ 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).

¹⁷⁵ 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>.

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.”¹⁷⁶

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

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

178. 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.”¹⁷⁷

179. 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!” set to the tune of the 1970s song “Magic.” The catchy 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 is not approved for weight loss.¹⁷⁸

180. From 2018 through 2023, Novo spent approximately \$884 million on television advertising in the United States to promote Ozempic and later, its other semaglutide, Wegovy (and

¹⁷⁶ *Cost of covering antiobesity drugs could be billions to Medicare despite, a new analysis finds*, VANDERBILT UNIVERSITY MEDICAL CENTER (March 15, 2023), <https://www.vumc.org/health-policy/medicare-antiobesity-medications-nejm>.

¹⁷⁷ Phoebe Bain, *Ozempic was 2023's buzziest drug*, AD AGE (July 10, 2023), <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 ‘diabetes’ drugs surge*, MEDICAL MARKETING AND MEDIA (September 29, 2023), <https://www.mmm-online.com/home/channel/spending-on-ozempic-wegovy-surges/>.

¹⁷⁸ *See Ozempic TV Spot, 'Oh!'*, ISPOT (July 30, 2018), <https://www.ispot.tv/ad/d6Xz/ozempic-oh>.

another of its lesser known GLP-1 agonists, Rybelsus).¹⁷⁹

181. This massive spending made Ozempic to become a household name and engrained it 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.¹⁸⁰

182. Ozempic's place in the culture was unquestionable. Jimmy Kimmel joked about Ozempic at the Oscars;¹⁸¹ Howard Stern joked about and discussed Ozempic (Stern noted that the "catchy" theme song "distracts" the listener from actually hearing any of the listed side effects);¹⁸² 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.¹⁸³

183. All of this extensive marketing made demand for Ozempic and other GLP-1 RAs skyrocket. People wanted to use these drugs to lose weight, regardless of whether the drugs had been approved for that purpose or not. In some instances, it led to patients seeking prescriptions

¹⁷⁹ 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.

¹⁸⁰ 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>.

¹⁸¹ 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 accessed Sept. 17, 2023).

¹⁸² The Howard Stern Show, *Howard Goofs on the Ozempic Commercial*, YOUTUBE (April 5, 2023), <https://www.youtube.com/watch?v=QD-nCQn1Ads>.

¹⁸³ 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>.

for GLP-1 RAs from their doctor rather than their doctor suggesting it as a treatment for obesity.

184. Defendants also created numerous marketing campaigns and online platforms designed to promote recognition of obesity as a disease and advocate for pharmaceutical treatment of obesity.¹⁸⁴

185. 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.

186. 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.

187. Novo also owns and operates several marketing campaign websites, such as “The Truth about Weight,”¹⁸⁵ that were purportedly created to educate on the science of obesity and create change in how obesity is understood and treated. It also created the advertising campaign website “It's Bigger Than Me”¹⁸⁶ that promotes the message that obesity is a chronic health condition that requires pharmaceutical drugs to manage.¹⁸⁷

188. The “The Truth about Weight” website is also specifically intended to target minority communities, some of which have heightened rates of obesity. It has included the tag line

¹⁸⁴ 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>.

¹⁸⁵ *Truth About Weight*, TRUTH ABOUT WEIGHT, <https://www.truthaboutweight.com/> (last visited on Sept. 18, 2023).

¹⁸⁶ *It's Bigger than Me*, IT'S BIGGER THAN ME, <https://www.itsbiggerthan.com> (last accessed Sept. 18, 2023).

¹⁸⁷ *Id.*

“my weight, my culture” intended to convey the message that struggles to achieve weight loss through more traditional methods such as lifestyle interventions (*e.g.*, diet and exercise) will not work in light of cultural hurdles. The goal is to move this community toward believing that pharmaceutical interventions are the only answer. The website also suggests pushing back against doctors because they just might not get it, stating: “Many health care professionals know there’s a science behind weight loss, but they may not know the impact that culture has on weight loss needs.” There are also “my weight, my culture” hashtags appearing on Instagram with an apparent focus to target Black, Brown, and Hispanic individuals.¹⁸⁸

189. 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.¹⁸⁹

190. Novo had long been a proponent of using analytics to target and maximize sales.¹⁹⁰ 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.¹⁹¹

191. These platforms allow for invasive targeted advertising. For example, on Facebook,

¹⁸⁸ *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>.

¹⁸⁹ 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>.

¹⁹⁰ *Hyperright AB*, Utilizing Advanced Marketing Analytics for Sales Optimization – Peter Vester, Novo Nordisk, YOUTUBE (Dec. 22, 2022), <https://www.youtube.com/watch?v=nCZR6wK7MIU>.

