

**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

CARYN SCHOLLMMEYER,

COMPLAINT AND JURY DEMAND

Plaintiff,

CIVIL ACTION NO.: 2:26-cv-05273

v.

NOVO NORDISK INC., and
NOVO NORDISK A/S,

Defendants.

COMPLAINT AND JURY DEMAND

COMES NOW, Plaintiff, CARYN SCHOLLMMEYER, by and through the undersigned counsel, and brings this complaint against Defendant Novo Nordisk Inc. hereinafter “Defendant” or “Novo Nordisk”), for damages suffered by Caryn Schollmeyer who was severely injured as a result of Defendant’s widespread marketing of its drug, Ozempic and Wegovy, and her subsequent use of Ozempic, an injectable prescription medication that is approved for improvement of blood sugar (glucose) in adults with type 2 diabetes, and alleges as follows:

PARTIES

1. At all relevant times hereto, Plaintiff Caryn Schollmeyer was a resident and citizen of the State of Florida in the county of Hillsborough.

2. Plaintiff was prescribed and took Ozempic as directed by her physicians.

3. As a result of his use of Ozempic, Ms. Schollmeyer developed non-arteritic anterior ischemic optic neuropathy (NAION) and suffers severe physical and emotional injuries and radical

changes to his lifestyle given her severe loss of sight.

4. Novo Nordisk Inc. (“Novo Nordisk”) is a Delaware corporation that has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

5. Defendant Novo Nordisk Inc. is wholly owned by Novo Nordisk US Commercial Holdings, Inc.

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7. Defendant Novo Nordisk US Commercial Holdings Inc., is wholly owned by Defendant Novo Nordisk US Holdings Inc.

8. Defendant Novo Nordisk US Holdings Inc. is a Delaware corporation with a principal place of business at 103 Foulk Road, Wilmington, Delaware.

9. Defendant Novo Nordisk US Holdings Inc. is wholly owned by Defendant Novo Nordisk A/S.

10. Defendant Novo Nordisk A/S is a public limited liability company organized under the laws of Denmark with a principal place of business in Bagsvaerd, Denmark.

11. Defendant Novo Nordisk A/S and its subsidiaries and affiliated named herein are collectively referred to as “the Novo Nordisk Defendants” and “Novo Nordisk”.

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

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

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

15. The Novo Nordisk Defendants' website states that "the vast majority of our U.S. injectable diabetes and obesity products are produced and packaged at the Clayton aseptic fill-finish site. Upon information and belief, this refers to Novo Nordisk's manufacturing facility in Clayton, North Carolina, operated by Novo Nordisk Pharmaceutical Industries LP.

16. Upon information and belief, Defendant Novo Nordisk Pharmaceutical Industries LP is the labeler for Ozempic and Wegovy, and Defendants Novo Nordisk A/S and Novo Nordisk Inc. are identified on Ozempic and Wegovy's label. The Novo Nordisk Defendants also designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic and Wegovy.

17. Upon information and belief, Defendants failed to warn physicians and the end users of Ozempic and/or Wegovy of the complications and devastating effects of which the companies knew or should have known, including NAION, which can result in blindness and permanent vision loss.

18. Upon information and belief, Defendants failed to warn the end users of Ozempic and/or Wegovy of the complications and devastating effects of which the company knew or should have known.

19. Upon information and belief, Defendants' marketing was deceptive and misleading about the true risks associated with the use of Ozempic and/or Wegovy, risks which the companies knew or should have known.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction under 28 U.S.C. §1332(a) as the matter in controversy exceeds the value of \$75,000, exclusive of interest and costs and is between citizens of different states and/or a foreign state, as Plaintiff is a citizen of the Commonwealth of

Pennsylvania, and each Defendant is neither incorporated nor has its principal place of business in the Commonwealth of Pennsylvania.

21. This Court has personal jurisdiction over Defendants consistent with the United States Constitution and 42 Pa. Consol. Stat. Ann. §5322 (Pennsylvania’s “long arm” statute), as Plaintiff’s claims arise out of Defendants’ transaction of business, their tortious acts within the Commonwealth of Pennsylvania, their doing a series of similar acts for the purpose of thereby realizing pecuniary benefit, and by virtue of Defendants’ substantial, continuous, and systematic contacts with the Commonwealth of Pennsylvania.

22. This Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

23. Venue is proper under 28 U.S.C. § 1391(b)(2) as a substantial part of the events or omissions giving rise to the claim occurred in this District. Defendants routinely market their products at issue in this District and conduct business in this District related to their products at issue in the Commonwealth of Pennsylvania.

24. Novo Nordisk’s contacts with Philadelphia, Pennsylvania include the following, which are related to the actions and transactions at issue in this complaint:

25. Novo Nordisk has retained U.S. private contract manufacturer PCI Pharma Services to handle assembly and packaging of Wegovy, including putting together the self-injection pens used to administer Wegovy.¹ The self-injection pens are required for a patient to use the drug and potentially suffer adverse effects underlying this complaint. PCI Pharma Services is headquartered in Philadelphia, PA.²³

¹ <https://www.reuters.com/business/healthcare-pharmaceuticals/novo-nordisk-hires-private-us-firm-handle-some-wegovy-pen-assembly-source-2023-09-18/>

² *Id.*

³ <https://pci.com/contact/>

26. Novo Nordisk routinely recruits employees within Philadelphia related to diabetes care⁴, and recruits sales associates in Pennsylvania.⁵ Novo Nordisk maintains employees in Philadelphia related to diabetes care.⁶ The Philadelphia Department of Public Health released a report on “Drug Marketing Through Gifts of Meals to Physicians in Philadelphia,” which showed Novo Nordisk’s Ozempic was #8 in the “Top 20 Drugs Marketed in Philadelphia” in 2018 through February 2020.⁷

27. Novo Nordisk’s marketing agency for Wegovy, Accenture Song (formerly Concentric Life), has multiple offices in Pennsylvania including Philadelphia.⁸

28. The marketing agency that leads the Wegovy account is now Accenture Song. Accenture Song has four Pennsylvania offices, including one in Philadelphia. The Wegovy marketing team was awarded the industry Launch award for the year, and specifically thanked “our partners at Novo Nordisk” whose dedication “made it possible.”⁹

29. Novo Nordisk funds extensive research at University of Pennsylvania in Philadelphia and Penn Medicine specifically related to diabetes care and weight loss.¹⁰ Moreover, University of Pennsylvania Professors have received research funds on behalf of the University of Pennsylvania while also serving on the advisory board of Novo Nordisk on studies directly related to semaglutide and obesity.^{11,12}

⁴ <https://novonordisk.dejobs.org/philadelphia-pa/medical-liaison-liver-health-pa/EF6DC568FC1E45E4B180EE94A52DBB1C/job/>

⁵ https://www.novonordisk-us.com/careers/find-a-job/job-ad.292229.en_US.html

⁶ <https://www.linkedin.com/in/lindsey-hunt-82911b55>

⁷ https://www.phila.gov/media/20200204150030/2020-drug-marketing-report_2_4_2020.pdf

⁸ <https://www.pm360online.com/elite-2023-marketing-team-wegovy-obesity-marketing-team-of-novo-nordisk-inc/>; and see <https://newsroom.accenture.com/news/2023/accenture-completes-acquisition-of-healthcare-marketing-agency-concentriclife>; and <https://www.accenture.com/us-en/about/locations/office-details?loc=Pennsylvania>.

⁹ <https://www.newswire.com/news/concentric-health-experience-named-agency-of-the-year-at-the-2022-21695158>

¹⁰ See, e.g., <https://www.nursing.upenn.edu/details/news.php?id=1522>; <https://www.pennmedicine.org/news/news-releases/2020/march/newly-discovered-brain-response-to-obesity-drug-may-inform-future-treatments>.

¹¹ <https://onlinelibrary.wiley.com/doi/full/10.1002/oby.23946>

¹² <https://www.med.upenn.edu/weight/wadden.html>; https://wfpc.sanford.duke.edu/podcast_guest/wadden-thomas/

30. Novo Nordisk has funded Philadelphia community programs to address obesity and diabetes.¹³ This includes Novo Nordisk serving as a “local sponsor” for the Philadelphia Walk from Obesity and Fun Run; targeting Philadelphia as its second city in its “Cities Changing Diabetes” initiative; and hosting a “Tackle Your Health” sweepstakes with the Philadelphia Eagles to educate Eagle fans on the risk factors associated with type 2 diabetes and obesity.¹⁴

BACKGROUND

I. An Accidental Blockbuster: The Development of Ozempic and Wegovy

31. In the early 1990s, Novo Nordisk researchers discovered that when they injected into rats a chemical compound known as liraglutide—a GLP-1 (glucagon-like peptide-1) agonist—the drug caused the rats to stop eating almost entirely.¹⁵

32. GLP-1 agonists are a class of medications that can help lower blood sugar levels and promote weight loss.¹⁶ An agonist is a manufactured substance that attaches to a cell receptor and causes the same action as the naturally occurring substance.¹⁷ Thus, GLP-1 agonists work by mimicking a naturally occurring GLP-1 hormone.

