

COMPLAINT AND DEMAND FOR A JURY TRIAL

Plaintiff Laura Marrero, by and through her attorneys, files this Complaint against Defendants Novo Nordisk A/S, et. al. for their failure to warn Plaintiff about the true risks of their weight loss drug, Ozempic, as well as for negligence and deceptive and unfair marketing of the same. This is an action for damages suffered Laura Marrero who was severely injured as a result Defendants' widespread, deceptive and unfair marketing of their drugs, Wegovy and Ozempic, and her subsequent use of Ozempic, an injectable prescription medication that is approved for weight loss. In support thereof, Plaintiff alleges as follows:

PARTIES

1. Plaintiff Laura Marrero is a citizen and resident of the State of Pennsylvania.
2. Defendant 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. Novo Nordisk has conducted business and derived substantial revenue from within the Commonwealth of Pennsylvania.
3. Defendant Novo Nordisk Inc. is wholly owned by Defendant Novo Nordisk US Commercial Holdings, Inc.
4. Defendant Novo Nordisk US Commercial Holdings Inc. is a Delaware corporation with its principal place of business at 103 Foulk Road, Wilmington, Delaware 19803.
5. Defendant Novo Nordisk US Commercial Holdings Inc. is wholly owned by Defendant Novo Nordisk US Holdings Inc.
6. Defendant Novo Nordisk US Holdings Inc. is a Delaware corporation with its principal place of business at 103 Foulk Road, Wilmington, Delaware 19803.

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

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

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

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

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

12. Novo Holdings A/S is a is a company organized under the laws of Denmark with its principal place of business in Hellerup, Denmark

13. Novo Holdings Equity US Inc. is a Delaware corporation with its principal place of business at 200 Clarendon Street Floor 45 Boston, MA 02142 USA.

14. Novo Ventures (US) Inc. is a Massachusetts corporation with its principal place of business at 501 2nd Street Suite 300 San Francisco, CA 94107.

15. Defendant Novo Nordisk A/S and its subsidiaries and affiliates named herein are collectively referenced as “the Novo Nordisk Defendants” and “Novo Nordisk.”

16. 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.”¹ Upon information and belief, this refers to Novo Nordisk’s manufacturing facility in Clayton, North Carolina, operated by Novo Nordisk Pharmaceutical Industries LP.

¹ <https://www.novonordisk-us.com/about/who-we-are/north-carolina.html> (last visited on Sept. 17, 2023).

17. 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.² The Novo Nordisk Defendants also designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic and Wegovy.

18. Upon information and belief, Defendants failed to warn the end users of Ozempic and 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 use of Ozempic and Wegovy of which the company 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 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

² <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=adec4fd2-6858-4c99-91d4-531f5f2a2d79> (last visited on Sept. 17, 2023).

realizing pecuniary benefit, and by virtue of Defendants' substantial, continuous, and systematic contacts with the Commonwealth of Pennsylvania.

22. 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, as 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. Venue is further proper as Plaintiff is a resident of Pennsylvania, was prescribed Defendant's product in the state of Pennsylvania, and it is where her injury and subsequent treatment has occurred.

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

24. 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.³ 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.⁴⁵

25. Novo Nordisk routinely recruits employees within Philadelphia related to diabetes care⁶, and recruits sales associates in Pennsylvania.⁷ Novo Nordisk maintains employees in Philadelphia related to diabetes care.⁸ The Philadelphia Department of Public Health released a report on "Drug Marketing Through Gifts of Meals to Physicians in Philadelphia," which showed

³ <https://www.reuters.com/business/healthcare-pharmaceuticals/novo-nordisk-hires-private-us-firm-handle-some-wegovy-pen-assembly-source-2023-09-18/>

⁴ *Id.*

⁵ <https://pci.com/contact/>

⁶ <https://novonordisk.dejobs.org/philadelphia-pa/medical-liaison-liver-health-pa/EF6DC568FC1E45E4B180EE94A52DBB1C/job/>

⁷ https://www.novonordisk-us.com/careers/find-a-job/job-ad.292229.en_US.html

⁸ <https://www.linkedin.com/in/lindsey-hunt-82911b55>

Novo Nordisk's Ozempic was #8 in the "Top 20 Drugs Marketed in Philadelphia" in 2018 through February 2020.⁹

26. Novo Nordisk's marketing agency for Wegovy, Accenture Song (formerly Concentric Life), has multiple offices in Pennsylvania including Philadelphia.¹⁰

27. 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."¹¹

28. Novo Nordisk funds extensive research at University of Pennsylvania in Philadelphia and Penn Medicine specifically related to diabetes care and weight loss.¹² 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.¹³¹⁴

29. Novo Nordisk has funded Philadelphia community programs to address obesity and diabetes.¹⁵ 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.¹⁶

⁹ https://www.phila.gov/media/20200204150030/2020-drug-marketing-report_2_4_2020.pdf

¹⁰ <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>.

¹¹ <https://www.newswire.com/news/concentric-health-experience-named-agency-of-the-year-at-the-2022-21695158>

¹² 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>.

¹³ <https://onlinelibrary.wiley.com/doi/full/10.1002/oby.23946>

¹⁴ <https://www.med.upenn.edu/weight/wadden.html>; https://wfpc.sanford.duke.edu/podcast_guest/wadden-thomas/

¹⁵ <https://hcfonline.org/tag/population-health/>

¹⁶ <https://bariatrictimes.com/walk-from-obesity-raising-funds-in-philadelphia-summer-2019/>;

30. Novo Nordisk has even partnered with a Philadelphia-based media company, 9.14 Pictures, to help produce and direct a docuseries entitled “Thick Skin” that focuses on the stigma of obesity in America and the lives of four Philadelphia-based women.¹⁷ 9.14 Pictures then worked with Philadelphia-based advertising agency REMADE to create explainer-style public service announcements “focused on science and facts surrounding obesity.”¹⁸

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.¹⁹

32. GLP-1 agonists are a class of medications that can help lower blood sugar levels and promote weight loss.²⁰ An agonist is a manufactured substance that attaches to a cell receptor and causes the same action as the naturally occurring substance.²¹ 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.²²

<https://www.citieschangingdiabetes.com/network/philadelphia.html>;

<https://static.clubs.nfl.com/image/upload/v1666020341/eagles/mp3pn3smy1yf2sj3cyrp.pdf>

¹⁷ <https://www.mmm-online.com/home/channel/campaigns/novo-nordisks-thick-skin-doc/>

¹⁸ <https://www.phillyadclub.com/work/novo-nordisk-amc-thick-skin-psas/>

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

²⁰ <https://my.clevelandclinic.org/health/articles/13901-glp-1-agonists> (last visited Sept. 17, 2023)

²¹ *Id.*

²² *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.”²³

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.²⁴

36. Consequently, Novo Nordisk decided study liraglutide as not only a diabetes drug which had been shown to lower blood sugars, but also as a drug to treat obesity.²⁵

37. Years later, in 2010, liraglutide was approved for the treatment of diabetes by the FDA under Novo Nordisk's brand name Victoza,²⁶ at which point Novo Nordisk moved forward with studying the drug for weight loss.²⁷

38. After clinical trials, in 2014, the FDA approved liraglutide for treatment of obesity under Novo Nordisk's brand name Saxenda as a daily injectable.²⁸

39. Saxenda’s effects on weight loss, however, were modest; patients lost about 5% of their weight.²⁹

40. In an effort to find ways to make a longer-lasting a GLP-1 agonist so patients would not have to inject themselves every day, Novo Nordisk created a new molecule with the chemical name semaglutide.³⁰

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

²⁴ *Id.*

²⁵ *Id.*

²⁶ [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, 2023).

²⁷ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited Sept. 17, 2023).

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

41. Novo Nordisk branded semaglutide as Ozempic, and on December 5, 2016, the Novo Nordisk Defendants announced submission of Ozempic’s new drug application (NDA) to the FDA for regulatory approval of once-weekly injectable in 0.5 mg or 1 mg for treatment of Type 2 diabetes. In the announcement, Defendants represented that in clinical trials “once-weekly” Ozempic had a safe and well-tolerated profile, and Defendants represented that the most common adverse event was nausea.³¹

42. On December 5, 2017, the FDA approved the application and granted premarket approval as NDA 209637.³²

43. In addition to diabetic control, Ozempic also caused 15% weight loss, which was three times the loss caused by its predecessor, Saxenda.³³

44. Just one year after Ozempic’s approval for diabetes, Defendants started a clinical trial in patients who were overweight or suffered from obesity.³⁴

45. 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.³⁵

46. Importantly, the trial data also pointed out that more participants in the semaglutide group than in the placebo group discontinued treatment owing to gastrointestinal events (59 [4.5%] vs. 5 [0.8%]).