¹⁹¹ *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>.

an advertiser can define the precise parameters of the audience they want to target (e.g., young women who struggle with weight, etc.) and Facebook can push an advertisement out to that exact audience based on its data analytics and algorithm.¹⁹² Instagram and other social media networks have similar features.

192. 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.¹⁹³ 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.”¹⁹⁴

193. It is recognized by the medical community that weight loss drugs may cause or worsen eating disorders.¹⁹⁵ Adolescent girls are particularly susceptible to eating disorders.

194. 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.¹⁹⁶ This was a lauded result presented in a case study

¹⁹² Meta Ads, *Audience ad targeting*, META, <https://www.facebook.com/business/ads/ad-targeting> (last visiting Jan. 17, 2025).

¹⁹³ *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/>.

¹⁹⁴ *Id.*

¹⁹⁵ 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>.

¹⁹⁶ *Novo Nordisk*, INSTAGRAM FOR BUSINESS, <https://business.instagram.com/success/novo->

by Meta.

195. 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.

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

197. For instance, 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 suggests that some people may need medication in order to lose weight.¹⁹⁷

198. These hashtags can also be used to facilitate engagement with the Defendants’ website. For example, the hashtag #ItsBiggerThan, was an advertising campaign on 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.

nordisk (last visited Sept. 17, 2023).

¹⁹⁷ Tiffany Lowe-Clayton (u/itsbiggerthan_me), REDDIT (Dec. 6, 2022), https://www.reddit.com/user/itsbiggerthan_me/comments/xqn6q7/comment/iz5ocg1/.

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

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

200. Novo's 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.

201. Novo was not permitted to market Ozempic for weight loss without FDA approval for that specific indication,¹⁹⁸ 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.¹⁹⁹

202. Novo's very first television ad for Ozempic touted that "adults lost on average up to 14 pounds" when taking Ozempic.²⁰⁰



¹⁹⁸ 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>.

¹⁹⁹ *Id.*

²⁰⁰ *Ozempic TV Spot, 'Oh!'*, iSPOT (July 30, 2018), <https://www.ispot.tv/ad/d6Xz/ozempic-oh>.

203. 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.”²⁰¹
- From 2018 to 2019, Novo’s OzempicPro.com homepage touted “Superior weight reduction.”²⁰²
- 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.”²⁰³
- In 2020, Novo’s OzempicPro.com homepage touted “significant weight reduction” with a link to “Examine weight data.”²⁰⁴
- 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.”²⁰⁵
- In 2021, Novo’s Ozempic.com says “People lost more than double the weight on Ozempic vs Trulicity.”²⁰⁶
- 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.”²⁰⁷
- From 2022 to 2024, Novo’s Ozempic.com, under “What is Ozempic?” says

²⁰¹ *Questions About Ozempic*, OZEMPIC, <https://web.archive.org/web/20180820075728/https://www.ozempic.com/FAQ/about-ozempic.html> (archived Aug. 20, 2018).

²⁰² *Ozempic*, OZEMPIC FOR HEALTHCARE PROFESSIONALS, <https://web.archive.org/web/20180826124503/https://www.ozempicpro.com/> (archived Aug. 6, 2018).

²⁰³ *Ozempic-significant weight reductions in a once-weekly injectable*, OZEMPIC, <https://web.archive.org/web/20201123163450/https://www.ozempicpro.com/alc-and-weight/ozempic-and-weight.html> (archived Nov. 23, 2020).

²⁰⁴ *Ozempic*, OZEMPIC FOR HEALTHCARE PROFESSIONALS, <https://web.archive.org/web/20210730195708/https://www.ozempicpro.com/> (archived July 30, 2021).

²⁰⁵ *Ozempic*, OZEMPIC, <https://web.archive.org/web/20211006213958/https://www.ozempic.com/> (archived Oct. 6, 2021).

²⁰⁶ *Id.*

²⁰⁷ *Ozempic*, OZEMPIC, <https://web.archive.org/web/20220808142658/https://www.ozempic.com/> (Archived Aug. 8, 2022).

“Adults taking Ozempic lost up to 14 pounds.”²⁰⁸

- From 2022 to 2024, Novo’s Ozempic.com said “People lost more than double the weight on Ozempic vs. Trulicity.”²⁰⁹
- From 2022 to 2024, Novo’s Novomedlink.com touted Ozempic Tri-Zone with “compelling weight loss.”²¹⁰
- 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.”