33. To describe the process in other words, GLP-1 medications bind to GLP receptors to trigger the effects (or roles) of the GLP-1 hormone. The higher the dose of the GLP-1 agonist, the more extreme the effects.¹⁸

¹³ <https://hcifonline.org/tag/population-health/>

¹⁴ <https://bariatrictimes.com/walk-from-obesity-raising-funds-in-philadelphia-summer-2019/>;
<https://www.citieschangingdiabetes.com/network/philadelphia.html>;
<https://static.clubs.nfl.com/image/upload/v1666020341/eagles/mp3pn3smy1yf2sj3cyrp.pdf>

¹⁵ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html>
 (last visited Sept. 17, 2025)

¹⁶ <https://my.clevelandclinic.org/health/articles/13901-glp-1-agonists> (last visited Sept. 17, 2025)

¹⁷ *Id.*

¹⁸ *Id.*

34. “These rats, they starved themselves,” said one Novo Nordisk scientist, Lotte Bjerre Knudsen, in a video series released by the Novo Nordisk Foundation, “so we kind of knew there was something in some of these peptides that was really important for appetite regulation.”¹⁹

35. Later testing in human subjects revealed that those who received an intravenous drip of GLP-1 agonist ate 12% less at a lunch buffet than those who got a placebo.²⁰

36. Consequently, Novo Nordisk decided to study liraglutide as not only a diabetes drug which had been shown to lower blood sugars, but also as a drug to treat obesity.²¹

37. Years later, in 2010, liraglutide was approved for the treatment of diabetes by the FDA under Novo Nordisk's brand name Victoza,²² at which point Novo Nordisk moved forward with studying the drug for weight loss.²³

38. After clinical trials, in 2014, the FDA approved liraglutide as a daily injectable for treatment of obesity under Novo Nordisk's brand name, Saxenda.²⁴

39. Saxenda's effects on weight loss, however, were modest; patients lost about 5% of their weight.²⁵

¹⁹ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited Sept. 17, 2025).

²⁰ *Id.*

²¹ *Id.*

²² [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2957743/#:~:text=The%20incretin%20mimetic%20liraglutide%20\(Victoza,adults%20with%20type%2D2%20diabetes.&text=Liraglutide%20is%20also%20approved%20in%20Europe%20and%20Japan](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2957743/#:~:text=The%20incretin%20mimetic%20liraglutide%20(Victoza,adults%20with%20type%2D2%20diabetes.&text=Liraglutide%20is%20also%20approved%20in%20Europe%20and%20Japan) (last visited Sept. 18, 2025).

²³ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited Sept. 17, 2025).

²⁴ *Id.*

²⁵ *Id.*

40. In an effort to find ways to make a longer-lasting GLP-1 agonist so patients would not have to inject themselves every day, Novo Nordisk created a new molecule with the chemical name semaglutide.²⁶

41. Novo Nordisk branded semaglutide as Ozempic, and on December 5, 2016, the Novo Nordisk Defendant announced submission of Ozempic’s new drug application (NDA) to the FDA for regulatory approval of a once-weekly injectable, in 0.5 mg or 1 mg doses, for treatment of Type 2 diabetes. In the announcement, Defendant represented that in clinical trials “once-weekly” Ozempic had a safe and well-tolerated profile, and Defendant represented that the most common adverse event was nausea.²⁷

42. On December 5, 2017, the FDA approved the Ozempic application and granted premarket approval as NDA 209637.²⁸

43. When Novo Nordisk 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 Nordisk offered an “Instant Savings Card to reduce co-pays to as low as \$25 per prescription for up to two years.”

44. In addition to diabetic control, Ozempic also caused 15% weight loss, which was three times the loss caused by its predecessor, Saxenda.²⁹

²⁶ *Id.*

²⁷ <https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183> (last visited Sept. 17, 2025).

²⁸ https://www.accessdata.fda.gov/Ozempicatfda_docs/appletter/2017/209637s000ltr.pdf (last visited Sept. 17, 2025).

²⁹ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited Sept. 17, 2025).

45. Just one year after Ozempic’s approval for diabetes, Defendant started a clinical trial in patients who were overweight or suffered from obesity.³⁰

46. The results of the trial demonstrated that for participants who were overweight or obese, 2.4 mg of semaglutide, once weekly, plus lifestyle intervention was associated with sustained, clinically relevant reduction in body weight.³¹

47. On March 20, 2019, Defendant submitted a supplemental new drug application (sNDA) for Ozempic 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.³² On January 16, 2020, the FDA approved this new indication.³³

48. By March of 2021, Defendant had completed the clinical trial studying semaglutide for weight loss, and its results were published March 18, 2021.³⁴

49. In addition to the results, the published study, which was funded by Defendant, argued: “Obesity is a chronic disease and global public health challenge.”³⁵

50. Then, on May 28, 2021, Defendant submitted another sNDA requesting approval for a higher, 2 mg dose of Ozempic injection. On March 28, 2022, the FDA approved this request.³⁶

³⁰ *Id.*

³¹ <https://www.nejm.org/doi/full/10.1056/NEJMoa2032183> (last visited Sept. 17, 2025)

³² <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> (last visited on Sept. 17, 2025).

³³ https://www.accessdata.fda.gov/Ozempicatfda_docs/appletter/2020/209637Orig1s003ltr.pdf (last visited Sept. 17, 2025).

³⁴ <https://www.nejm.org/doi/full/10.1056/NEJMoa2032183> (last visited Sept. 17, 2025)

³⁵ *Id.*

³⁶ https://www.accessdata.fda.gov/Ozempicatfda_docs/appletter/2022/209637Orig1s009ltr.pdf (last visited Sept. 17, 2025).

51. In its press release, Defendant represented Ozempic as having “proven safety and efficacy” and Defendant continued to advertise that “it can help many patients lose some weight.”³⁷ As with its prior press releases, Defendant disclosed Important Safety Information and provided links to the Medication Guide and Prescribing Information. However, severe gastrointestinal events, including gastroparesis and gastroenteritis, were not identified as risks. Nor was there any disclosure about risks of vision loss, including NAION.

52. On September 22, 2023, Novo Nordisk added “ileus” under Section 6-3 Postmarketing Experience of the Prescribing Information (“PI” or “label”) in a revised Ozempic label.

53. The new label listed ileus as an adverse reaction reported during post-approval use of semaglutide, the active ingredient in Ozempic.³⁸

54. On September 6, 2024, the FDA notified Novo Nordisk 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.

55. On October 4, 2024, Novo Nordisk submitted a supplemental new drug application (sNDA 209637/S-032) and amendments for Ozempic incorporating the FDA’s required safety modifications to the label.

56. On November 1, 2024, the FDA provided supplemental approval for sNDA 209637/S-032.³⁹

³⁷ <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> (last visited Sept. 17, 2025).

³⁸ Ozempic Label (dated 9/22/23), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s0202s0211bl.pdf

³⁹ FDA Supplement Approval Letter for NDA 209637/S-032 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/209637Orig1s32ltr.pdf

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

II. Defendant Creates a Market: Millions Spent on Marketing and Promotion Create a Media Frenzy and Mega Seller

58. Novo Nordisk was not permitted to market Ozempic for weight loss without FDA approval for that specific indication,⁴⁰ but before Ozempic ever received separate approval for treatment of weight loss, Novo Nordisk had already begun mentioning weight loss in its Ozempic



commercials.⁴¹

59. On July 30, 2018, Novo Nordisk launched its first television ad for Ozempic to the tune of the 1970s hit pop song “Magic” by Pilot, wherein Novo Nordisk advertised that “adults lost on average up to 14 pounds” when taking Ozempic.⁴²

⁴⁰ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited Sept. 18, 2025).

⁴¹ *Id.*

⁴² *Id.*

60. Over the next five years, Novo Nordisk spent \$884,000,000 running television ads in the United States to promote its semaglutides, Ozempic, Wegovy, and its lesser known GLP-1 agonists, Rybelsus, with most advertisements allocated towards Ozempic.⁴³

61. Defendant also employed sophisticated use of social media to market Ozempic.

62. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,⁴⁴ and currently has over 1.2 billion views.⁴⁵

63. The hashtag #ozempicjourney has 199.5 million views, as of September 9, 2023, on TikTok.

64. Novo Nordisk partnered directly with Meta and Instagram to run marketing campaigns. One diabetes marketing campaign achieved a dramatic 28% direct engagement rate with their polls.⁴⁶ This was a lauded result presented in a case study by Meta.

65. On July 10, 2023, a global media company declared Ozempic as “2023’s buzziest drug” and one of the “Hottest Brands, disrupting U.S. culture and industry.”⁴⁷

66. Novo Nordisk reportedly spent approximately one hundred million dollars advertising Ozempic last year.⁴⁸ Ozempic ranked as the sixth most advertised prescription drug brand in 2022, with a U.S. measured media spend of \$181 million, according to Vivvix spending data and Pathmatics paid social data as reported in Ad Age Leading National Advertisers 2023.⁴⁹

⁴³ https://medwatch.com/News/Pharma_Biotech/article15680727.ece (last visited Sept. 18, 2023).