³¹ <https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183> (last visited Sept. 17, 2023).

³² https://www.accessdata.fda.gov/Ozempicatfda_docs/appltr/2017/209637s000ltr.pdf (last visited Sept. 17, 2023).

³³ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited Sept. 17, 2023).

³⁴ *Id.*

³⁵ <https://www.nejm.org/doi/full/10.1056/NEJMoa2032183> (last visited Sept. 17, 2023)

47. By March of 2021, Defendants had completed the clinical trial studying semaglutide for weight loss, and its results were published March 18, 2021.³⁶

48. In addition to the results, the published study, which was funded by Defendants, argued: “Obesity is a chronic disease and global public health challenge.”³⁷

49. On March 20, 2019, Defendant Novo Nordisk Inc. submitted supplemental a new drug application 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.³⁸ On January 16, 2020, the FDA approved this new indication.³⁹

50. Then, on May 28, 2021, Defendant Novo Nordisk Inc. submitted another sNDA requesting approval for a higher 2 mg dose of Ozempic injection. On March 28, 2022, the FDA approved this request.⁴⁰

51. In their press release, Defendants represented Ozempic as having “proven safety and efficacy” and they continued to advertise that “it can help many patients lose some weight.”⁴¹ As with its prior press releases, Defendants disclosed Important Safety Information and provided link to the Medication Guide and Prescribing Information. However, severe gastrointestinal events, including gastroparesis and gastroenteritis, were not identified as risks.

³⁶ <https://www.nejm.org/doi/full/10.1056/NEJMoa2032183> (last visited Sept. 17, 2023)

³⁷ *Id.*

³⁸ <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, 2023).

³⁹ https://www.accessdata.fda.gov/Ozempicatfda_docs/applletter/2020/209637Orig1s003ltr.pdf (last visited Sept. 17, 2023).

⁴⁰ https://www.accessdata.fda.gov/Ozempicatfda_docs/applletter/2022/209637Orig1s009ltr.pdf (last visited Sept. 17, 2023).

⁴¹ <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, 2023).

52. On June 4, 2021, the FDA announced that Wegovy was approved for use in adults with obesity (BMI over 30) or overweight (BMI over 27) and at least one chronic health condition,⁴² and was the first FDA approved drug for weight loss since 2014.⁴³

53. Wegovy and Ozempic are chemically identical and primarily differ based upon dosage.

54. On December 23, 2022, Novo Nordisk announced FDA approval of Wegovy injection, along with reduced calorie meal plan and exercise, for the treatment of obesity in adolescents aged 12 years and older.⁴⁴

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

55. Since Defendants discovered GLP-1 agonists potential use for weight loss, Defendants began working to change medical consensus as it relates to obesity.

56. Conventionally, evidence-based approaches to obesity focused on lifestyle: eating whole, nutrition foods, exercising, reducing stress, and obtaining adequate sleep. In contrast, Defendants have spent millions of dollars marketing the belief that sustained weight loss is only achievable by using Defendants' medications at a cost of more than \$1000 a month.

57. Throughout their marketing, Defendants fail to disclose the true serious side effects of Ozempic and Wegovy, including but not limited to hospitalization and death.

58. Defendants also fail to disclose in their label and patient brochure for Ozempic and/or Wegovy that in order to maintain any weight loss, the patient must stay on the drug

⁴² <https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014> (last accessed Sept. 17, 2023)

⁴³ *Id.*

⁴⁴ <https://www.novonordisk-us.com/media/news-archive/news-details.html?id=151389> (last visited Sept. 17, 2023).

permanently or most patients will regain most of the weight within one year and virtually all the weight will be regained within five years.⁴⁵

59. When the Novo Nordisk Defendants 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[.]” The Novo Nordisk Defendants offered an “Instant Savings Card to reduce co-pays to as low as \$25 per prescription fill for up to two years.”

60. Indeed, some patients will regain even more weight after stopping the drug, so that they end up heavier than before starting Ozempic and/or Wegovy.⁴⁶ This is also not disclosed in the label or patient brochure.

61. Novo Nordisk was not permitted to market Ozempic for weight loss without F.D.A. approval for that specific indication,⁴⁷ but before Wegovy ever received separate approval for treatment of weight loss, Novo Nordisk had already begun mentioning weight loss in their Ozempic commercials.⁴⁸

⁴⁵ <https://www.cnn.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html>; <https://pubmed.ncbi.nlm.nih.gov/35441470/>

⁴⁶ <https://www.cnn.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html>

⁴⁷ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited Sept. 18, 2023).

⁴⁸ *Id.*

62. On July 30, 2018, the Novo Nordisk Defendants launched their first television ad for Ozempic to the tune of the 1970s hit pop song “Magic” by Pilot, wherein the Novo Nordisk Defendants advertised that “adults lost on average up to 14 pounds” when taking Ozempic.⁴⁹



63. Over the next five years, the Novo Nordisk Defendants spent \$884,000,000 on running television ads in the United States to promote its semaglutide Ozempic, Wegovy, and another of its lesser known GLP-1 agonists, Rybelsus, with most advertisements allocated towards Ozempic.⁵⁰

64. By 2021, Defendants’ aggressive marketing of the weight loss benefits of Ozempic, sophisticated use of social media, and America’s socially ingrained desire to be thin had reached a tipping point.⁵¹

65. Defendants’ aggressive marketing includes a number of different platforms,

⁴⁹ <https://www.ispot.tv/ad/d6Xz/ozempic-oh> (last visited Sept. 18, 2023).

⁵⁰ https://medwatch.com/News/Pharma_Biotech/article15680727.ece (last visited Sept. 18, 2023).

⁵¹ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited Sept. 18, 2023).

including over 4,000 marketing advertisements for Ozempic and similar weight-loss medications that have been placed on Facebook and Instagram.⁵²

66. According to open payments data, Novo Nordisk spent \$33,927,336.42 on marketing/consulting/travel/food and beverage/etc. to physicians in 2022 alone.⁵³

67. For its two drugs approved specifically for obesity, Wegovy and Saxenda, Novo Nordisk has spent at least \$25.8 million over the past decade to U.S. medical professionals to promote sales of the drug.⁵⁴

68. Overall, at least 57 U.S. physicians each accepted at least \$100,000 from Novo in payments associated with Wegovy or Saxenda over the past decade. A Reuters special report found these physicians were an influential group: Forty-one were obesity specialists who run weight-management clinics, work at academic hospitals, write obesity-treatment guidelines or hold top positions at medical societies.⁵⁵

69. Dr. Donna Ryan, a Louisiana researcher and former president of The Obesity Society, has accepted more than \$1 million from Novo over the last decade, including \$600,691 related to Wegovy and Saxenda, the analysis found.⁵⁶ As reported in Reuters, Ryan was instrumental in persuading the U.S. Office of Personnel Management to cover Wegovy and similar drugs for millions of federal workers.⁵⁷

70. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,⁵⁸ and currently has over 1.2 billion views.⁵⁹

⁵² <https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602> (last visited Sept. 18, 2023).

⁵³ <https://openpaymentsdata.cms.gov/company/100000000144> (last visited Sept. 18, 2023).

⁵⁴ <https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/>

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ <https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html> (last visited Sept. 18, 2023).

⁵⁹ <https://www.tiktok.com/tag/ozempic> (last visited on August 1, 2023).

71. The hashtag #wegovyweightloss has 163.2 million views as of September 9, 2023, on TikTok.

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

73. 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.⁶⁰ This was a lauded result presented in a case study by Meta.

74. 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.”⁶¹

75. Novo Nordisk reportedly spent approximately one hundred million dollars advertising Ozempic last year.⁶² 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 2023.⁶³

76. In 2023, over \$491 million was spent advertising “diabesity” drugs, including Ozempic and Wegovy.⁶⁴

77. Jimmy Kimmel joked about Ozempic at the Oscars.⁶⁵

78. Howard Stern has joked and discussed Ozempic.⁶⁶ Interestingly, Stern notes that the “catchy” theme song “distracts” the listener from actually hearing any of the listed side

⁶⁰ <https://business.instagram.com/success/novo-nordisk> (last visited Sept. 17, 2023).

⁶¹ <https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571> (last visited on Sept. 17, 2023).

⁶² <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, 2023).

⁶³ https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571?utm_source=exchange&utm_medium=email&utm_campaign=t5687390

⁶⁴ <https://www.mmm-online.com/home/channel/spending-on-ozempic-wegovy-surges/>

⁶⁵ <https://www.usatoday.com/story/life/health-wellness/2023/03/13/ozempic-sweeping-hollywood-celebrities-weight-loss/11428801002/> (last accessed Sept. 17, 2023).