204. Novo has also promoted weight loss in its public statements. For instance, the March 28, 2022 press release announcing the approval of a higher dose of Ozempic, mentions that “[Ozempic] can help many patients lose some weight.”²¹¹

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

205. On October 1, 2019, Novo announced a partnership with Noom, a leading online weight loss platform, for “digital health solutions to help people with obesity lose weight and keep it off.”²¹²

²⁰⁸ *What Is Ozempic®?*, OZEMPIC

<https://web.archive.org/web/20220818181119/https://www.ozempic.com/why-ozempic/what-is-ozempic.html> (archived Aug. 18 2022).

²⁰⁹ *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).

²¹⁰ *Ozempic*, NOVOMEDLINK,

<https://web.archive.org/web/20240919183819/https://www.novomedlink.com/diabetes/products/treatments/ozempic.html> (archived Sep. 19, 2024).

²¹¹ 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>.

²¹² 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->

206. Since 2021, Novo has been an investor in Noom.²¹³

207. Noom Med now provides to consumers, using physicians hired by Noom, prescriptions for GLP-1 RAs directly to patients.²¹⁴ Noom Med promotes off label usage of GLP-1 RAs on its website.²¹⁵ Noom currently has over 45 million users.²¹⁶

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

- Weight Watchers, which has purchased telehealth startup Sequence for \$132 Million so that it could provide weight loss medications to its subscribers.²¹⁷ There are currently over 3.5 Million Weight Watchers subscribers.²¹⁸
- This also includes Calibrate, yet another telehealth provider for GLP-1 RAs, which raised \$100 Million in capital funding from investors in 2021.

209. Collectively, the telehealth providers that Novo directly and indirectly partnered with and/or promotes account for approximately half of all weight loss prescriptions in 2022.²¹⁹

digital-health-solutions-to-help-people-with-obesity-lose-weight-and-keep-it-off-811725389.html.

²¹³ Noom, NOVO HOLDINGS, <https://novoholdings.dk/investments/noom/> (last accessed Jan. 16, 2025).

²¹⁴ 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>.

²¹⁵ *Weight loss medication, the right way, with Noom*, NOOM, <https://www.noom.com/med/> (last accessed Sept. 18, 2023).

²¹⁶ *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/>.

²¹⁷ Karen Weintraub, *WeightWatchers is adding next-generation weight loss drugs like Wegovy to its program*, USA TODAY (March 9, 2023), <https://www.usatoday.com/story/news/health/2023/03/07/weightwatchers-sequence-wegovy-obesity-weight-loss-drugs/11415201002/>.

²¹⁸ 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>.

²¹⁹ 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/>.

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

211. 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.”²²⁰

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

212. 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.”²²¹

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

G. 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

214. As set forth previously in this Complaint, Defendants knew, or should have known,

²²⁰ 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>.

²²¹ See Novo Nordisk, *Novo Nordisk Launches Ozempic and Fiasp, Expanding Treatment Options for Adults With Diabetes*, PR NEWswire (Feb. 5, 2018), <https://www.prnewswire.com/news-releases/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment-options-for-adults-with-diabetes-300592808.html>.

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.

215. 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.

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

217. 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.

218. The FDA's Changes Being Effectuated ("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.

219. 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.

220. 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.

221. 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.

222. 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.

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

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

225. Despite developing this knowledge, Defendants did not disclose these risks and/or intentionally downplayed these risks in their labelling, promotion materials, marketing, advertising, and other public facing communications. Defendants' failure to disclose and/or intentional downplaying of these conditions prevented patients and doctors from taking appropriate precautions to reduce or mitigate the risk of these conditions. Defendants' failure deprived patients, like Plaintiff, and doctors, like Plaintiff's 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

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

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

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

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

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

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

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

233. If a drug company has reason to know the risks of a drug may result in adverse events, even if it develops that knowledge in the post-approval context, that company has a

responsibility to investigate those risks and to provide necessary information healthcare providers. FDA standards govern a manufacturer's duty to warn.

234. 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."²²²

235. 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."²²³

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

237. 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.

238. FDA's 2011 Guidance on Warnings in labeling advises: The 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."

239. FDA's Guidance also states: "Adverse reactions that do not meet the definition of a serious adverse reaction, but are otherwise clinically significant because they have implications

²²² 21 C.F.R. § 201.57(c)(6).

²²³ *Id.*

for prescribing decisions or patient management, should also be included in the WARNINGS AND PRECAUTIONS section.”

II. The Labels for Ozempic Were Inadequate at All Relevant Times From Launch to Present

240. At all relevant times, the “Warnings and Precautions” sections of the Prescribing Information for Ozempic omitted and continue to omit any “Warnings and Precautions” concerning NAION, the potential for emergent care, hospitalization, long term treatment or permanent vision loss.

241. 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 Ozempic.

242. 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.