⁴⁴ <https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html> (last visited Sept. 18, 2025).

⁴⁵ <https://www.tiktok.com/tag/ozempic> (last visited on August 1, 2023).

⁴⁶ <https://business.instagram.com/success/novo-nordisk> (last visited Sept. 17, 2025).

⁴⁷ <https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571> (last visited on Sept. 17, 2025).

⁴⁸ <https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin> (last visited Sept. 17, 2025).

⁴⁹ <https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular->

67. In 2023, over \$491 million was spent advertising “diabetesity” drugs, including Ozempic and Wegovy.⁵⁰

68. Jimmy Kimmel joked about Ozempic at the Oscars.⁵¹

69. Howard Stern has joked and discussed Ozempic.⁵² Interestingly, Stern notes that the “catchy” theme song “distracts” the listener from actually hearing any of the listed side effects.⁵³

70. Novo Nordisk has spent millions of dollars delivering their message to physicians, healthcare providers, and consumers.

71. For example, Novo Nordisk spent over \$33,000,000 in 2022 on traditional physician marketing and detailing according to Open Payments Data.⁵⁴

72. In sum, Novo Nordisk promoted the safety, efficacy, and sale of Ozempic in the United States on its websites, in press releases, through in-person presentations, through the drug’s label, in print materials, on social media, advocacy groups, lobbying groups, celebrity partnerships, telehealth partnerships, key opinion leaders, and through other public outlets.

73. However, throughout its marketing, Defendant failed to disclose the true serious side effects of Ozempic, including but not limited to hospitalization and death.

III. Marketing Works: Novo Nordisk’s Rampant Promotion Result in Thousands of Prescriptions and Billions in Sales

marketing-

2023/2500571?utm_source=exchange&utm_medium=email&utm_campaign=t5687390

⁵⁰ <https://www.mmm-online.com/home/channel/spending-on-ozempic-wegovy-surges/>

⁵¹ <https://www.usatoday.com/story/life/health-wellness/2023/03/13/ozempic-sweeping-hollywood-celebrities-weight-loss/11428801002/> (last accessed Sept. 17, 2025).

⁵² <https://www.youtube.com/watch?v=QD-nCQn1Ads> (last visited on Sept. 17, 2025).

⁵³ *Id.*

⁵⁴ <https://openpaymentsdata.cms.gov/company/100000000144> (last visited Sept. 18, 2025)

74. As a result of Novo Nordisk's all-encompassing advertising and promotion efforts, Ozempic is widely prescribed throughout the United States.

75. As of August 10, 2023, Novo Nordisk reported that in the first six months of 2023 sales of Ozempic jumped 50% to more than \$3.7 billion.⁵⁵

76. In July of 2021, doctors in the US wrote 62,000 prescriptions a week for Ozempic.⁵⁶

77. It has been reported that the huge demand created by extensive marketing has led to rampant off-label usage and "gaming" the system to allow for insurance coverage.⁵⁷

78. In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.⁵⁸

79. This surge has reshaped Denmark's economy as the country has reaped huge profits from the sale of the drug, which is now solely responsible for the country's economic growth.⁵⁹

80. Ozempic has become so popular, Novo Nordisk has recently limited shipment to the US and paused advertising while it addresses shortages.⁶⁰

IV. Defendant has long known that Ozempic is a powerful, dangerous drugs.

⁵⁵ <https://www.cnn.com/2023/09/09/big-pharma-blockbuster-obesity-drug-battle-is-headed-for-100-billion.html#:~:text=Novo%20traded%20earnings%20jabs%20with,to%20more%20than%20%20243.7%20billion>. (last visited Sept. 18, 2025).

⁵⁶ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited on Sept. 18, 2025).

⁵⁷ *Id.*

⁵⁸ <https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance/> (last visited on 8/1/25).

⁵⁹ https://www.nytimes.com/2023/08/28/business/denmark-ozempic-wegovy.html?action=click&pgtype=Article&state=default&module=styleIn-weight-loss-drugs&variant=show®ion=MAIN_CONTENT_1&block=storyline_top_links_recirc (last visited on Sept. 18, 2025).

⁶⁰ <https://www.theatlantic.com/health/archive/2023/05/ozempic-teen-obesity-treatment-health-promises-risks/674204/> (last visited on Sept. 18, 2025).

81. As detailed below, Defendant knew from both pre-market and post-market research and analytics that Ozempic could cause malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, esophageal and bowel injury, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, and intraoperative aspiration.

82. Novo Nordisk has repeatedly failed to warn about the known dangerous side effects of Ozempic. This includes malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, esophageal and bowel injury, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, and intraoperative aspiration. All of these conditions can, and have, lead to hospitalization and/or death in patients across America.

83. Some doctors estimate that as many as 10% of patients discontinue use of these drugs due to the severity of side effects.⁶¹

84. Thousands of adverse event reports have been filed by the public with the FDA Adverse Event Reporting System. As of June 2022, the FDA has posted an alert that Ozempic has potential safety signals for intestinal blockage.⁶²

85. On September 22, 2023, FDA updated the label for Ozempic to include “ileus,” the medical term for blocked intestines.⁶³

⁶¹ <https://www.cbsnews.com/news/ozempic-side-effects-weight-loss-drugs-wegovy-mounjaro-doctors-warn/> (last visited Sept. 18, 2025)

⁶² <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/april-june-2022-potential-signals-serious-risksnew-safety-information-identified-fda-adverse-event> (last visited Sept. 18, 2025)

⁶³ <https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=2183>; <https://www.healthline.com/health-news/fda-updates-ozempic-label-to-include-blocked-intestines-as-potential-side-effect#:~:text=Ozempic%20Label%20Updated%20to%20Include%20Blocked%20Intestines%20as%20Potential%20Side%20Effect&text=The%20FDA%20is%20warning%20patients,serious%20and%20potentially%20fatal%20condition.>

86. Wegovy, chemically identical to Ozempic, already carried a warning on ileus.

87. As early as 2014, Defendant knew that Saxenda (liraglutide), Ozempic's predecessor, caused serious side effects and warned the end user of same.⁶⁴

88. As early as 2019, Defendant knew that Rybelsus (Semaglutide), Ozempic's predecessor, caused serious side effects and warned the end user of same.

V. Development of NAION and Its Sequela

89. Non-arteritic anterior ischemic optic neuropathy (NAION) is a medical condition involving damage to the optic nerve resulting in the loss of vision.

90. NAION is irreversible and permanent.

91. NAION falls within the category of an eye stroke.

92. NAION is untreatable and can lead to permanent blindness.

93. While the precise cause of NAION is unknown, the general belief amongst the medical community is that the condition is caused by insufficient blood supply or ischemia to the optic nerve.

94. “[T]ransient hypoperfusion of the short posterior ciliary arteries causes acute ischemia to the optic nerve head (ONH), resulting in axonal swelling. This swelling compromises the axoplasmic flow, which subsequently increases the axonal swelling, contributing to the compression of ONH microcirculation, exacerbating the ischemia.”

95. Anterior ischemic optic neuropathy (AION) involves the 1mm segment of the optic nerve head, also known as the optic disc, and results in visible disc swelling.

⁶⁴ https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206321orig1s000lbl.pdf (last visited on Sept. 18, 2025).

96. Typically, NAION patients present with acute, painless vision loss in one eye that is often described as blurry or cloudy while 8-12% of patients may have accompanying pain such as a headache or periocular pain.

97. The vision loss may occur over hours to days, but generally NAION patients notice vision loss or even total blindness upon waking in the morning.

98. After glaucoma, NAION is the second most common cause of blindness due to optic nerve damage.

99. Some NAION patients lose complete vision with no recovery in affected eye(s).

100. Reduced or loss of vision has a detrimental impact on a person's day-to-day life. Many NAION patients cannot drive or have driving restrictions, cannot read or have trouble reading, and may be unable to continue in their line of employment. Being blind in one eye, and certainly both eyes, results in bumps and falls and injuries related to the unseen impacts and accidents.

101. 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.⁶⁵

102. About 15% of patients who have NAION in one eye eventually develop it in their other eye.⁶⁶

103. GLP-1 RAs are treated as an established pharmacologic class (EPC) by the FDA, and the class of drugs shares a similar mechanism of action, similar physiologic effects, and similar chemical structure.

⁶⁵ *Ischemic Optic Neuropathy*, Cleveland Clinic, (last reviewed 6/30/2024), available at <https://my.clevelandclinic.org/health/diseases/ischemic-optic-neuropathy>

⁶⁶ *Id.*

104. It has been known since at least 2016 that the human eye contains GLP-1 receptors.⁶⁷

105. Defendant knew or should have known of the causal association between the use of Ozempic and/or Wegovy and the risk of developing NAION and its sequelae, but they ignored it.

106. The FDA's Adverse Events Reporting System (FAERS) shows multiple reports of "Optic Ischemic Neuropathy" reported in connection with the use of GLP-1 RAs.