⁶⁶ <https://www.youtube.com/watch?v=QD-nCQn1Ads> (last visited on Sept. 17, 2023).

effects.⁶⁷

79. Both Elon Musk and Chelsea Handler are among the celebrities who have admitted to using the drug for weight loss.⁶⁸

80. Novo Nordisk has partnered directly with other celebrities as paid spokespersons, including Queen Latifah.⁶⁹

81. As part of overall campaigns to target Black, Brown, and Hispanic consumers with their marketing campaigns and social media partnerships with influencers, in addition to Queen Latifah Novo Nordisk has compensated Yvette Nicole Brown to serve as a paid spokesperson.⁷⁰

82. In 2021, Novo Nordisk even gave between \$100,000 and \$399,999 to the Congressional Black Caucus Foundation.⁷¹

83. Novo Nordisk combined with Eli Lilly are spending roughly ten million dollars annually on lobbying.⁷²

84. A primary focus of that lobbying is the proposed Treat and Reduce Obesity Act, which has been introduced in congressional sessions annually since 2012. The Treat and Reduce Obesity Act would require Medicare to cover, among other treatments, chronic-weight-management drugs.⁷³

85. Defendants and their competitors have promoted the message that “obesity is a

⁶⁷ *Id.*

⁶⁸ <https://www.insider.com/ozempic-celebrities-denied-semaglutide-wegovy-weight-loss-drugs-khloe-kardashian-2023-3#chelsea-handler-said-she-was-on-semaglutide-without-realizing-it-7> (last visited on Sept. 18, 2023).

⁶⁹ <https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicare-favor> (last visited Sept. 17, 2023)

⁷⁰ <https://www.essence.com/health-and-wellness/yvette-nicole-brown-fighting-obesity/> (last visited on Sept. 18, 2023).

⁷¹ <https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicare-favor> (last visited Sept. 17, 2023)

⁷² <https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicare-favor> (last visited Sept. 17, 2023)

⁷³ <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, 2023); <https://www.fiercepharma.com/pharma/novo-nordisk-eli-lilly-and-boehringer-get-behind-lawmakers-bill-enable-obesity-drug-coverage> (accessed Sept. 17, 2023)

disease” and largely due to “genetics” and “not a choice,” in addition to promoting the message that coverage of pharmaceutical drugs for obesity is a step toward health equity.⁷⁴ What is not promoted is that this message directly impacts Defendants’ pocketbooks by encouraging insurance to cover their drugs. Defendants’ messaging encourages patients and prescribers to forgo lifestyle changes – long the cornerstone of healthy weight loss – in favor of powerful, dangerous, and expensive drugs.

86. Anticipating the passage of this bill within the next few years, Morgan Stanley forecasts that U.S. revenue from such drugs will increase four-hundredfold by the end of the decade. Obesity looks “set to become the next blockbuster pharma category,” it declared in a report last year, which also predicted that social media and word of mouth will create an “exponential virtuous cycle” around the new medications: a quarter of people with obesity will seek treatment from physicians, up from the current seven per cent, and more than half of those who do will begin taking medicine.⁷⁵

87. Defendants also own and operate several marketing campaign websites that are created for the purposes of educating on the science of obesity and creating a change in how obesity is understood and treated.

88. This includes the website “The Truth about Weight.”⁷⁶

89. This website includes headings such as “my weight, my culture,” with these “my weight, my culture” hashtags appearing on Instagram with an apparent focus to target Black, Brown, and Hispanic individuals.⁷⁷

⁷⁴ <https://www.statnews.com/2022/01/06/recognizing-obesity-as-a-disease-is-a-step-toward-health-equity/> (last visited on Sept. 18, 2023); <https://www.womenshealthmag.com/health/a42679413/causes-of-obesity-genetics-lifestyle/> (last visited on Sept. 18, 2023)

⁷⁵ <https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin> (last visited on Sept. 18, 2023).

⁷⁶ <https://www.truthaboutweight.com/> (last visited on Sept. 18, 2023).

⁷⁷ <https://www.truthaboutweight.com/understanding-excess-weight/my-weight-my-culture.html> (last visited on Sept.

90. Defendants also own and operate the website “It’s Bigger Than Me.”⁷⁸ This advertising campaign website promotes the message that obesity is a chronic health condition that requires pharmaceutical drugs to manage.⁷⁹

91. The hashtag #itsbiggerthan also reveals paid social media influencers promoting “body positivity” and linking back to Novo Nordisk’s website (and ultimately to their weight loss drugs).

92. Novo Nordisk’s presentation on capital markets day makes it clear that these campaigns are designed to “activate more people to seek treatment for obesity.”⁸⁰

93. Defendants have also spent significant resources aligning themselves and infiltrating their influence into physician and advocacy groups.

94. This includes the American Board of Obesity Medicine. The former Director of the American Board of Obesity Medicine who served from 2017 to November of 2021 received payments by Novo Nordisk during her time as director of the American Board of Obesity Medicine.⁸¹

95. This former director of the American Board of Obesity Medicine currently promotes their GLP-1 agonists for weight loss as part of their telehealth company and continues to receive payments.⁸²

96. At least one member of the American Board of Obesity Medicine that helped write

18, 2023).

⁷⁸ <https://www.itsbiggerthan.com> (last accessed Sept. 18, 2023).

⁷⁹ *Id.*

⁸⁰ <https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/capital-markets-day-2022/P5-obesity-care.pdf> (last visited on Sept. 18, 2023).

⁸¹ <https://joinfound.com/pages/medication-biology> (last visited on Sept. 18, 2023);

<https://openpaymentsdata.cms.gov/physician/1294300> (last visited on Sept. 18, 2023);

<https://www.linkedin.com/in/rekha-kumar-m-d-m-s-70b481237/> (last visited on Sept. 18, 2023).

⁸² <https://joinfound.com/pages/medication-biology> (last visited on Sept. 18,

2023); <https://openpaymentsdata.cms.gov/physician/1294300> (last visited on Sept. 18, 2023);

<https://www.linkedin.com/in/rekha-kumar-m-d-m-s-70b481237/> (last visited on Sept. 18, 2023).

the guidelines for obesity management has received payments directly from Novo Nordisk according to Open Payments Data during the same time he wrote those guidelines.⁸³

97. Dr. Jamy Ard of Wake Forest University, is the incoming president of The Obesity Society. In that role, he will oversee the group’s effort to write new “standards of care,” which primary-care doctors often use as a quick-reference guide, with advice on Wegovy and similar therapies.⁸⁴ Dr. Ard has accepted more than \$200,000 from Novo Nordisk, according to Reuters.⁸⁵

98. Novo Nordisk contributes money directly to education courses used to satisfy continuing education requirements or to prepare for certification in obesity medicine. This includes contributing \$10,000 to Dr. Kaplan – a physician who has received over \$1 million dollars from Novo Nordisk over the past decade – popular education course on obesity treatment.⁸⁶

99. Novo Nordisk has also influenced and infiltrated the public health partners of the American Board of Obesity Medicine.

100. The American Board of Obesity Medicine lists public health “partners” on their website.⁸⁷

101. Novo Nordisk serves on the board and/or provides direct financial contributions to many of these public health advocacy groups.

102. This includes Obesity in Action Coalition, to which Novo Nordisk contributes more than \$500,000 annually.⁸⁸ Novo Nordisk has been a partner since 2013, before any of its drugs were approved for weight loss.

⁸³<https://openpaymentsdata.cms.gov/physician/1379381> (last visited Sept. 18, 2023); *see also* <https://www.abom.org/karl-nadolsky/>.

⁸⁴ <https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/>

⁸⁵ <https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/>

⁸⁶ <https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/>

⁸⁷ <https://www.abom.org/> (last visited on Sept. 18, 2023).

⁸⁸ <https://www.obesityaction.org/corporate-partners/> (last accessed Sept. 18, 2023).

103. Novo Nordisk also serves on the Corporate Council of American Society for Metabolic and Bariatric Society, another public health partner of the American Board of Obesity Medicine.⁸⁹

104. Novo Nordisk is also a corporate member and directly financially contributes to Stop Obesity Alliance, yet another public health partner of the American Board of Obesity Medicine.⁹⁰

105. Novo Nordisk is a member of additional advocacy organizations and lobbying groups separate and apart from these public health partners of the American Board of Obesity Medicine.

106. This includes the Obesity Care Advocacy Network, which lobbies for legislation to expand access to Novo Nordisk's drugs.⁹¹

107. In addition to promoting lobbying groups, Novo Nordisk has "paid more than \$250,000 in campaign contributions to members of Congress in an effort to pass legislation to make the U.S. government pay for Wegovy, a \$1,300-per-month-per-person proposition."⁹²

108. Novo Nordisk has also partnered with think tanks to promote their narrative that obesity is disease for which treatment requires their billion-dollar pharmaceutical drugs.