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

244. At all relevant times, Defendants failed to disclose information regarding the serious risks of NAION with Ozempic.

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

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

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

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

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

250. Upon information and belief, had Defendants adequately warned Plaintiff's prescribing physicians that Ozempic are causally associated with NAION and its sequelae, then the physicians' prescribing decisions would have changed.

251. 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.

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

252. 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 Ozempic.

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

254. In addition, Defendants intentionally omitted other facts that they knew to be true from all of 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); (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.

255. ***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.

256. 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.²²⁴ 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.²²⁵

257. ***Non-responders.*** Some research suggests that patients taking semaglutide (*i.e.*, Ozempic) "found about 14% of patients lost less than 5% of their body weight and one-third lost

²²⁴ See Patricia J. Rodriguez et al., *Semaglutide vs Tirzepatide for Weight Loss in Adults With Overweight or Obesity*, 184 JAMA INTERN MED., 1056 (2024).

²²⁵ 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>.

less than 10%.”²²⁶ 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.”

258. ***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.²²⁷ 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.”²²⁸

259. Novo has publicly recognized that most individuals will regain all the weight back within five years of stopping Ozempic or Wegovy.²²⁹ A trial published by Novo showed that after a year participants had gained back two thirds of the weight lost after they stopped taking semaglutide.²³⁰ Indeed, Novo has acknowledged that some individuals will regain even more weight after stopping Ozempic or Wegovy than they initially lost.²³¹

²²⁶ 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>.

²²⁷ 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>.

²²⁸ 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>.

²²⁹ Annika Kim Constantino, *People taking obesity drugs Ozempic 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>

²³⁰ 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).

²³¹ Annika Kim Constantino, *People taking obesity drugs Ozempic 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>

260. 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*.”²³²

261. Wegovy and Ozempic are often marketed as part of a “metabolic reset”²³³ 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.”²³⁴ Not only is it not a “reset,” some patients will actually regain even more weight after stopping the drug.²³⁵

262. A meta-analysis of GLP-1 RA clinical trials found that “several GLP-1 RAs showed a gradual decline in effects on body weight throughout the long term intervention. In comparison to placebo, semaglutide resulted in a reduction of body weight from a mean difference of –3.28 kg (95% confidence interval –4.20 to –2.37) with medium term intervention to –2.75 kg (–4.60 to –0.89) with long term intervention. Liraglutide and dulaglutide also showed a similar trend.”²³⁶

263. ***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

²³² 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).

²³³ *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>.

²³⁴ Annika Kim Constantino, *People taking obesity drugs Ozempic 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>

²³⁵ *Id.*

²³⁶ 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)

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.).

264. 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 has an additional health condition or gains 5 pounds (or simply says he weighs 5 pounds more during a telehealth visit), this NFL Quarterback qualifies for one of the Defendants' weight loss drugs.

265. Because of the obvious shortcomings of BMI, the AMA has urged doctors to deemphasize their use of BMI in determining healthy weights for patients.²³⁷ On June 14, 2023, the AMA adopted a new policy clarifying how BMI should be used as a measure in medicine.²³⁸ 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.²³⁹

266. 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

²³⁷ *Id.*

²³⁸ 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>.

²³⁹ *Id.*

metrics of obesity can misclassify excess adiposity and could both underdiagnose and over diagnose disease.”²⁴⁰

267. 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.²⁴¹ These clinicians have cautioned that “a lower body weight does not always mean a person is healthier.”²⁴² In many instances, when someone loses weight, they lose fat (a good result) and also lose muscle mass (a bad result).

268. The medical community recognizes that weight loss achieved by Ozempic is often a result of a significant loss of muscle mass.²⁴³ As a result, individuals may be lighter than they were initially but have a higher percentage of body fat.²⁴⁴

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

²⁴⁰ Francesca Rubino et al, The Lancet Diabetes & Endocrinology Commission, *Definition and Diagnostic Criteria of Clinical Obesity*, 13 LANCET DIABETES & ENDOCRINOLOGY 221 (2025).

²⁴¹ 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>.

²⁴² 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>.

²⁴³ 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>.

²⁴⁴ 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>.

270. The loss of too much muscle mass can lead to sarcopenia, a condition called being “skinny fat,” in which the patient has decreased muscle mass, lessened bone density, and lower resting metabolic rate—all of which results in a loss of strength and functionality.²⁴⁵

271. 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 is a “healthy” weight loss.²⁴⁶ At the same time, Novo told investors: “Healthy weight loss is, I don’t want to call it the next frontier. But it is certainly important. There is a risk if you do introduce very fast and dramatic weight loss you will lose almost 50-50 lean body mass and fat mass. So the tempered, but consistent body weight loss could potentially be healthier than a very dramatic fast weight loss.”²⁴⁷ 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.”²⁴⁸

272. 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.²⁴⁹

²⁴⁵ 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>.