107. The earliest reported Optic Ischemic Neuropathy event associated with any GLP-1 RA occurred in 2012, and the earliest associated with semaglutide specifically was in 2019.⁶⁸

108. A meta-analysis of all clinical trials of GLP-1RA drugs, including Novo Nordisk's own clinical trials, found a non-statistically significant increased risk of optic ischemic neuropathy.⁶⁹

109. The authors note that optic ischemic neuropathy is rare and may have been underreported in clinical trials, leading to a lower estimated risk.⁷⁰

110. 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

⁶⁷ 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.

⁶⁸ 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>.

⁶⁹ Silverii GA et al, Glucagon-like peptide 1 (GLP1) receptor agonists and risk for ischemic optic neuropathy. A meta-analysis of randomised controlled trials, Diabetes Obes Metab, 2024 (available as a pre-print manuscript as of November 20, 2024), <https://dom-pubs.pericles-prod.literatumonline.com/doi/10.1111/dom.16076>.

⁷⁰ Id.

with low cardiovascular risk could be associated with rare, but severe, adverse effects, possibly including NAION.⁷¹

111. A Novo Nordisk spokesperson acknowledged that cases of NAION, which leads to severe and irreversible vision loss, were identified in Novo Nordisk's clinical trials.⁷²

112. Defendant knew or should have known of the risk of NAION with use of Ozempic.

113. Defendant conducts clinical trials and has access to case reports and medical literature that provides it with superior knowledge compared to the general public as to potential risks of its medications.

114. For example, a clinical trial entitled "A Research Study to Compare Two Doses of Semaglutide Taken Once Weekly in People With Type 2 Diabetes (SUSTAIN FORTE)" with results first submitted in August 2021, involved a participant who developed optic ischemic neuropathy which was categorized as a serious adverse event.⁷³

115. The event occurred within the Semaglutide 2.0 mg dosage group, which included 479 participants, which is significant given the low background incidence of NAION.⁷⁴

116. Clinical observations by astute neuro-ophthalmologists at the Harvard affiliated Massachusetts Eye and Ear ("Mass Eye and Ear") who noted a surge of NAION cases amongst

⁷¹ *Id.*

⁷² 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), available at <https://www.fiercepharma.com/pharma/novo-nordisk-faces-new-reports-suggesting-link-between-ozempic-and-blindness> (last visited 12/18/2024); See also Naomi Kresge, Ozempic Link to Rare Vision Loss Risk Confirmed in Study, Bloomberg, (December 13, 2024), available at <https://www.bloomberg.com/news/articles/2024-12-13/ozempic-link-to-rare-vision-loss-risk-confirmed-in-large-trial?leadSource=uverify%20wall> (last visited 12/18/2024).

⁷³ A Research Study to Compare Two Doses of Semaglutide Taken Once Weekly in People With Type 2 Diabetes (SUSTAIN FORTE). ClinicalTrials.gov identifier: NCT03989232. Updated February 13, 2023. Accessed February 18, 2025.

⁷⁴ *Id.*

patients on Ozempic led them to conduct a retrospective, matched cohort study of neuro-ophthalmic patients at Mass Eye and Ear, Boston.

117. The study “Risk of Nonarteric Anterior Ischemic Optic Neuropathy in Patients Prescribed Semaglutide”, authored by Hathaway *et al.*, involved patients examined in the neuro-ophthalmology clinic between December 1, 2017, and November 30, 2023, and consisted of 17,298 patients, including 16,827 patients over the age of 12, 710 of which had type 2 diabetes (T2D), and 979 were overweight or obese.⁷⁵

118. Of the 710 T2D patients, 194 patients were prescribed semaglutide and 516 were prescribed other non-GLP-1 RA antidiabetic medications.⁷⁶

119. Of the 979 overweight/obese patients, 361 were prescribed semaglutide and 618 were prescribed other non-GLP-1 RA anti-obesity medications.⁷⁷

120. Within the T2D study population, NAION occurred in 17 patients in the semaglutide cohort vs. 6 in the non-GLP-1 RA cohort. The Kaplan-Meier survival analysis at 36 months showed a cumulative incidence of NAION of 8.9% (95% CI, 4.5%-13.1%) for the semaglutide cohort vs 1.8% (95% CI, 0%-3.5%) for the nonsemaglutide cohort and the Cox proportional hazards regression model showed a higher NAION risk in the semaglutide cohort vs the nonsemaglutide cohort (HR, 4.28; 95% CI, 1.62-11.29; $P < .001$; concordance coefficient = 0.84).⁷⁸

⁷⁵ Hathaway JT, Shah MP, Hathaway DB, et al. Risk of Nonarteritic Anterior Ischemic Optic Neuropathy in Patients Prescribed Semaglutide. *JAMA Ophthalmol.* 2024;142(8):732–739. doi:10.1001/jamaophthalmol.2024.2296

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

121. Within the overweight/obese cohort, NAION occurred in 20 patients in the semaglutide cohort vs. 3 in the non-GLP-1 RA cohort. The Kaplan-Meier survival analysis at 36 months showed a cumulative incidence of NAION of 6.7% (95% CI, 3.6%-9.7%) for the semaglutide cohort vs 0.8% (95% CI, 0%-1.8%) for the nonsemaglutide cohort and the Cox proportional hazards regression model showed a higher NAION risk in the semaglutide cohort vs the nonsemaglutide cohort (HR, 7.64; 95% CI, 2.21-26.36; $P < .001$; concordance correlation coefficient = 0.86).⁷⁹

122. The primary outcome of the Hathaway *et al.* study is that use of Ozempic is associated with an increased risk of NAION. “The relatively high HRs (4.28 and 7.64 for our T2D and overweight or obese cohorts, respectively) identified by our Cox regression analyses reveal a substantially increased risk of NAION among individuals prescribed semaglutide relative to those prescribed other medications to treat T2D and obesity or overweight.”⁸⁰

123. Acknowledging the pathogenesis or cause of NAION remains unknown. The authors did not determine the mechanism in which semaglutide causes NAION, however, it was hypothesized that expression of the GLP-1 receptor in the 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.⁸¹

124. A meta-analysis of all clinical trials of GLP-1 receptor drugs, including Defendant’s own clinical trials, found a non-statistically increased risk of optic ischemic neuropathy.⁸² Because optic ischemic neuropathy is rare, the authors note there may have been

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² Silverii GA, Pala L, Cresci B, Mannucci E. Glucagon-like peptide 1 (GLP1) receptor agonists

underreporting in the clinical trials, leading to a lower estimated risk.⁸³ However, the study concluded the overall rate of optic ischemic neuropathy was higher in the GLP1-RA group compared to the placebo group: 5.6 and 3.0 cases per 100,000 patient-years, respectively which is nearly a doubling of the risk.⁸⁴

125. On December 11, 2024, a pre-print of an article entitled “Use of semaglutide and risk of non-arteritic anterior ischemic optic neuropathy: A Danish- Norwegian cohort study”, found an association between use of semaglutide for type 2 diabetes.⁸⁵

126. This cohort study compared the risk of NAION among individuals with type 2 diabetes using semaglutide compared to those using sodium-glucose co-transporter 2 inhibitors (SGLT-2s), another diabetes medication.⁸⁶ The authors concluded there is “an association between use of semaglutide for type 2 diabetes and risk of NAION, with a more than two-fold increased hazard ratio.”⁸⁷

127. In a registry-based prospective cohort study identifying 424,152 patients diagnosed with type 2 diabetes in Denmark between December 1, 2018, and December 31, 2023,⁸⁸ 106,454 of these patients were exposed to semaglutide and 67 developed NAION.⁸⁹

and risk for ischemic optic neuropathy: A meta-analysis of randomised controlled trials. *Diabetes Obes Metab.* 2025; 27(2): 1005-1009. doi:[10.1111/dom.16076](https://doi.org/10.1111/dom.16076)

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ Simonsen E, Lund LC, Ernst MT, et al. Use of semaglutide and risk of non-arteritic anterior ischemic optic neuropathy: A Danish–Norwegian cohort study. Published online December 11, 2024. doi:[10.1101/2024.12.09.24318574](https://doi.org/10.1101/2024.12.09.24318574)

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ Grauslund J, Taha AA, Molander LD, 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. *Intl. Journal of Retina and Vitreous.* 2024;10(1):97. doi:[10.1186/s40942-024-00620-x](https://doi.org/10.1186/s40942-024-00620-x)

⁸⁹ *Id.*

128. “Exposure to once weekly semaglutide was followed by 67 events of NAION during 294,395 years of observation as compared to 151 events during the 1,620,725 years of observation for non-exposed.”⁹⁰

129. The study concluded use of semaglutide “more than doubles the risk of NAION, even when multiple other factors have been taken into account.”⁹¹

130. Interestingly, the study also 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.”⁹²

131. Due to the findings of the two studies out of Denmark, as of January 17, 2025, the Pharmacovigilance Risk Assessment Committee (PRAC) of the Danish Medicines Agency has required Novo Nordisk to review and submit available data related to semaglutide and NAION. The PRAC will review and determine if a label change is warranted or if other risk minimization efforts should be pursued.⁹³

132. In response, Novo Nordisk has acknowledged cases of NAION were identified within their clinical trials.⁹⁴

133. A recent case series published by Katz *et al.*, “Ophthalmic Complications Associated With the Antidiabetic Drugs Semaglutide and Tirzepatide,” also examined nine

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ <https://laegemiddelstyrelsen.dk/en/news/2024/suspicion-of-rare-eye-condition-from-ozempic-use-to-be-investigated-further/>

⁹⁴ <https://www.fiercepharma.com/pharma/novo-nordisk-faces-new-reports-suggesting-link-between-ozempic-and-blindness>

patients taking GLP1-RA medications who had experienced ophthalmologic complications. Of the nine patients, seven developed NAION.⁹⁵

134. The Katz article included a report of a woman with type 2 diabetes taking insulin and semaglutide and evidence of positive challenge and rechallenge with semaglutide.⁹⁶

135. The morning after the patient's first injection of semaglutide, she experienced painful vision loss in her left eye and was diagnosed with bilateral optic nerve swelling and the initial impression was optic neuritis with poor recovery. She discontinued the medication only to start it again approximately two months later after which she experienced painful vision loss in her right eye. Imaging performed on the right eye was consistent with NAION.