109. For example, the Milken Institute is a think tank focused on accelerating measurable progress on the path to a meaningful life.⁹³

110. As early as 2019, before Ozempic or Wegovy was approved for weight loss,

⁸⁹ <https://asmbs.org/corporate-council> (last visited Sept. 18, 2023).

⁹⁰ <https://stop.publichealth.gwu.edu/membership> (last visited on Sept. 18, 2023).

⁹¹ https://assets.obesitycareadvocacynetwork.com/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0.pdf (last visited on Sept. 18, 2023).

⁹² <https://www.fiercepharma.com/marketing/health-group-lambasts-novo-nordisk-60-minutes-paid-news-program-weight-loss-med-wegovy> (last visited Sept. 18, 2023).

⁹³ <https://milkeninstitute.org/about> (last visited on Sept. 18, 2023).

Defendants were publishing articles on the Milken Institute about the “untold story of obesity.”⁹⁴

111. Defendants have deceptively promoted their weight loss drugs on television and news segments.

112. For example, Novo Nordisk’s drugs were the subject of an investigative report on 60 Minutes that aired New Year’s Day of 2023.⁹⁵

113. Complaints have been filed alleging that the “news” piece was in reality “deceptive marketing” in which all physicians interviewed had received payments by Novo Nordisk.⁹⁶

114. The financial relationship between the physicians speaking about Wegovy and Ozempic and Novo Nordisk was not explicitly disclosed.⁹⁷ The reporter stated that the physicians had *advised* Novo Nordisk but failed to state they had been compensated by the company.⁹⁸

115. The nonprofit public health advocacy group the Physicians Committee issued a formal complaint that a recent CBS “60 Minutes” segment was a promotion for Novo Nordisk’s obesity drug, Wegovy, that was dressed up as a news segment.⁹⁹

116. The Washington, D.C.-based group has filed a complaint with federal bodies alleging that the CBS “60 Minutes” segment that aired on New Year’s Day breached the FDA’s “fair balance” rules for drug ads.¹⁰⁰

117. The Physician’s Committee said in a release that the feature failed to talk about alternatives to the drug or about other weight-loss methods; that only experts “paid by Novo” were

⁹⁴ <https://milkeninstitute.org/article/untold-story-obesity-collaborating-across-sectors-make-care-happen> (last visited on Sept. 18, 2023).

⁹⁵ <https://www.cbsnews.com/news/wegozy-ozempic-explainer-60-minutes-2023-01-01/> (last visited Sept. 18, 2023).

⁹⁶ <https://www.fiercepharma.com/marketing/health-group-lambasts-novo-nordisk-60-minutes-paid-news-program-weight-loss-med-wegovy> (last visited Sept. 18, 2023).

⁹⁷ <https://fair.org/home/60-minutes-weight-loss-tip-dont-bite-the-hand-that-feeds-you/> (last visited on Sept. 18, 2023).

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

used in the program; and that the piece used overly promotional language.¹⁰¹

118. The FDA is currently investigating the marketing practices of Novo Nordisk.¹⁰²

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

120. For example, Novo Nordisk spent over \$33,000,000 in 2022 on traditional physician marketing and detailing according to Open Payments Data.¹⁰³

121. Defendants have directly and indirectly partnered with telehealth providers to promote their weight loss drugs.

122. This includes a 2019 direct partnership between Novo Nordisk and Noom, a leading behavior weight loss company.¹⁰⁴ After Saxenda was approved for weight loss, Noom joined with Novo Nordisk again to develop custom programs to accompany this weight loss medication.¹⁰⁵

123. In 2021, Novo Holdings participated in a \$540 million round of financing with Noom.¹⁰⁶ At that time, Novo Holdings tweeted that it “is pleased to note that it has participated in the \$540 million Series F round in @noom, a leading digital health platform...”.¹⁰⁷

124. Novo Holdings currently lists on its website that it has “venture investments” in Noom.¹⁰⁸

125. Noom Med now provides to consumers, using physicians hired by Noom,

¹⁰¹ *Id.*

¹⁰² <https://www.pcrm.org/news/news-releases/fda-confirms-investigation-novo-nordisk-ad-posed-60-minutes-story-about-weight> (last visited Sept. 18, 2023)

¹⁰³ <https://openpaymentsdata.cms.gov/company/100000000144> (last visited Sept. 18, 2023)

¹⁰⁴ <https://www.prnewswire.com/in/news-releases/novo-nordisk-and-noom-to-partner-around-digital-health-solutions-to-help-people-with-obesity-lose-weight-and-keep-it-off-811725389.html> (last visited on Sept. 18, 2023).

¹⁰⁵ <https://www.noom.com/blog/in-the-news/noom-announces-two-new-studies-on-impact-of-mobile-coaching-on-binge-eating-disorder-and-obesity/> (last visited on Sept. 18, 2023).

¹⁰⁶ <https://www.businesswire.com/news/home/20210525005492/en/Noom-Announces-540-Million-in-Growth-Funding-to-Further-Accelerate-Expansion-of-its-Digital-Health-Platform>

¹⁰⁷ <https://twitter.com/novoholdings/status/1397170264702599171>

¹⁰⁸ <https://novoholdings.dk/investments/noom/>

prescriptions for weight loss directly to patients.¹⁰⁹

126. Noom Med promotes off label usage of these weight loss drugs on its website.¹¹⁰

127. Noom currently has over 45 million users.¹¹¹

128. Other telehealth providers have jumped on board the band wagon in offering prescriptions directly to consumers for Defendants' weight-loss medications.

129. This includes Weight Watchers, who purchased telehealth startup Sequence for \$132,000,000 in order to provide weight loss medications to its subscribers.¹¹²

130. There are currently over 3.5 million Weight Watchers subscribers.¹¹³

131. It also includes Calibrate, yet another telehealth provider for weight loss medications, which raised \$100 million in capital funding from investors in 2021.

132. Calibrates' clinical advisory board includes Dr. Fatima Cody Stanford.¹¹⁴

133. Dr. Cody Stanford is an obesity specialist that frequently speaks on behalf of Novo Nordisk, is featured on Novo Nordisk's website, and has received payments directly from Novo Nordisk.¹¹⁵ Upon information and belief, Dr. Cody Stanford is one of the highest paid key opinion leaders for Novo Nordisk.

134. This financial and professional conflict of interest is not disclosed on Calibrate's website.

¹⁰⁹ <https://abcnews.go.com/GMA/Wellness/noom-joins-weight-watchers-offering-medications-wegovy-weight/story?id=99841160> (last visited on Sept. 18, 2023).

¹¹⁰ <https://www.noom.com/med/> (last visited on Sept. 18, 2023).

¹¹¹ <https://exitsandoutcomes.com/free-excerpt-from-the-noom-report-a-45-million-moat/> (last visited Sept. 18, 2023).

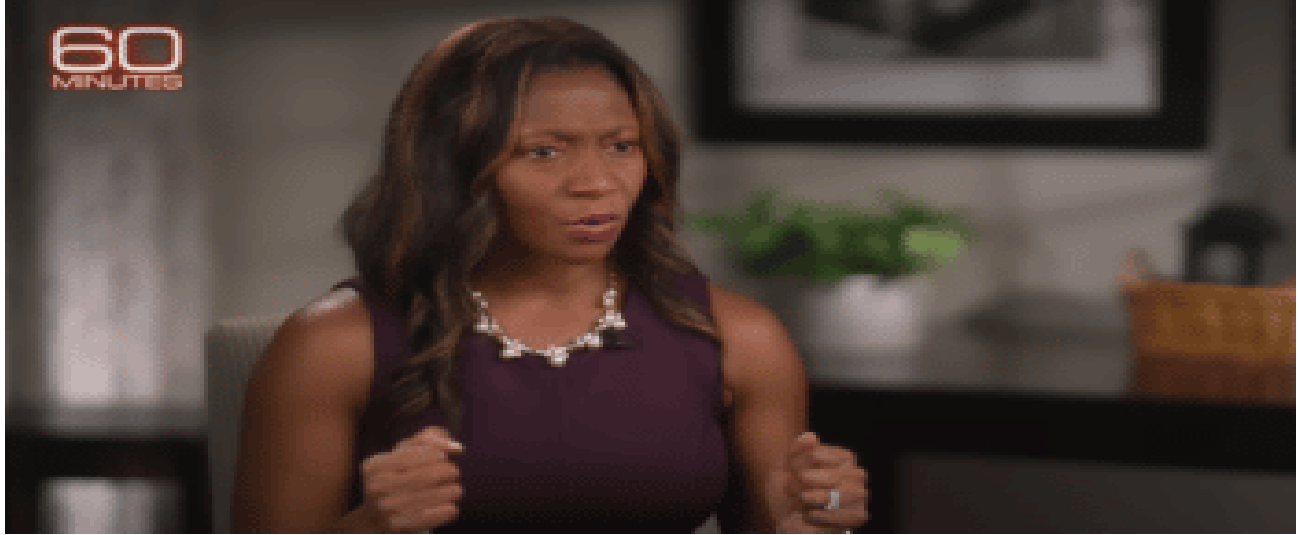
¹¹² <https://www.usatoday.com/story/news/health/2023/03/07/weightwatchers-sequence-wegovy-obesity-weight-loss-drugs/11415201002/> (last visited on Sept. 18, 2023).