²⁴⁶ 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>.

²⁴⁷ 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>.

²⁴⁸ *Id.*

²⁴⁹ 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->

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

273. 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.²⁵⁰ This means that “[the] value [GLP-1 RA treatment] is not likely to be realized” in most patients.²⁵¹

274. 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 events are more likely to occur during dose escalation with Ozempic.²⁵²

275. 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 are clear indications that could impact a patient’s decision to take a GLP-1 RA.

EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

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

277. Defendants are and were under a continuing duty to disclose the true character, quality and nature of risks and dangers associated with Ozempic. Because of Defendants’

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²⁵⁰ 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.

²⁵¹ 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).

²⁵² 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).

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

NEGLIGENCE – INADEQUATE WARNING OR INSTRUCTION

N.C. GEN. STAT. §§ 99B-1, 99B-5
(AGAINST ALL DEFENDANTS)

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

279. This count is brought pursuant to North Carolina's Products Liability Act, N.C. Gen. Stat. § 99B-1 et seq., which governs all product liability actions - including claims based on inadequate warnings or instructions.

280. Defendants had a duty to exercise reasonable care in designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, labeling, sale and/or distribution of Ozempic into the stream of commerce, including a duty to assure Ozempic would not cause users to suffer unreasonable, dangerous side effects.

281. 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 Ozempic 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.

282. Defendant acted unreasonably by failing to provide adequate warnings or instructions regarding the true scope, severity, and permanence of vision risks associated with Ozempic.

283. Defendants' Ozempic 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.

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

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

286. Despite the fact that Defendants knew or should have known that Ozempic caused unreasonably dangerous injuries, Defendants continued to market Ozempic to prescribing physicians, including Plaintiff's prescribing physicians, without adequate warnings.

287. 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.

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

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

290. 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 Ozempic into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as NAION and its sequelae.

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

292. The Ozempic 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.

293. The Ozempic designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including the increased risks of NAION and its sequelae, as well as other severe, debilitating and permanent health consequences from Ozempic, 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.

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

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

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

297. At all relevant times, the labels for Ozempic 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.

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

299. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physicians were inadequate because Defendants failed to warn and/or adequately warn that their Ozempic had not been sufficiently and/or adequately tested for safety risks, including the increased risks of NAION and its sequelae.

300. 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.

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

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

303. Upon information and belief, had Plaintiff's prescribing physicians been warned that Ozempic had not been sufficiently and/or adequately tested for safety risks, including the increased risks of NAION and its sequelae, the prescribing physicians would not have prescribed Ozempic and/or would have provided Plaintiff with adequate warnings regarding the lack of

sufficient and/or adequate testing of Ozempic so as to allow Plaintiff to make an informed decision regarding his use of Ozempic.

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

305. If Plaintiff had been warned that Ozempic 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 Ozempic and/or suffered from NAION and its sequelae.

306. If Plaintiff had been warned of the increased risk of NAION and its sequelae, which has reasonable evidence of a causal association with Ozempic, then Plaintiff would have informed their prescribers that they did not want to take Ozempic.

307. Upon information and belief, if Plaintiff had informed their prescribing physicians that they did not want to take Ozempic due to the increased risks of NAION and its sequelae, or the lack of adequate testing for safety risks, then Plaintiff's prescribing physicians would not have prescribed Ozempic.

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

309. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed 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.

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

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

312. 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.

313. 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 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
BREACH OF EXPRESS WARRANTY UNDER
NORTH CAROLINA GENERAL STATUTE
SECTION 25-2-313
(AGAINST ALL DEFENDANTS)

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

315. At all relevant times, Defendants designed, researched, manufactured, tested,

316. At all relevant times, Defendants expressly represented to Plaintiff and Plaintiff's prescribing physicians that Ozempic was safe as an adjunct to diet and exercise to improve glycemic control and to reduce cardiovascular risks in adults with type 2 diabetes mellitus, and/or to aid in chronic weight management.

317. The aforementioned express representations were made to Plaintiff and Plaintiff's prescribing physicians by way of Ozempic's labels, websites, advertisements, promotional materials, and through other statements.

318. As a result of Defendants' express representations, Plaintiff's prescribing physicians were induced to prescribe Ozempic to Plaintiff, and Plaintiff was induced to use Ozempic.