136. A study published on April 7, 2025, analyzing FDA Adverse Event reports indicates increased reports of vision impairment linked to semaglutide use. Compared to other diabetes and weight loss medications, users of semaglutide showed "significantly higher" reports of vision impairment.⁹⁷

137. Despite the growing number of articles, reports, and an investigation by PRAC of the Danish Medicines Agency, Defendant still provides no warnings about the dangerous side effect of NAION in conjunction with use of Ozempic.

VI. Defendant's Continuing Failure to Disclose the Risk of NAION and its Sequela

⁹⁵ Katz BJ, Lee MS, Lincoff NS, et al. Ophthalmic Complications Associated With the Antidiabetic Drugs Semaglutide and Tirzepatide. *JAMA Ophthalmol*. Published online January 30, 2025. doi:10.1001/jamaophthalmol.2024.6058

⁹⁶ *Id.*

⁹⁷ Massy, et al. Increased vision impairment reports linked to semaglutide: analysis of FDA adverse event data, *BMC Medicine* (2025) 23:203, available at <https://bmcmmedicine.biomedcentral.com/articles/10.1186/s12916-025-04031-z>.

138. According to the Drugs@FDA website, the label for Ozempic has been updated on at least thirteen (13) occasions since 2017, with the most recent update on January 28, 2025.⁹⁸ Despite the fact there are at least fourteen (14) iterations of the Ozempic label, Defendant's labels have not contained any warning or any information whatsoever on the increased propensity of Ozempic to cause NAION and permanent vision loss as suffered by Plaintiff.

139. According to the Drugs@FDA website, the label for Wegovy has been updated on at least nine (9) occasions since 2021, with the most recent update on November 27, 2024.⁹⁹ Despite the fact that there are at least ten (10) iterations of the Wegovy label, Defendant's labels have not contained any warning or any information whatsoever on the increased propensity of Wegovy to cause NAION and permanent vision loss as suffered by Plaintiff.

140. On June 6, 2025 the European Medicines Agency (EMA) recommended that the product information for semaglutide medicines including Ozempic, Wegovy, Rybelsus include NAION as a side effect.¹⁰⁰

141. To date, the Ozempic warning label is still devoid of any mention of NAION.

142. To date, the Wegovy warning label is still devoid of any mention of NAION.

143. Furthermore, Defendant has failed to take any steps to otherwise warn the medical community, particularly physicians within the ophthalmologic community, to encourage a baseline eye exam prior to starting Ozempic and/or Wegovy, monitoring of patients while on the

⁹⁸ See Drugs@FDA: FDA-Approved Drugs, Ozempic, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209637> (last visited February 19, 2025).

⁹⁹ <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process> (last visited June 12, 2025)

¹⁰⁰ <https://www.ema.europa.eu/en/news/prac-concludes-eye-condition-naion-very-rare-side-effect-semaglutide-medicines-ozempic-rybelsus-wegovy>

medication, advising patients to cease use of the medication if they develop symptoms consistent with NAION, or after the fact as to not risk the potential for injury in the other eye.

144. Nothing was or is stopping Defendant from adding a warning regarding the risk of NAION. Defendant could have at any time made “moderate changes” to the labels.

145. Specifically, Defendant could have filed a “Changes Being Effectuated” (“CBE”) supplement under Section 314.70(c) of the FDCA to make “moderate changes” to Ozempic and/or Wegovy’s label without any prior FDA approval.

146. Examples of moderate label changes that can be made via a CBE supplement explicitly include changes “to reflect newly acquired information” in order to “add or strengthen a contraindication, warning, precaution, or adverse reaction.” By definition and by regulation, such changes to add a warning based on newly acquired information—such as that imparted by newly emerging literature like the litany of studies cited above—are considered a “moderate change.” § 340.70(c)(6)(iii).

147. On July 3, 2024, the Journal of the American Medical Association (“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.¹⁰¹

¹⁰¹ Specifically, the study showed a cumulative incidence of NAION of 8.9% in type 2 diabetes patients taking semaglutide, compared to only 1.8% for patients not taking GLP-1RA medications, with a hazard ratio of 4.28. For overweight/obese patients, the cumulative incidence of NAION was 6.7% for patients taking semaglutide, compared to only 0.8% for those not taking GLP-1RAs,

148. 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.”¹⁰²

149. 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 2019.¹⁰³

PARTY PLAINTIFF

150. Plaintiff Caryn Schollmeyer is a resident of Florida and is currently 64 years old.

151. On or around September 18, 2019, she consulted with Khalilah Knight, M.D., to discuss options for treatment of his type 2 diabetes.

152. As a result of this appointment, on or around September 18, 2019, Khalila Knight, M.D., prescribed Ms. Schollmeyer Ozempic.

153. On or around January 15, 2021, Ms. Schollmeyer started experiencing sudden vision loss.

154. Ms. Schollmeyer stopped taking Ozempic.

155. Her eyesight loss is permanent.

with a hazard ratio of 7.64. Jimena Tatiana Hathaway, et al., Risk of Nonarteritic Anterior Ischemic Optic Neuropathy in Patients Prescribed Semaglutide, JAMA OPHTHALMOLOGY 2024;142(8):732-739 (published online July 3, 2024), available at <https://jamanetwork.com/journals/jamaophthalmology/fullarticle/2820255> (last visited 12/17/2024).

¹⁰² *Id.*

¹⁰³ 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>.

156. At all times material to the above, the Ozempic label failed to adequately warn Ms. Schollmeyer and her medical providers of the true risks of taking Ozempic.

157. At all times material to the above, the marketing and advertising failed to adequately warn Ms. Schollmeyer and her medical providers of the true risks of taking Ozempic.

158. Her life is forever changed because of her usage of Ozempic.

159. Ms. Schollmeyer will never see clearly again as a result of her usage of Ozempic.

160. Defendant knew or should have known that use of semaglutide could lead to severe and debilitating injuries suffered by Plaintiff and numerous other patients.

161. Defendant continues to downplay the risk of NAION and has not changed or provided any warnings to the public and medical community.

162. Defendant's Ozempic was at all times utilized and prescribed in a manner foreseeable to Defendant.

163. Plaintiff used Ozempic, and did not misuse, or alter Ozempic in an unforeseeable manner.

164. Through its affirmative misrepresentations and omissions, Defendant actively concealed from Plaintiff and his physicians the true and significant risks associated with this medication.

165. As a result of Defendant's actions, Plaintiff and his physicians were unaware, and could not have reasonably known or learned through reasonable diligence, that Plaintiff would be exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendant's conduct.

166. As a direct result of being prescribed and using Ozempic, Plaintiff has been permanently and severely injured, having suffered serious consequences.

167. As a direct and proximate result of her Ozempic use, Plaintiff suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress, loss of earnings, loss of ability to earn money and other economic losses including past and future medical expenses.

168. Plaintiff diligently investigated the potential cause of these injuries, but their relationship to Ozempic was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

169. Had Plaintiff and/or Plaintiff's physicians known of the true risks of NAION associated with the use of Ozempic and/or Wegovy, Plaintiff and/or Plaintiff's physicians would not have used the medication and would have chosen a different option for the treatment of her Type II diabetes.

170. Plaintiff's life is forever changed as a result of Defendant's actions and inactions.

COUNT I
STRICT LIABILITY – FAILURE TO WARN
(Pursuant to Applicable Product Liability Law)

171. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

172. Ozempic and/or Wegovy are products within the meaning of Pennsylvania products liability law.

173. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ozempic and/or Wegovy and placed these drugs into the stream of commerce in

a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

174. Defendant, as the holder of the NDA, is responsible for communications to the FDA and associated regulatory authorities, reporting adverse events, label changes, post-market surveillance and pharmacovigilance.

175. Defendant, as a manufacturer, distributor, and marketer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks associated with the use of Ozempic and/or Wegovy were inadequate.

176. Plaintiff did not have the same knowledge as Defendant and no adequate warning, other clinically relevant information, or data was communicated to Plaintiff or to Plaintiff's prescribing and treating physicians.