¹¹³ <https://finance.yahoo.com/news/ww-international-inc-announces-first-200100340.html#:~:text=%E2%80%9CWe%20expect%20to%20end%202023,including%203.5%20million%20WeightWatchers%20subscribers.> (last visited on Sept. 18, 2023).

¹¹⁴ <https://www.joincalibrate.com/about-us> (last visited on Sept. 18, 2023).

¹¹⁵ <https://openpaymentsdata.cms.gov/physician/807348> (last visited on Sept. 18, 2023); <https://www.novonordisk-us.com/about/perspectives/changing-the-mindset-around-obesity.html> (last visited on Sept. 18, 2023).

135. This same clinical advisory board member, speaker, and promoter of Novo Nordisk is one of the doctors who appeared on the controversial 60 minutes news segment discussed above.¹¹⁶



News reports have recognized that such marketing, particularly with telehealth providers, is a “gray area.”¹¹⁷

136. Dr. Fatima Cody Stanford is also included on Novo Nordisk’s website, arguing that access to their weight loss drugs is an issue of equity and disparity for communities of color.¹¹⁸

137. Their full financial relationship is not disclosed on Defendants’ website.

138. Nor has Dr. Stanford disclosed this relationship in other seemingly independent publications arguing that obesity is a chronic disease that necessitates weight loss medications.¹¹⁹

¹¹⁶ <https://mronline.org/2023/02/13/60-minutes-weight-loss-tip/> (last visited on Sept. 18, 2023).

¹¹⁷ https://www.statnews.com/2023/04/06/weight-loss-drugs-wegovy-ro-telehealth-ozempic/?utm_campaign=morning_rounds&utm_medium=email&_hsmi=253265291&_hsenc=p2ANqtz-6H01FfkCg2JOnqJnju52tvRIJrTnn-KTwSkzAvlqkbBHi4MR2mN8wdPsbzj6Csbzm5s5M56muD-1rjaA-IF60zzjN1A&utm_content=253265291&utm_source=hs_email (last visited on Sept. 18, 2023).

¹¹⁸ <https://www.novonordisk-us.com/about/perspectives/changing-the-mindset-around-obesity.html> (last visited on Sept. 18, 2023).

¹¹⁹ <https://www.statnews.com/2022/01/06/recognizing-obesity-as-a-disease-is-a-step-toward-health-equity/> (last visited on Sept. 18, 2023).

139. Collectively, the telehealth providers that Novo Nordisk directly and indirectly partners with and/or promotes account for approximately half of all weight loss prescriptions in 2022.¹²⁰

140. In sum, the Novo Nordisk Defendants promoted the safety, efficacy, and sale of Ozempic and Wegovy 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.

141. Novo Nordisk's comprehensive, immersive marketing has left no stone unturned in delivering their message that physicians and patients must use their drugs to treat obesity.

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

142. As a result of the Novo Nordisk Defendants' all-encompassing advertising and promotion efforts, Ozempic and Wegovy are widely prescribed throughout the United States.

143. As of August 10, 2023, Novo Nordisk reported that in the first six months of 2023 sales of Wegovy soared 344% in the U.S. to nearly \$1.7 billion, while sales of Ozempic jumped 50% to more than \$3.7 billion.¹²¹

144. In July of 2021, doctors in the US wrote 94,000 prescriptions a week for Wegovy and 62,000 a week for Ozempic.¹²²

¹²⁰ <https://www.statnews.com/2023/08/10/wegovy-ozempic-weight-loss-telehealth-prescriptions/>

¹²¹ <https://www.cnn.com/2023/09/09/big-pharma-blockbuster-obesity-drug-battle-is-headed-for-100-billion.html#:~:text=Novo%20traded%20earnings%20jobs%20with,to%20more%20than%20%243.7%20billion.> (last visited Sept. 18, 2023).

¹²² <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited on Sept. 18, 2023).

145. 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.¹²³

146. On a year-end earnings call in 2022, Novo Nordisk cited worldwide market growth of fifty percent, with almost forty thousand new Wegovy prescriptions being written every week.¹²⁴

147. The number of prescriptions filled reached an all-time high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.¹²⁵

148. In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.¹²⁶

149. 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.¹²⁷

150. Wegovy hit such a high demand that the company was not able to make enough, the company’s spokeswoman Ambre James- Brown said.¹²⁸

151. There is now a shortage for the drugs, including those for people who have diagnosed Type II diabetes.¹²⁹

¹²³ *Id.*

¹²⁴ <https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin> (last accessed Sept. 18, 2023).

¹²⁵ <https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/> (last visited on Sept. 18, 2023).

¹²⁶ <https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance/> (last visited on 8/1/23).

¹²⁷ https://www.nytimes.com/2023/08/28/business/denmark-ozempic-wegovy.html?action=click&pgtype=Article&state=default&module=stylIn-weight-loss-drugs&variant=show®ion=MAIN_CONTENT_1&block=storyline_top_links_recirc (last visited on Sept. 18, 2023).

¹²⁸ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited on Sept. 18, 2023).

¹²⁹ <https://www.forbes.com/sites/brianbushard/2023/09/16/shortage-of-weight-loss-drugs-like-wegovy-and-ozempic-persist-and-could-for-some-years/?sh=191877ce631e> (last visited Sept. 17, 2023)

152. Ozempic and Wegovy have become so popular, Novo Nordisk has recently limited shipment to the US and paused advertising to address shortages.¹³⁰

IV. Deceptive Marketing: Defendants Continuously Spread Misleading Marketing to Alter Perceptions of Ozempic and Wegovy's Safety Risks.

153. Despite Defendants focus on BMI and their marketing of Ozempic and Wegovy as health-promoting drugs, overall health is more than a simple number.

154. On June 14, 2023, the AMA adopted a new policy clarifying how body mass index should be used as a measure in medicine.¹³¹

155. The American Medical Association has urged doctors to deemphasize their use of body mass index (BMI) in determining healthy weights for patients.¹³²

156. Due to significant limitations associated with the widespread use of BMI in clinical settings, the AMA suggests that it be used in conjunction with other valid measures of risk such as, but not limited to, measurements of visceral fat, body adiposity index, body composition, relative fat mass, waist circumference and genetic/metabolic factors.¹³³

157. A recent study examined subjects' B.M.I. in relation to their blood pressure, cholesterol levels, and insulin resistance. Nearly a third of people with a "normal" B.M.I. had unhealthy metabolic metrics, and nearly half of those who were technically overweight were metabolically healthy. About a quarter of those who were classified as obese were healthy, too.¹³⁴

158. In short, BMI is a poor indicator of health outcomes for an individual.¹³⁵

¹³⁰ <https://www.theatlantic.com/health/archive/2023/05/ozempic-teen-obesity-treatment-health-promises-risks/674204/> (last visited on Sept. 18, 2023).

¹³¹ <https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measure-medicine> (last visited Sept. 18, 2023).

¹³² *Id.*

¹³³ *Id.*

¹³⁴ <https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin> (last access Sept. 18, 2023).

¹³⁵ <https://newsroom.uw.edu/resource/why-body-mass-index-doesnt-give-whole-health-picture> (last visited Sept. 18, 2023).