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

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

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

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

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

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

325. At the time Ozempic left Defendants' control, Ozempic did not conform to Defendants' express representations because Ozempic was not safe to use as an adjunct to diet and exercise to improve glycemic control and to reduce cardiovascular risks in adults with type 2 diabetes, and/or to aid in chronic weight management, in that the drug was causally associated with increased risks of NAION and its sequelae.

326. The express representations made by Defendants regarding the safety of Ozempic were made with the intent to induce Plaintiff to use the products and/or Plaintiff's prescribing physicians to prescribe the products.

327. Defendants knew and/or should have known that by making the express representations to Plaintiff and/or Plaintiff's prescribing physicians, it would be the natural tendency of Plaintiff to use Ozempic and/or the natural tendency of Plaintiff's prescribing physicians to prescribe Ozempic.

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

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

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

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

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

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

334. Plaintiff's injuries and damages arose from a reasonably anticipated use of Ozempic by Plaintiff.

335. 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.

336. 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 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
NEGLIGENCE
(AGAINST ALL DEFENDANTS)

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

338. Defendants, directly or indirectly, caused Ozempic to be sold, distributed, packaged, labeled, marketed, promoted, and used by Plaintiff. At all relevant times, Defendants

registered, researched, manufactured, distributed, marketed, overpromoted, and sold Ozempic throughout the United States.

339. 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 Ozempic, 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.

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

341. 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 Ozempic 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.

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

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

344. 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 Ozempic, without thorough and adequate pre- and post-market testing of the product;
- b. Manufacturing, producing, overpromoting, marketing, advertising, formulating, creating, developing, and distributing Ozempic, and upon

information and belief, while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risks of serious harm associated with the use of Ozempic;

- c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Ozempic was safe for its intended 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 Ozempic was indeed unreasonably unsafe and unfit for use by reason of the product's defects and risks of harm to its users;
- e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that Ozempic's risks of harm 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 Ozempic;
- g. Advertising, marketing, and recommending the use of Ozempic, 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 Ozempic;
- h. Representing that Ozempic was 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 Ozempic with the knowledge that Ozempic, when used for weight management, was unreasonably unsafe and dangerous;
- j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of Ozempic so as to avoid the risks of serious harm associated with the use of Ozempic. Failing to design and manufacture Ozempic so as to ensure the drug was at least as safe and effective as other similar products;
- k. Failing to ensure that Ozempic was accompanied by proper and accurate warnings about the increased risks of NAION and its sequelae;
- l. Failing to ensure that Ozempic was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Ozempic and that use of Ozempic created a high risk of severe 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 Ozempic.

345. A reasonable manufacturer, designer, distributor, promoter, or seller under the same

346. As a direct and proximate result of Defendants' negligent testing, monitoring, and pharmacovigilance of Ozempic, Defendants introduced a drug into the State of North Carolina which they knew or should have known would cause serious, severe and debilitating injuries, including NAION and its sequelae.

347. 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.

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

349. 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.

350. 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 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 OF
MERCHANTABILITY
N.C. GEN. STAT. §§99B-1, 99B-2, 25-2-314
(AGAINST ALL DEFENDANTS)

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

352. Defendants are “merchants” with respect to goods of the kind at issue within the meaning of N.C. Gen. Stat. § 25-2-104, and [DRUG] is a “good” within the meaning of N.C. Gen. Stat. § 25-2-105

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

354. Ozempic was 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.

355. By placing Ozempic into the stream of commerce, Defendants impliedly warranted that Ozempic was merchantable and fit for the ordinary purposes for which such drugs are used, pursuant to N.C. Gen. Stat. § 25-2-314.

356. At all relevant times, Defendants impliedly warranted to Plaintiff, Plaintiff’s prescribing physicians, and the medical community that Ozempic was of merchantable quality and safe and fit for its ordinary purpose.

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

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

359. At the time Ozempic left Defendants’ control, Ozempic 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.

360. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as Plaintiff's prescribing physicians, would recommend, prescribe and/or dispense Ozempic for use by their patients to improve glycemic control in adults with type 2 diabetes, to reduce cardiovascular risk, and/or to aid in chronic weight management.

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

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

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

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

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

366. Plaintiff reasonably relied upon Defendants' skill and judgment as to whether Ozempic was of merchantable quality and safe and fit for its intended uses.

367. Upon information and belief, Plaintiff's prescribing physicians relied on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to Ozempic.

368. Upon information and belief, Plaintiff's prescribing physicians, reasonably relied upon the skill and judgment of Defendants as to whether Ozempic was of merchantable quality and safe and fit for its intended use.

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

370. Defendants herein breached the aforesaid implied warranties of merchantability because Ozempic was not merchantable or safe for its intended use because it contained an undisclosed defect - namely, the propensity to cause NAION - rendering it unreasonably dangerous to the ordinary consumer.