177. Defendant had a duty to provide adequate warnings and instructions for Ozempic and/or Wegovy, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately understand, test, and monitor their products.

178. Defendant had a continuing duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Ozempic and/or Wegovy, as it became or could have become available to Defendant.

179. Defendant marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drugs, Ozempic and/or Wegovy, to health care providers empowered to prescribe and dispense Ozempic and/or Wegovy to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and

affirmative misstatements, Defendant misled and continues to mislead the medical community about the risk and benefit balance of Ozempic and/or Wegovy, which resulted in permanent injuries to Plaintiff.

180. Defendant knew or should have known through testing, scientific knowledge, advances in the field, or otherwise, that Ozempic and/or Wegovy created a risk of serious and potentially irreversible vision issues, sudden vision loss or blindness, severe optic nerve damage, and NAION in one or potentially both eyes.

181. Despite the fact that Defendant knew or should have known that Ozempic and/or Wegovy caused unreasonable and dangerous side effects, it continues to promote and market Ozempic and/or Wegovy without providing adequate clinically relevant information.

182. Defendant knew or should have known that consumers, Plaintiff, specifically, would foreseeably and needlessly suffer injury as a result of Defendant's failures.

183. The Ozempic and/or Wegovy supplied to Plaintiff by Defendant was defective, unreasonably dangerous, and had inadequate warnings or instructions at the time it was sold. Defendant possessed knowledge and information confirming the defective and unreasonably dangerous nature of Ozempic and/or Wegovy but, despite this knowledge and information, Defendant failed and neglected to issue adequate warnings that Ozempic and/or Wegovy cause serious and potentially irreversible vision issues, optic nerve damage, and NAION. Defendant has yet to issue any warnings or recommendations that patients taking Ozempic and/or Wegovy undergo ophthalmological monitoring.

184. Defendant's failure to provide adequate warnings or instructions rendered Ozempic and/or Wegovy unreasonably dangerous in that it failed to perform as safely as an ordinary patient,

prescriber, and/or other consumer would expect when used as intended and/or in a manner reasonably foreseeable by the Defendant, and in that the risk of danger outweighs the benefits.

185. Defendant continues to fail to provide adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and Plaintiff's intermediary physicians.

186. Defendant failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Ozempic and/or Wegovy including, among other things, potentially irreversible vision issues such as NAION and optic nerve damage.

187. Defendant failed to provide adequate post-marketing warnings and instructions after Defendant knew or should have known of the significant risks of, among other things, potentially irreversible vision issues and optic nerve damage.

188. Defendant continued to aggressively promote and sell Ozempic and/or Wegovy, even after they knew or should have known of the unreasonable risks of potentially irreversible vision issues and optic nerve damage from the drugs.

189. Defendant had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Ozempic and/or Wegovy, and/or that there existed safer and or equally effective alternative drug products that do not pose this same risk.

190. By failing to adequately test and research harms associated with Ozempic and/or Wegovy , and by failing to provide appropriate warnings and instructions about use, patients and the medical community, including prescribing doctors, were inadequately informed about the true risk-benefit profile of Ozempic and/or Wegovy and were not sufficiently aware that serious and potentially irreversible vision issues and optic nerve damage might be associated with use of

Ozempic and/or Wegovy. Nor were the medical community, patients, patients' families, or regulators appropriately informed that serious and potentially irreversible vision issues and optic nerve damage might be a side effect of Ozempic and/or Wegovy and should or could be reported as an adverse event.

191. The semaglutide products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant were defective due to inadequate post-marketing surveillance and/or warnings because, even after Defendant knew or should have known of the risks of severe and permanent vision loss and optic nerve injuries from using Ozempic and/or Wegovy, Defendant failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote.

192. Ozempic and/or Wegovy is defective and unreasonably dangerous to Plaintiff and other consumers regardless of whether Defendant had exercised all possible care in their preparation and sale.

193. The foreseeable risk of serious and potentially irreversible vision issues and harm to the optic nerve caused by Ozempic and/or Wegovy could have been reduced or avoided by Plaintiff, prescribers, and/or other consumers had Defendant provided reasonable instructions or warnings of these foreseeable risks of harm.

194. As a direct and proximate result of Defendant's conduct, including the inadequate warnings, lack of information, lack of adequate testing and research, and the defective and dangerous nature of Ozempic and/or Wegovy, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic

losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT II

STRICT LIABILITY – DESIGN DEFECT **Pursuant to Applicable Product Liability Law**

195. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

196. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ozempic and/or Wegovy and placed these drugs into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

197. Defendant, as the holder of NDA, are responsible for communications to the FDA and associated regulatory authorities, reporting adverse events, label changes, post-market surveillance, and pharmacovigilance.

198. Defendant, as a manufacturer, designer, distributor, and marketer of pharmaceutical drugs, had a duty to design a product free from a defective condition that was unreasonably dangerous to the Plaintiff.

199. Ozempic and/or Wegovy are designed in such a way that posed an unreasonable risk of permanent vision loss and optic nerve injuries and were kept on the market despite being in a defective condition.

200. Defendant knew or should have known the Ozempic and/or Wegovy they developed, manufactured, labeled, marketed, sold, and/or promoted were defectively designed in that they posed a serious risk of severe and permanent vision and optic nerve injuries.

201. Defendant had a continuing duty to design a product that is not unreasonably dangerous to users and to adequately understand, test, and monitor their product.

202. Defendant sold, marketed and distributed products that are unreasonably dangerous for their normal, intended, and foreseeable use.

203. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Ozempic and/or Wegovy, a defective product which created an unreasonable risk to the health of consumers, and Defendant is therefore strictly liable for the injuries sustained by Plaintiff.

204. The Ozempic and/or Wegovy supplied to Plaintiff by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it was in an unreasonably dangerous and a defective condition because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendant, posing a risk of serious and potentially irreversible vision issues and optic nerve damage to Plaintiff and other consumers.

205. The Ozempic taken by Plaintiff was expected to, and did, reach Plaintiff without substantial change in the condition in which it is sold.

206. The Ozempic taken by Plaintiff was in a condition not contemplated by the Plaintiff in that it was unreasonably dangerous, posing a serious risk of permanent vision loss and optic nerve damage.

207. Ozempic is a medication indicated for treatment of type 2 diabetes. Ozempic in fact causes serious and potentially irreversible vision issues, severe optic nerve damage, sudden blindness, and NAION, in one or both eyes, harming Plaintiff and other consumers.

208. Plaintiff, ordinary consumers, and prescribers would not expect a diabetes drug designed, marketed, and labeled for weight loss and marketed for its supposed health benefits to cause irreversible vision issues and optic nerve damage.

209. The Ozempic supplied to Plaintiff by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it had not been adequately tested, was in an unreasonably dangerous and defective condition, and posed a risk of serious and potentially irreversible vision issues and optic nerve damage to Plaintiff and other consumers.

210. The Ozempic supplied to Plaintiff by Defendant was defective in design or formulation in that its alleged benefits did not outweigh the risks of serious and potentially irreversible vision issues and optic nerve damage posed by the drug. In light of the utility of the drug and the risk involved in its use, the design of Wegovy makes the product unreasonably dangerous.

211. Ozempic and/or Wegovy's design is more dangerous than a reasonably prudent consumer would expect when used in its intended or reasonably foreseeable manner. It was more dangerous than Plaintiff expected.

212. The intended or actual utility of Ozempic and/or Wegovy is not of such benefit to justify the risk of optic nerve damage that may be irreversible and permanently disabling thereby rendering the product unreasonably dangerous.

213. The design defects render Ozempic and/or Wegovy more dangerous than other drugs and therapies designed to treat type 2 diabetes and obesity and cause an unreasonable increased risk of injury, including, but not limited, to potentially irreversible vision issues and optic nerve damage.

214. Defendants knew or should have known through testing, scientific knowledge, advances in the field, or otherwise, that Ozempic and/or Wegovy created a risk of serious and potentially irreversible vision issues, severe optic nerve damage, sudden blindness, and NAION in one or both eyes.

215. Ozempic and/or Wegovy is defective and unreasonably dangerous to Plaintiff and other consumers in that, despite knowledge that Ozempic and/or Wegovy use could result in vision issues, Defendant failed to adequately test or study the drugs, including but not limited to: pharmacokinetics and pharmacodynamics of the drugs, its effects on vision and the optic disc, the potential for inter-patient variability, and/or the potential for a safer effective dosing regimen.

216. Defendant acted unreasonably in its design of Ozempic and/or Wegovy in that Defendant failed to adopt a safer design for the product that was practical, feasible, and otherwise a reasonable alternative design or formulation that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.

217. Defendant knew or should have known that consumers, and Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Ozempic and/or Wegovy's defective design.

218. Ozempic and/or Wegovy is defective and unreasonably dangerous to Plaintiff and other consumers even if Defendant had exercised all possible care in the preparation and sale of these products.