159. Weight loss as the sole indicator of health has also been rejected by many clinicians in favor of improvements in other health outcomes and the assessing the whole health of an individual.¹³⁶

160. These clinicians have cautioned that “a lower body weight does not always mean a person is healthier.”¹³⁷

161. It’s recognized in the medical community that weight loss achieved by Ozempic and Wegovy is often a result of a significant loss of muscle mass.¹³⁸

162. This loss of muscle mass can lead to sarcopenia, a condition called being “skinny fat,” in which the patient has decreased muscle mass, lessened bone density, and lower resting metabolic rate— all of which results in a loss of strength and functionality.¹³⁹

163. Ongoing use of Ozempic and Wegovy for weight loss can lead to malnutrition and key vitamin deficiencies, such a vitamin B12, that can lead to poor health outcomes.¹⁴⁰

164. Given these adverse effects on overall health, the National Institute of Care and Excellence (NICE) has recommended that people stop taking Wegovy after 2 years.¹⁴¹

165. The problem, of course, is that individuals immediately begin to gain the weight back once they stop taking Ozempic and Wegovy.¹⁴²

¹³⁶ <https://link.springer.com/content/pdf/10.1007/s11606-022-07821-w.pdf?pdf=button> (last visited on Sept. 18, 2023); <https://newsroom.uw.edu/resource/why-body-mass-index-doesnt-give-whole-health-picture> (last accessed Sept. 18, 2023).

¹³⁷ <https://www.healthline.com/health-news/ozempic-muscle-mass-loss> (last accessed Sept. 18, 2023).

¹³⁸ <https://www.nbcnews.com/health/health-news/weight-loss-drugs-muscle-loss-rcna84936> (last accessed Sept. 18, 2023).

¹³⁹ <https://www.healthline.com/health-news/ozempic-muscle-mass-loss> (last accessed Sept. 18, 2023).

¹⁴⁰ <https://www.nytimes.com/2023/04/21/well/eat/ozempic-side-effects-malnutrition.html> (last accessed Sept. 18, 2023).

¹⁴¹ National Institute for Health and Care Excellence. (2023). Semaglutide for managing overweight and obesity. *NICE*. Retrieved from: <https://www.nice.org.uk/guidance/ta875/chapter/1-Recommendations> (last visited on Sept. 18, 2023).

¹⁴² <https://www.psychologytoday.com/ie/blog/the-neuroscience-of-eating-disorders/202303/ozempic-and-wegovy-is-semaglutide-a-miracle-weight> (last visited on Sept. 18, 2023).

166. Studies show that as the weight rebounds once individuals stop taking Ozempic and Wegovy, the weight gain is predominantly fat and not muscle.

167. Paradoxically, individuals may be lighter than they were initially but have a higher percentage of body fat.¹⁴³ Individuals who are unable or not warned of the need to mitigate this muscle loss with dietary changes and strength training can create a loss of muscle mass that accelerates normal ageing of the muscles.¹⁴⁴

168. Upon information and belief, the weight that is gained back is often visceral fat, which is considered more harmful to health than other types of fat.

169. A trial published by Novo Nordisk showed that after a year, participants had gained back two thirds of the weight lost after they stopped taking semaglutide.¹⁴⁵

170. Novo Nordisk has publicly recognized that most individuals will regain all the weight back within five years of stopping Ozempic or Wegovy.¹⁴⁶

171. Remarkably, Novo Nordisk has publicly stated that some individuals will regain even more weight after stopping Ozempic or Wegovy than they initially lost.¹⁴⁷

172. Ozempic and Wegovy's label and marketing materials do not warn about the need to remain on Wegovy or Ozempic permanently to maintain weight loss. Nor does the label and marketing materials warn that once the drug is stopped that the individual may gain even more weight back than they lost and ultimately weigh more than before starting the drug.

173. Wegovy and Ozempic are often marketed as part of a "metabolic reset."¹⁴⁸

¹⁴³ <https://www.afr.com/policy/health-and-education/lighter-but-fatter-the-ozempic-paradox-20230718-p5dp5w>

¹⁴⁴ *Id.*

¹⁴⁵ <https://dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.14725>

¹⁴⁶ <https://www.cNBC.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html>

¹⁴⁷ <https://www.cNBC.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html>

¹⁴⁸ <https://www.joincalibrate.com/resources/how-long-does-it-take-to-lose-weight-on-ozempic>

174. However, Novo Nordisk has recognized that GLP-1s do not rewire “your neural networks to really define a new body weight setpoint.”¹⁴⁹

175. Many clinicians recognize that a need to acknowledge that additional factors besides weight influence a person's health trajectory, including healthcare access, stress, poverty, and environmental threats (*e.g.*, chemicals).¹⁵⁰

V. Defendants have long known that Ozempic and Wegovy are powerful, dangerous drugs.

176. As detailed below, Defendants knew from their required premarket and post-market research and analytics that Ozempic and Wegovy could cause malnutrition, cyclical vomiting, and gastroparesis, gastroenteritis, and intestinal obstruction/blockage.

177. The Novo Nordisk Defendants have repeatedly failed to warn about the known dangerous side effects of Ozempic and Wegovy. This includes gastroparesis, gastroenteritis, intestinal blockage or obstruction, and malnutrition. All of these conditions can, and have, lead to hospitalization and/or death in patients across America.

178. Some doctors estimate that as many as 10% of patients discontinue use of these drugs due to the severity of side effects.¹⁵¹

179. 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 alerts that both Ozempic and Wegovy had potential safety signals for intestinal blockage.¹⁵²

¹⁴⁹ <https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html>

¹⁵⁰ <https://www.psychologytoday.com/ie/blog/the-neuroscience-of-eating-disorders/202303/ozempic-and-wegovy-is-semaglutide-a-miracle-weight> (last visited on Sept. 18, 2023).

¹⁵¹ <https://www.cbsnews.com/news/ozempic-side-effects-weight-loss-drugs-wegovy-mounjaro-doctors-warn/> (last visited Sept. 18, 2023)

¹⁵² <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, 2023)

180. As early as 2014, Defendants knew that Saxenda (liraglutide), Ozempic's predecessor, caused serious side effects and warned the end user of same.¹⁵³

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

182. These side effects for Rybelsus included: nausea, abdominal pain, diarrhea, decreased appetite, vomiting, constipation, pancreatitis, diabetic retinopathy complication, hypoglycemia; acute kidney injury, and hypersensitivity reactions.¹⁵⁴

183. According to the FDA Adverse Event Reporting System, Defendants were aware of reports of intestinal obstruction no later than 2019 for Ozempic and/or Wegovy.¹⁵⁵ These reports to the FDA also stated that many of these patients reporting intestinal obstruction or blockage were hospitalized.¹⁵⁶

184. The Prescribing Information for Ozempic discloses warnings, precautions, and adverse reactions associated with Ozempic, but it does not disclose the risk of severe gastrointestinal events, including gastroparesis and gastroenteritis. Instead, it discloses delayed gastric emptying under the "Drug Interactions" heading and notes that Ozempic "may impact absorption of concomitantly administered oral medications." Further, under the "Mechanism of Action" section, the Prescribing Information states that "[t]he mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase."¹⁵⁷ These statements do not disclose

¹⁵³ https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206321orig1s000lbl.pdf (last visited on Sept. 18, 2023).

¹⁵⁴ <https://www.novo-pi.com/rybelsus.pdf> (last visited on Sept. 18, 2023).

¹⁵⁵ <https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ec/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis> (last access Sept. 18, 2023).

¹⁵⁶ *Id.*

¹⁵⁷ <https://www.novo-pi.com/ozempic.pdf> (last visited on Sept. 18, 2023).

gastroparesis or delayed gastric emptying as risks of taking Ozempic, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Ozempic.

185. The Prescribing Information for Wegovy discloses warnings, precautions, and adverse reactions associated with taking Wegovy, but it does not disclose the risk of severe gastrointestinal events, including gastroparesis and gastroenteritis. Instead, it discloses delayed gastric emptying under the “Drug Interactions” heading and notes that Wegovy “may impact absorption of concomitantly administered oral medications.”¹⁵⁸ These statements do not disclose gastroparesis or delayed gastric emptying as risks of taking Wegovy, nor do they disclose gastroparesis as a chronic condition that can result because of taking Wegovy.

186. Despite their experience and knowledge, Defendants have downplayed the severity of the gastrointestinal events caused by Ozempic, never, for example, warning of the risk of gastroparesis (“paralyzed stomach”), gastroenteritis, or intestinal blockage or obstruction.

187. Gastroparesis is a condition that affects normal muscle movement in the stomach. Ordinarily, strong muscular contractions propel food through the digestive tract. However, in a person suffering from gastroparesis, the stomach’s motility is slowed down or does not work at all, preventing the stomach from emptying properly. Gastroparesis can interfere with normal digestion, and can cause nausea, vomiting, abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, vomiting undigested food, undigested food that hardens and remains in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, malnutrition, and a decreased quality of life. There is no cure for gastroparesis.¹⁵⁹

¹⁵⁸ https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215256s0001b1.pdf (last visited on Sept. 18, 2023).

¹⁵⁹ <https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787> (last visited on Sept. 18, 2023).