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

372. Privity is not required to maintain this claim under North Carolina law. N.C. Gen. Stat. § 99B-2(a).

373. 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.

374. 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 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)

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

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

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

378. At all relevant times, Defendants knew or should have known that Ozempic 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.

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

380. Nonetheless, Defendants consciously and deliberately withheld and concealed from Plaintiff's prescribing physician(s), Plaintiff, the medical and healthcare community, and the general public this material information.

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

382. Defendants' omissions and concealment of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and patients, such as Plaintiff, to dispense,

provide, prescribe, accept, purchase, and/or consume Ozempic for treatment of type 2 diabetes and/or to promote weight loss.

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

384. Defendants knew that Plaintiff and Plaintiff's prescribing physicians (s) had no way to uncover the concealed information and determine the truth surrounding Ozempic, as set forth herein.

385. Upon information and belief, Plaintiff's prescribing physician(s) justifiably relied on Defendants' material omissions when making the decision to dispense, provide, and prescribe Ozempic.

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

387. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic had not been sufficiently and/or adequately tested for safety risks, including NAION and its sequelae, they would not have prescribed Ozempic and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic.

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

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

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

391. 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.

392. 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.

393. 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 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)

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

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

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

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

398. At all relevant times, Defendants knew or should have known that Ozempic was not safe to improve glycemic control in adults with type 2 diabetes, reduce cardiovascular risk in patients with type 2 diabetes, or promote weight loss, given its increased risk of NAION and its sequelae.

399. Nonetheless, Defendants made material misrepresentations to Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Ozempic.

400. Defendants represented affirmatively and by omission on television advertisements, social media and other online advertisements, and on the labels of Ozempic that Ozempic was a safe and effective drug for treatment of adults with Type 2 diabetes, or for chronic weight management, despite being aware of increased risks of NAION and its sequelae causally associated with using Ozempic.

401. 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 physician(s), the medical and healthcare community, and the general public.

402. Defendants' misrepresentations of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Ozempic for treatment of type 2 diabetes and/or to promote weight loss.

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

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

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

406. Had Plaintiff been informed of the increased risk of NAION and its sequelae causally associated with Ozempic, Plaintiff would not have used Ozempic.

407. As a direct and proximate result of Defendants' fraudulent and/or intentional misrepresentations, 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.

408. As a direct and proximate result of Defendants' fraudulent and/or intentional misrepresentations, 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 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII
NEGLIGENT MISREPRESENTATION / MARKETING
(AGAINST ALL DEFENDANTS)

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

410. At all relevant times, Defendants negligently provided Plaintiff, Plaintiff's healthcare providers, the general medical community, and the public with false, fraudulent, and/or

incorrect information or omitted or failed to disclose material information concerning Ozempic, including, but not limited to, misrepresentations and marketing regarding the safety and known risks of Ozempic.

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

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

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

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

415. Defendants made continued omissions in Ozempic's labeling, including promoting it as safe and effective while failing to warn of its propensity to cause NAION and its sequelae.

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

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

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

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

420. 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.

421. 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.

422. 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.

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

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

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

426. Defendants failed to exercise ordinary care in making representations concerning Ozempic while they were involved in the manufacture, design, sale, testing, quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate commerce, because Defendants negligently misrepresented Ozempic's high risk of unreasonable and dangerous adverse side effects.

427. 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 Ozempic

428. 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 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIBRADLII
VIOLATION OF NORTH CAROLINA
UNFAIR AND DECEPTIVE TRADE PRACTICES ACT (UDTPA)
N.C. GEN. STAT. §75-1.1 ET SEQ.
(AGAINST ALL DEFENDANTS)

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

430. Plaintiff is an individual who is a consumer who purchased Defendants' Ozempic

431. Defendants' marketing, promotion, and sale of Ozempic constitute conduct "in or affecting commerce" within the meaning of N.C. Gen. Stat. § 75-1.1(a).

432. Independent of the warning and design defects alleged above, Defendants engaged in unfair and/or deceptive acts or practices in connection with the marketing and promotion of Ozempic that had the capacity and tendency to deceive prescribing physicians and consumers, including Plaintiff. These acts include, without limitation:

- a. Affirmatively representing to prescribing physicians, the medical community, and the public - through promotional materials, sales representative detailing, key opinion leaders, and direct-to-consumer advertising - that Ozempic was safe for its approved and promoted uses, while in possession of pre-clinical, adverse-event, and epidemiological data indicating an undisclosed risk of NAION;
- b. Continuing to market and promote Ozempic - including messaging characterizing the product to consumers as a safe, low-risk solution for diabetes management and weight loss - after Defendants knew or should have known of mounting evidence linking Ozempic to NAION;
- c. Omitting and concealing material safety information regarding the risk of NAION from prescribing physicians, regulators, and consumers, including Plaintiff, in order to protect Ozempic's commercial success and market share.