219. As a direct and proximate result of Defendant's conduct, including the inadequate warnings, lack of adequate testing and research, and the defective and dangerous nature of Ozempic and/or Wegovy, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT III
NEGLIGENT FAILURE TO WARN

220. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

221. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ozempic and/or Wegovy and placed these drugs into the stream of commerce in

a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

222. Defendant, as the holder of the NDA, is responsible for communications to the FDA and associated regulatory authorities, reporting of adverse events, label changes, post-market surveillance and pharmacovigilance.

223. Ozempic and/or Wegovy was expected to reach, and did reach, users and/or consumers, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

224. Defendant owed Plaintiff and other Ozempic and/or Wegovy users a duty to exercise reasonable care in marketing, advertising, promoting, distributing and/or selling Wegovy.

225. At all times material, Ozempic and/or Wegovy was used in a manner intended and/or foreseeable to Defendants.

226. A reasonable patient or consumer of Ozempic and/or Wegovy would expect the drug to be free of significant defects.

227. Defendant knew or had reason to know of facts establishing that Ozempic and/or Wegovy could cause NAION and failed to warn of the risk.

228. At all times relevant hereto, the defective nature of Ozempic and/or Wegovy was known to Defendant, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold Ozempic and/or Wegovy, and not known to ordinary physicians who would be expected to prescribe the drug to their patients.

229. In disregard of its duty to timely warn consumers of health risks associated with Ozempic and/or Wegovy, Defendant committed one or more of the following negligent acts or omissions:

- a. Failing to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physicians that Ozempic and/or Wegovy was designed and/or manufactured in a way that it could cause injuries and damages, including permanent vision loss;
- b. Failing to timely disclose to Plaintiff and Plaintiff's prescribing and treating physicians the risk of NAION;
- c. Failing to timely warn Plaintiff and Plaintiff's physicians that a base line eye exam should be performed and monitoring was necessary.

230. At all relevant times, the label for Ozempic and/or Wegovy was inadequate because it did not warn and/or adequately warn of all possible adverse side effects of NAION and permanent vision loss.

231. At all relevant times, the label for Ozempic and/or Wegovy was inadequate because it did not warn and/or adequately warn that Wegovy had not been sufficiently and/or adequately tested for safety risks, including NAION.

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

233. Defendant's failure to warn of the above was the proximate cause of Plaintiff's injuries, harm, and economic loss, from which Plaintiff continues to suffer.

234. Defendant's failure to warn of the significant risks of Ozempic and/or Wegovy use prevented Plaintiff and Plaintiff's treating physicians from conducting a proper assessment of the risks and benefits of using Ozempic and/or Wegovy .

235. Had Plaintiff and/or Plaintiff's treating physicians been properly warned of the significant risks of Ozempic and/or Wegovy, Plaintiff would not have elected to begin and/or continue Ozempic and/or Wegovy .

236. Reasonable, safer alternative treatments were available to Plaintiff and/or Plaintiff's treating physicians had they been warned of these significant risks outlined herein.

237. As a direct and proximate result of Defendant's conduct, including the inadequate warnings, lack of adequate testing and research, and the defective and dangerous nature of Ozempic and/or Wegovy, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IV
NEGLIGENCE

238. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

239. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ozempic and/or Wegovy and placed these drugs into the stream of commerce in

a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

240. Defendant, as the holder of NDA, are responsible for communications to the FDA and associated regulatory authorities, reporting of adverse events, label changes, post-market surveillance and pharmacovigilance.

241. At all relevant times, Defendant had a duty to exercise reasonable care in the manufacture, marketing, advertisement, supply, storage, transport, packaging, sale, and distribution of Ozempic and/or Wegovy products, 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.

242. Defendant failed to exercise ordinary care in the labeling, design, manufacturing, testing, marketing, distribution and/or sale of Ozempic and/or Wegovy in that Defendant knew or should have known these drugs created a high risk of unreasonable harm to Plaintiff and other users.

243. Defendant had no reason to believe that intended and foreseeable users of Ozempic and/or Wegovy, such as Plaintiff, would realize the potential harm from use of these products.

244. Defendant failed to exercise reasonable care to inform users, such as Plaintiff, of Ozempic and/or Wegovy's risk of serious and potentially irreversible vision issues and harm to the optic nerve.

245. Defendant breached its duty of care to the Plaintiff and Plaintiff's physicians, in the testing, monitoring, and pharmacovigilance of Ozempic and/or Wegovy.

246. In disregard of its duty, Defendant committed one or more of the following negligent acts or omissions:

- a. Manufacturing, producing, overpromoting, formulating, creating, developing, designing, selling, and distributing Ozempic and/or Wegovy without thorough and adequate pre- and post-market testing of the products;
- b. Manufacturing, producing, overpromoting, advertising, formulating, creating, developing, and designing, and distributing Ozempic and/or Wegovy while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Ozempic and/or Wegovy;
- c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Ozempic and/or Wegovy was safe for their intended use;
- d. Failing to disclose and warn of the product defect to the medical community, and consumers that Defendant knew and had reason to know that Ozempic and/or Wegovy was indeed unreasonably unsafe and unfit for use by reason of the product defects and risk of harm to its users;
- e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the Ozempic and/or Wegovy's risk of harm was 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 and/or Wegovy;
- g. Advertising, marketing, and recommending the use of Ozempic and/or Wegovy, while concealing and failing to disclose or warn of the dangers known by Defendant to be connected with, and inherent in, the use of this product;
- h. Representing that Ozempic and/or Wegovy was safe for their intended use when in fact Defendant knew and should have known the product were not safe for their intended purpose;
- i. Continuing to manufacture and sell Ozempic and/or Wegovy with the knowledge that Ozempic and/or Wegovy is unreasonably unsafe and dangerous;

- j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of Ozempic and/or Wegovy so as to avoid the risk of serious harm associated with the use of semaglutide. Failing to design and manufacture Ozempic and/or Wegovy so as to ensure these drugs were at least as safe and effective as other similar products;
- k. Failing to design and manufacture Ozempic and/or Wegovy was reasonably safe for their intended purpose in violation of objective safety standards;
- l. Failing to ensure that Ozempic and/or Wegovy were accompanied by proper and accurate warnings about requiring baseline visual examinations and regular eye examinations while using the drug;
- m. Failing to ensure that Ozempic and/or Wegovy were accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Ozempic and/or Wegovy and that use of semaglutide created a high risk of severe, permanent injuries to vision; and
- n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Ozempic and/or Wegovy.

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

248. As a direct and proximate result of the Defendant's negligent testing, monitoring, and pharmacovigilance of Ozempic and/or Wegovy, Defendant introduced products they knew or should have known would cause injury to the optic nerve, NAION and resulting serious and permanent injuries to an individual's vision, and Plaintiff has been injured catastrophically and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

249. As a direct and proximate result of Defendant's conduct, including the inadequate warnings, lack of adequate testing and research, and the defective and dangerous nature of Ozempic and/or Wegovy, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and

treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT V
NEGLIGENT MISREPRESENTATION AND MARKETING

250. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

251. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ozempic and/or Wegovy and placed these drugs into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

252. Defendant, as the holder of NDA, are responsible for communications to the FDA and associated regulatory authorities, reporting of adverse events, label changes, post-market surveillance and pharmacovigilance.

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

254. The information distributed by the Defendant to the public, the medical community, Plaintiff and Plaintiffs' healthcare providers, including advertising campaigns, labeling materials, print advertisements, commercial media, was false and misleading and contained omissions and concealment of truth about the dangers of Ozempic and/or Wegovy.

255. Defendant's conduct had the capacity to deceive and/or 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/or Wegovy and induce the public and medical community, including Plaintiff and Plaintiff's healthcare providers to request, recommend, purchase, and prescribe Ozempic and/or Wegovy .

256. Defendant's intent and 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/or Wegovy and induce the public and medical community, including Plaintiff and Plaintiff's healthcare provider to request, recommend, purchase, and prescribe Ozempic and/or Wegovy.

257. Defendant had a duty to accurately and truthfully represent and market to the medical and healthcare community, Plaintiff, Plaintiff's healthcare providers and the public, the known risks of Ozempic and/or Wegovy, including its propensity to cause permanent vision loss, NAION and injury to the optic nerve.

258. Defendant made continued omissions in the Ozempic and/or Wegovy labeling, including promoting it as safe and effective while failing to warn of its propensity to cause permanent vision loss, NAION and injury to the optic nerve.

259. Defendant made additional misrepresentations beyond the product labeling by representing Ozempic and/or Wegovy as a safe and effective treatment for type 2 diabetes and/or weight loss with only minimal risks.

260. Defendant misrepresented and overstated the benefits of Ozempic and/or Wegovy to Plaintiff, Plaintiff's treaters, and the medical community without properly advising of the known risks to permanent vision loss.

261. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's healthcare providers were induced to, and did use Ozempic and/or Wegovy, thereby causing Plaintiff to endure severe and permanent injuries.

262. In reliance upon the false and negligent misrepresentations and omissions made by the Defendant, Plaintiff and Plaintiff's healthcare providers were unable to associate the injuries sustained by Plaintiff with Plaintiff's Ozempic and/or Wegovy use before it was too late. Defendant knew or should have known that the Plaintiff, Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendant.