188. Gastroenteritis refers to inflammation of the stomach and intestines. While viral gastroenteritis is also known as stomach flu, gastroenteritis may also be caused by ingesting medications.¹⁶⁰ Its symptoms include vomiting, nausea, diarrhea, stomach cramps, muscle aches, headaches, and fever.¹⁶¹ Notably, vomiting and diarrhea can cause dehydration, which is the main complication of gastroenteritis, and which can lead to death.¹⁶²

189. Defendants do not disclose any risks associated with severe gastrointestinal events, including the risk of gastroparesis, gastroenteritis, and intestinal blockage or obstruction within the “Important Safety Information” section of their promotional website.

190. None of Defendants’ additional advertising or promotional materials warned prescription providers or the general public of the risk of severe gastrointestinal events, including gastroparesis, gastroenteritis, or intestinal blockage or obstruction.

191. A 2011 published article notes that “From extensive studies in experimental animals and humans we have found that GLP-1 also exerts a motility-inhibiting and antispasmodic effect in the gut that was verified in healthy volunteers...”.¹⁶³ It is explicitly noted that GLP-1s have slow down gastric emptying.¹⁶⁴

192. A similar published article in 2013 found that after a review of PubMed articles it was evident that GLP-1s inhibit gastric emptying; notably, they separately found that delayed gastric emptying could lead to malnutrition.¹⁶⁵

¹⁶⁰ <https://www.merckmanuals.com/home/digestive-disorders/gastroenteritis/drug-related-gastroenteritis-and-chemical-related-gastroenteritis> (last visited on Sept. 18, 2023).

¹⁶¹ <https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847> (last visited on Sept. 18, 2023)

¹⁶² <https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847> (last visited on Sept. 18, 2023).

¹⁶³ Hellström PM. GLP-1 playing the role of a gut regulatory compound. *Acta Physiol (Oxf)*. 2011 Jan;201(1):151-6. doi: 10.1111/j.1748-1716.2010.02150.x. PMID: 20518750; available at <https://pubmed.ncbi.nlm.nih.gov/20518750/> (last visited Sept. 18, 2023).

¹⁶⁴ *Id.*

¹⁶⁵ Luttikhoud J, de Ruijter FM, van Norren K, Diamant M, Witkamp RF, van Leeuwen PA, Vermeulen MA. Review

193. A 2018 Case report found that liraglutide had caused acute gastroparesis and noted that: “This case highlights the importance of considering drug-induced gastroparesis as an etiology of unexplained upper abdominal pain, nausea, and early satiety, especially in the absence of mechanical obstruction.”¹⁶⁶

194. In August of 2020, medical literature advised that some “patients do not know they have diabetic gastroparesis until they are put on a glucagon-like peptide 1 (GLP-1) receptor agonist such as ... semaglutide ... to manage their blood glucose.” The article went on to explain that “[t]his class of Ozempic can exacerbate the symptoms of diabetic gastroparesis. ... Thus, GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis.”¹⁶⁷

195. In 2021, a case report was published regarding a 52-year-old female who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis symptoms. The case report authors concluded that “thorough history taking revealed the cause [of gastroparesis] to be medication induced.”¹⁶⁸

196. A second case report also published in 2021 involved a 57-year-old female who had been taking weekly dulaglutide injections (another GLP-1 receptor agonist) for 15 months and suffering from bloating, nausea and vomiting for 12 of those months. Testing revealed delayed gastric emptying which improved with cessation of dulaglutide.¹⁶⁹

article: the role of gastrointestinal hormones in the treatment of delayed gastric emptying in critically ill patients. *Aliment Pharmacol Ther.* 2013 Sep;38(6):573-83. doi: 10.1111/apt.12421. Epub 2013 Jul 23. PMID: 23879699. (last visited Sept. 18, 2023).

¹⁶⁶ Rai P, Madi MY, Dickstein A. Liraglutide-induced Acute Gastroparesis. *Cureus.* 2018 Dec 28;10(12):e3791. doi: 10.7759/cureus.3791. PMID: 30868005; PMCID: PMC6402745; available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6402745/pdf/cureus-0010-00000003791.pdf> (last visited Sept. 18, 2023).

¹⁶⁷ Young CF, Moussa M, Shubrook JH, *Diabetic Gastroparesis: A Review*, *Diabetes Spectr.* 2020 Aug; 33(3): 290–297, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/> (last visited on Sept. 18, 2023).

¹⁶⁸ Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, *J Investig Med High Impact Case Rep.* 2021 Jan-Dec; 9: 23247096211051919, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/> (last visited on Sept. 18, 2023).

¹⁶⁹ Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, *J Investig Med High Impact Case Rep.* 2021 Jan-Dec; 9: 23247096211051919, available at

197. In 2022, a large, population-based study indicated that the use of GLP-1 RAs was associated with an increased risk of intestinal obstruction.¹⁷⁰

198. On June 29, 2023, the American Society of Anesthesiologists issued a warning that patients taking Ozempic should stop the medication at least a week before elective surgery because Ozempic and other GLP-1 agonists “delay gastric (stomach) emptying” and “the delay in stomach emptying could be associated with an increased risk of regurgitation and aspiration of food into the airways and lungs during general anesthesia and deep sedation.”¹⁷¹

199. On July 25, 2023, it was reported that patients taking Ozempic had been diagnosed “with severe gastroparesis, or stomach paralysis, which their doctors think may have resulted from or been exacerbated by the medication they were taking, Ozempic.” Additionally, “[t]he US Food and Drug Administration said it has received reports of people on the Ozempic experiencing stomach paralysis[.]”¹⁷²

200. Case reports continue to be published regarding the use of semaglutide and intraoperative pulmonary aspirations.¹⁷³

201. From the date the Novo Nordisk Defendants received FDA approval to market Ozempic until the present time, the Novo Nordisk Defendants made, distributed, marketed, and/or sold Ozempic without adequate warning to Plaintiff’s prescribing physician(s) and/or Plaintiff that Ozempic was associated with and/or could cause severe gastrointestinal issues including gastroparesis, gastroenteritis, and intestinal blockage or obstruction.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/> (last visited on Sept. 18, 2023).

¹⁷⁰ Faillie, J.-L., Yin, H., Yu, O.H.Y., Herrero, A., Altwegg, R., Renoux, C. and Azoulay, L. (2022), Incretin-Based Drugs and Risk of Intestinal Obstruction Among Patients with Type 2 Diabetes. *Clin. Pharmacol. Ther.*, 111: 272-282. <https://doi.org/10.1002/cpt.2430> (last visited Sept. 18, 2023).

¹⁷¹ <https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery> (last visited on Sept. 18, 2023).

¹⁷² <https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-Ozempic-gastroparesis/index.html> (last visited Sept. 18, 2023).

¹⁷³ <https://pubmed.ncbi.nlm.nih.gov/36977934/> (last visited Sept. 18, 2023)

202. Defendants knew of the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues, including gastroparesis and gastroenteritis. Defendants' knowledge derived from their clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced above in this Complaint.

203. Upon information and belief, Defendants ignored the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues, including gastroparesis and gastroenteritis.

204. Defendants' failure to disclose information that they possessed regarding the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues, including gastroparesis and gastroenteritis, rendered the warnings for this medication inadequate.

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

206. Defendants also fail to provide adequate instructions for use and warnings and precautions for Ozempic and Wegovy, including failing to warn that a patient needs to remain permanently on the drug, or the weight will be regained within a one-to-five year period. Nor do the Defendants provide instructions on how to safely use the drug to mitigate harms, including how to safely monitor the patient for adverse effects and how to safely take the patient off the drug without causing a worsening of those adverse events, such as gastroparesis.

VI. The Dark Side of Ozempic and Wegovy

207. It has been recognized in the media that in the aftermath of the marketing frenzy created by Novo Nordisk that the full risks of these drugs are not understood or readily available to the average patient—and perhaps the average provider.¹⁷⁴

208. For example, one physician has stated that “I suspect the drug companies are downplaying this risk because women are probably the biggest part of the market share,” she said. “The world doesn’t value women, and this is seen in women’s health as well.”¹⁷⁵

209. Strikingly, Novo Nordisk’s own hired spokesperson and consultant has stated on national television that “[d]octors do not understand obesity.”¹⁷⁶

210. It is unclear how Novo Nordisk would expect a doctor to understand the mechanism of their weight loss drug—and its corresponding risks—if they do not understand the condition it is supposed to treat.

211. Defendants have much greater knowledge of their obesity drugs, including their dangerous risks, than the medical community or American public.

212. This includes the fact that female sex is an independent risk factor associated with an increased risk of adverse effects when taking GLP-1s.¹⁷⁷

213. Neither the Ozempic nor Wegovy label warns that being female increases the risk of suffering adverse effects when taking these drugs.