433. This conduct is distinct from, and goes beyond, the inadequate warning alleged elsewhere in this Complaint. It consists of Defendants' affirmative and ongoing promotional representations of safety made with knowledge of contrary information, not merely a passive omission from the product label.

434. Defendants' conduct described above had the capacity to deceive, and was likely to deceive, an ordinary consumer and prescribing physician acting reasonably under the circumstances.

435. Defendants' unfair and deceptive acts and practices proximately caused actual injury to Plaintiff, in that Plaintiff and/or Plaintiff's prescribing physician relied on Defendants' representations regarding the safety of Ozempic in choosing to use Ozempic, resulting in Plaintiff's NAION and associated damages, including medical expenses, lost wages, diminished earning capacity, and amounts paid for Ozempic that Plaintiff would not have paid had adequate disclosures been made.

436. Pursuant to N.C. Gen. Stat. § 75-16, Plaintiff is entitled to recover three times the amount of actual damages sustained as a result of Defendants' violations of N.C. Gen. Stat. § 75-1.1.

437. Pursuant to N.C. Gen. Stat. § 75-16.1, Plaintiff is entitled to recover reasonable attorneys' fees, in that Defendants willfully engaged in the acts and practices giving rise to this claim and/or unwarrantedly refused to fully resolve the matter giving rise to this claim.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for treble damages pursuant to N.C. Gen. Stat. § 75-16, reasonable attorneys' fees pursuant to N.C. Gen. Stat. § 75-16.1, costs, and such other relief as the Court deems just and proper.

PUNITIVE DAMAGES

438. Plaintiff repeats and incorporates by reference each preceding paragraph as though fully set forth herein.

439. Pursuant to N.C. Gen. Stat. § 1D-15(a), Plaintiff is entitled to recover punitive damages because Defendants' conduct giving rise to Plaintiff's injuries was characterized by fraud and/or willful or wanton conduct, as those terms are defined in N.C. Gen. Stat. § 1D-5, and Plaintiff will prove these aggravating factors by clear and convincing evidence.

440. Defendants' conduct constituted willful or wanton conduct within the meaning of N.C. Gen. Stat. § 1D-5(7) in that Defendants consciously and intentionally disregarded, and were indifferent to, the rights and safety of Plaintiff and other foreseeable users of Ozempic, when

Defendants knew or should have known that their conduct was reasonably likely to result in injury, including by:

- a. Failing to investigate or differentiate the ocular vascular safety signal observed in Defendants' own 2016 SUSTAIN-6 trial data before bringing Ozempic to market (*supra*)
- b. Continuing to market and promote Ozempic as safe to physicians, key opinion leaders, and consumers after Defendants knew or should have known of accumulating post-marketing evidence linking Ozempic to NAION (*supra*)
- c. Failing to update Ozempic's labeling to disclose the risk of NAION despite the evidence described herein. (*supra*)

441. Defendants' conduct constituted fraud within the meaning of N.C. Gen. Stat. § 1D-5(5) for the reasons alleged in this Complaint.

442. Pursuant to N.C. Gen. Stat. § 1D-15(c), punitive damages may not be awarded against a corporation solely on a theory of vicarious liability for the acts of its employees. Plaintiff alleges that the conduct constituting the aggravating factors described above was participated in or condoned by Defendants' officers, directors, and/or managers, including those responsible for: Defendants' regulatory and labeling decisions concerning Ozempic; Defendants' corporate strategy decisions regarding the marketing and promotion of Ozempic and the broader GLP-1 RA product line, as reflected in Defendants' own public statements at investor and capital markets presentations, and Defendants' pharmacovigilance and safety-signal evaluation functions.

443. Pursuant to N.C. Gen. Stat. § 1D-25(b), the statutory cap on punitive damages set forth in N.C. Gen. Stat. § 1D-25(a) does not apply, because Defendants' conduct was committed in a manner consistent with a pattern or practice of conduct, Defendants and/or their officers, directors, and managers actually knew or should have known that this pattern or practice created a high risk of injury to others, and Defendants and/or their officers, directors, and managers, with knowledge of that high risk, continued the conduct that proximately caused Plaintiff's injuries.

444. An award of punitive damages is necessary and appropriate to punish Defendants for their conduct and to deter Defendants and others similarly situated from engaging in similar conduct in the future.

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 19, 2026

RESPECTFULLY SUBMITTED,

/s/ Bradley D. Honnold
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