263. Plaintiff and Plaintiff's healthcare providers would not have used or prescribed Ozempic and/or Wegovy had the true facts not been concealed by the Defendant.

264. Defendant had sole access to many of the material facts concerning the defective nature of Ozempic and/or Wegovy and its propensity to cause serious and dangerous side effects.

265. At the time Plaintiff was prescribed and administered Ozempic and/or Wegovy, Plaintiff and Plaintiff's healthcare providers were unaware of Defendant's negligent misrepresentations and omissions.

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

267. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the misrepresentations and omissions made by the Defendant, where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Ozempic and/or Wegovy.

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

269. As a direct and proximate result of reliance upon Defendant's negligent misrepresentations, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VI
BREACH OF EXPRESS WARRANTY

270. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

271. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ozempic and/or Wegovy and placed them into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

272. Defendant, as the holder of NDA, are responsible for communications to the FDA and associated regulatory authorities, reporting of adverse events, label changes, post-market surveillance and pharmacovigilance.

273. Defendant expressly warranted to Plaintiff, Plaintiff's healthcare providers, and the general public, by and through Defendant and/or its authorized agents or sales representatives, in publications, labeling, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that Ozempic and/or Wegovy were safe, effective, fit and proper for their intended use.

274. Ozempic and/or Wegovy materially failed to conform to those representations made by Defendant, in package inserts and otherwise, concerning the properties and effects of Ozempic, which Plaintiff purchased and injected in direct or indirect reliance upon these express representations. Such failures by Defendant constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Ozempic sold to Plaintiff.

275. Defendant expressly warranted that Ozempic and/or Wegovy was safe and well-tolerated. However, Defendant did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Ozempic and/or Wegovy was particularly dangerous to the well-being of Plaintiff and Plaintiff's vision.

276. Ozempic and/or Wegovy does not conform to those express representations

because they are defective, not safe, and have serious adverse side effects.

277. Plaintiff and Plaintiff's physicians justifiably relied on Defendants' representations regarding the safety of Ozempic and/or Wegovy, and Defendant's representations became part of the basis of the bargain.

278. Plaintiff and Plaintiff's healthcare providers justifiably relied on Defendant's representations that Ozempic and/or Wegovy was safe and well-tolerated in their decision to ultimately prescribe, purchase and use the drug.

279. Plaintiff's healthcare providers justifiably relied on Defendant's representations through Defendant's marketing and sales representatives in deciding to prescribe Ozempic and/or Wegovy over other alternative treatments on the market, and Plaintiff justifiably relied on Defendant's representations in deciding to purchase and use the drug.

280. Plaintiff purchased and used Ozempic without knowing that drug is not safe and well-tolerated, but that Ozempic instead causes significant and irreparable vision loss and eye damage.

281. As a direct and proximate result of Defendant's conduct, including the inadequate warnings, lack of adequate testing and research, and the defective and dangerous nature of Ozempic, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in

excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VII
BREACH OF IMPLIED WARRANTY

282. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

283. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Ozempic and/or Wegovy, and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

284. Defendant, as the holder of NDA, are responsible for communications to the FDA and associated regulatory authorities, reporting of adverse events, label changes, post-market surveillance and pharmacovigilance.

285. Defendant was the seller of Ozempic and/or Wegovy and sold Ozempic and/or Wegovy to be taken for treatment of type 2 diabetes and/or weight loss.

286. When Ozempic was prescribed by Plaintiff's physician and taken by Plaintiff, the product was being prescribed and used for the ordinary purpose for which it was intended.

287. Defendant impliedly warranted their product, which they manufactured and/or distributed and sold, and which Plaintiff purchased and used, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the product was sold.

288. Defendant breached their implied warranties of the Ozempic product because the Ozempic sold to Plaintiff was not fit for its ordinary purpose to help with weight loss.

289. Ozempic and/or Wegovy would not pass without objection in the trade; they are

not of fair average quality; they are not fit for their ordinary purposes for which the products are used; were not adequately contained, packaged and labeled; and fail to conform to the promises or affirmations of fact made on the container or label.

290. Defendant's breach of their implied warranties resulted in use of the unreasonably dangerous and a defective product by Plaintiff, which placed Plaintiff's health and safety at risk and resulted in the damages alleged herein.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VIII
VIOLATION PENNSYLVANIA UNFAIR TRADE PRACTICES / CONSUMER FRAUD
ACT (73 P.S. SECT. 201-1) AND/OR PA CONSUMER PROTECTION ACT

291. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

292. Plaintiff purchased and used Ozempic and/or Wegovy primarily for personal use and therefore suffered ascertainable losses as a result of Defendant's actions in violation of Pennsylvania Unfair Trade Practices/Consumer Fraud Act, 73 P.S. Sect. 201-1, *et seq.*

293. Had Defendant not made affirmative misrepresentations, material omissions, and engaged in the deceptive conduct described herein, Plaintiff would not have purchased Ozempic and/or Wegovy and would not have incurred damages.

294. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiff that would not have been paid had Defendant not engaged in unfair and deceptive conduct.

295. Despite knowing the falsity and misleading nature of their claims, Defendant engaged in unconscionable commercial practices, deception, fraud, false promise, misrepresentation and/or the knowing concealment, suppression or omission of material facts relative to the safety and efficacy of Ozempic and/or Wegovy.

296. Defendant intended such actions to mislead patients, healthcare providers, and the general public with respect to the safety and efficacy of Ozempic and/or Wegovy.

297. Such actions did, in fact, mislead patients, healthcare providers, and the general public with respect to the safety and efficacy of Ozempic and/or Wegovy.

298. Defendant had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Ozempic and/or Wegovy.

299. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Caryn Schollmeyer constituted unfair and deceptive acts and trade practices in violation of Pennsylvania Unfair Trade Practices/Consumer Fraud Act, 73 P.S. Sect. 201-1, *et seq.*

300. As a direct and proximate result of Defendant's conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Ozempic, Caryn Schollmeyer suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally,

for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IX
PUNITIVE DAMAGES

301. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

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

303. Defendant's actions amounted to actual malice or reckless indifference to the likelihood of harm associated with their acts and omissions.

304. Defendant sold Ozempic and/or Wegovy to Plaintiff and other consumers throughout the United States despite their knowledge that Ozempic and/or Wegovy can cause the problems as set forth in this Complaint, thereby causing the severe and debilitating injuries suffered by Plaintiff.

305. Defendant misled both the medical community and the public, including Plaintiff and his physicians, by making false representations about the safety and effectiveness of Ozempic and/or Wegovy and by failing to provide adequate instructions concerning its use.

306. Defendant downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Ozempic despite available information demonstrating that drug could cause NAION and irreversible vision loss.

307. Defendant was or should have been in possession of evidence demonstrating that Ozempic and/or Wegovy use could cause NAION and irreversible vision loss. Nevertheless,

Defendant continues to market Ozempic and/or Wegovy by providing false and misleading information with regard to their safety and effectiveness.

308. Defendant failed to provide warnings that would have dissuaded health care professionals from using Ozempic and/or Wegovy, thus preventing health care professionals, including Plaintiff's prescribing physician, and consumers, including Plaintiff, from weighing the true risks against the benefits of using Ozempic and/or Wegovy.

309. As a proximate result of Defendant's acts and omissions, Plaintiff was diagnosed with NAION and suffers from irreparable vision loss due to Plaintiff's use of Ozempic and/or Wegovy.

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

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

312. Defendant has engaged in conduct entitling Plaintiff to an award of punitive damages pursuant to Common Law principles.

313. Defendant's actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff and the public.

314. Plaintiff's injuries and damages are severe, permanent and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendant.

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

conduct in the future.

316. Consequently, Defendant is liable for punitive damages in an amount to be determined by the jury.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

317. Defendant is estopped from relying on the statute of limitations defense because Defendant actively concealed information concerning known risks, side effects, and defects in Ozempic and/or Wegovy. Instead of revealing such information to the FDA or the public, Defendant has continued to represent Ozempic and/or Wegovy as safe for its intended use.

318. Defendant is and was under a continuing duty to disclose the true character, quality and nature of risks and dangers associated with Ozempic and/or Wegovy. Because of Defendant's purposeful and fraudulent concealment of material information concerning the true character, quality and nature of risks of such products, Defendant is estopped from relying on any statute of limitations defense.

DEMAND FOR JURY TRIAL

319. Plaintiff demands a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein, and prays for judgment in her favor and against Defendant awarding the following:

1. A monetary award, sufficient to compensate Plaintiff for the following categories of damages:
 - a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;
 - b. actual and treble damages in such amount to be determined by this Court and as provided by law;
 - c. exemplary and punitive damages sufficient to punish and deter Defendant and others from future wrongful practices;
 - d. pre-judgment and post-judgment interest;
 - e. costs including court costs, and other litigation expenses; and
 - f. any other relief the Court may deem just and proper.

Dated: July 27, 2026

Respectfully Submitted,

/s/ Daniel A. Nigh

Daniel

A. Nigh (FL Bar No. 30905)
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