214. Recently, news articles have begun to publicize the dark side of these drugs.¹⁷⁸

¹⁷⁴ <https://www.vox.com/science/23683383/ozempic-pregnancy-risks-side-effect-semaglutide-wegovy>

¹⁷⁵ <https://www.vox.com/science/23683383/ozempic-pregnancy-risks-side-effect-semaglutide-wegovy> (last visited Sept. 18, 2023).

¹⁷⁶ <https://www.cbsnews.com/news/weight-loss-obesity-drug-2023-01-01/> (last visited Sept. 18, 2023).

¹⁷⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8950819/> (“In contrast, female sex appears to be a well-recognized independent factor linked to greater weight loss achievement after treatment with GLP-1 RAs. **This is also the case for adverse events resulting from the use of these medications**, which appear to manifest in higher percentages in women, mainly affecting the GI tract.”) (emphasis added).

¹⁷⁸ <https://www.cnn.com/2023/06/07/opinions/ozempic-weight-loss-drug-diet-culture-wellness-carr-goldynia-sole->

215. Consumers of Ozempic and Wegovy are reporting major health problems, including gastroparesis, stomach paralysis, gastroenteritis, and intestinal blockage or obstruction.¹⁷⁹

216. Consumers are not aware that taking Ozempic or Wegovy can lead to severe malnutrition.¹⁸⁰

217. Consumers are not aware that taking Ozempic and Wegovy can lead to severe muscle loss.¹⁸¹

218. Muscle loss (sarcopenia) can lead to death.¹⁸²

219. Consumers are not warned that if they stop taking Ozempic and/or Wegovy, they will quickly regain the weight back.

220. Nor are consumers warned that the weight regain is predominantly fat and not muscle – essentially rendering the consumer worse off than before they started the drug.

221. Other industry experts, including physicians, believe that there needs to be greater awareness of the risks of Ozempic and Wegovy.¹⁸³

222. Yet Defendants have continued selling Ozempic and Wegovy to a point where there are mass shortages and waitlists.¹⁸⁴

[smith/index.html](#) (last visited Sept. 18, 2023).

¹⁷⁹ <https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis> (last visited Sept. 18, 2023).

¹⁸⁰ [An Extreme Risk of Taking Ozempic: Malnutrition – The New York Times \(nytimes.com\)](#) (last visited Sept. 18, 2023).

¹⁸¹ <https://www.healthline.com/health-news/ozempic-muscle-mass-loss> (last visited Sept. 18, 2023)

¹⁸² <https://my.clevelandclinic.org/health/diseases/23167-sarcopenia#:~:text=Sarcopenia%20affects%20your%20musculoskeletal%20system,risk%20of%20complications%20including%20death> (last visited on Sept. 18, 2023).

¹⁸³ <https://www.vox.com/science/23683383/ozempic-pregnancy-risks-side-effect-semaglutide-wegovy> (last visited Sept. 18, 2023).

¹⁸⁴ https://www.nytimes.com/2023/08/28/business/denmark-ozempic-wegovy.html?action=click&pgtype=Article&state=default&module=style&weight-loss-drugs&variant=show®ion=MAIN_CONTENT_1&block=storyline_top_links_recirc (last visited Sept. 18, 2023).

223. This is despite the fact the FDA has investigated and found “objectionable” conditions at Novo Nordisk’s Clayton, N.C. manufacturing plant that is responsible for making weight loss drugs like Ozempic and Wegovy.¹⁸⁵

224. This is not the first time the FDA has cited a company for failures related to the manufacturing of Wegovy and Ozempic. In January 2021, a US FDA Form 483 revealed that Catalent failed to impellent sustainable corrective action and preventive action and had inadequate maintenance at a Catalent fill/finish facility.¹⁸⁶ Novo Nordisk confirmed that “a contract manufacturer doing syringe filling on the GLP-1 med had temporarily halted delivered following a good manufacturing practices glitch.”¹⁸⁷

225. Defendants are profiting while the end consumers, mostly women, are suffering.

PARTY PLAINTIFF

226. Plaintiff, Laura Marrero, was born on October 13, 1975 and is 48 years old.

227. Ms. Marrero is a Type-2 Diabetic and was diagnosed with diabetes at 38 years old.

228. Even though Ms. Marreo’s diabetes was well-controlled, on or about May 16, 2023, Dr. Raluchukwu Attah prescribed Ozempic to Ms. Marrero at .25 mg every week.

229. While prescribed Ozempic, Ms. Marrero suffered from nausea, vomiting and diarrhea with bloating the night of and the day after taking Ozempic.

¹⁸⁵ [https://www.investors.com/news/technology/novo-nordisk-stock-skids-as-report-finds-objectionable-conditions-at-wegovy-plant/#:~:text=Novo%20Nordisk%20\(NVO\)%20stock%20skidded,diabetes%20and%20weight%2Dloss%20drugs](https://www.investors.com/news/technology/novo-nordisk-stock-skids-as-report-finds-objectionable-conditions-at-wegovy-plant/#:~:text=Novo%20Nordisk%20(NVO)%20stock%20skidded,diabetes%20and%20weight%2Dloss%20drugs) (last visited Septebmer 18, 2023).

¹⁸⁶ <https://bioprocessintl.com/bioprocess-insider/regulations/fda-483-shows-7-observations-at-catalent-fill-finish-plant-in-belgium/> (last visited Sept. 18, 2023); <https://www.fiercepharma.com/manufacturing/inside-catalent-fda-citation-allegedly-at-heart-novo-nordisk-s-wegovy-supply-hiccup> (last visited Sept. 18, 2023).

¹⁸⁷ *Id.*

230. On or about July 24, 2023, Dr. Attah prescribed Ozempic to Ms. Marrero at 2 mg every week.

231. On or about July 27, 2023, Dr. Attah prescribed Ozempic to Ms. Marrero at 1 mg every week.

232. On or about August 28, 2023, Ms. Marrero was admitted to Temple University Hospital with abdominal pain in the pit of her stomach, nausea and vomiting as well as difficulty swallowing and rectal bleeding. Testing revealed that Ms. Marrero was suffering from moderate chronic gastritis and reactive gastropathy.

233. Ms. Marrero continued to suffer from vomiting while prescribed Ozempic.

234. On October 24, 2023, Ms. Marrero's Nurse Practitioner, Ms. Kimberli Brawner, advised that Ms. Marreo stop taking Ozempic due to the side effects she was suffering from, specifically the constant vomiting.

235. As a direct result of Ms. Marrero's use of Ozempic, she suffered and continues to suffer from complications causing her damage, including but not limited to pain, suffering, mental anguish, depression, loss of enjoyment of life, medical expenses and other out of pocket losses, and loss of income.

COUNT I: NEGLIGENCE

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

237. Defendants, directly or indirectly, caused Ozempic to be sold, distributed, packaged, labeled, marketed, promoted, and used by Plaintiff. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, overpromoted, and sold Wegovy and

its sister approved only for diabetes, Ozempic, within the Commonwealth of Pennsylvania and throughout the United States.

238. At all relevant times, Defendants 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.

239. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known of the hazards and dangers associated with Ozempic and/or Wegovy, and specifically that use of these drugs could cause gastroparesis, gastroenteritis, malnutrition, intestinal obstruction, hospitalization, and death.

240. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known that the use of Ozempic and/or Wegovy could cause Plaintiff's injuries, and thus, created a dangerous and unreasonable risk of injury to the users of these products that Defendants did not warn of.

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

242. Defendants breached their duty of care to Plaintiff and her physician, in the warning, testing, monitoring, and pharmacovigilance of Ozempic.

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

- a. Manufacturing, producing, overpromoting, marketing, formulating, creating, developing, designing, selling, and distributing Ozempic and Wegovy, without thorough and adequate pre- and post-market testing of the product;
- b. Manufacturing, producing, overpromoting, marketing, advertising, formulating, creating, developing, and distributing Ozempic and Wegovy, and upon information and belief, 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 Wegovy;
- c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Ozempic and Wegovy were safe for their intended use;
- d. Upon information and belief, failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Ozempic/Wegovy was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;
- e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that Ozempic and 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 Wegovy;
- g. Advertising, marketing, and recommending the use of Ozempic and Wegovy, including off-label usage, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Ozempic and Wegovy;
- h. Representing that Ozempic and Wegovy were safe for weight loss when in fact Defendants knew and/or should have known the products were not safe for those purposes;

- i. Continuing to manufacture and sell Ozempic and Wegovy with the knowledge that Ozempic and Wegovy, when used for weight loss, were unreasonably unsafe and dangerous;
- j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of Ozempic and Wegovy so as to avoid the risk of serious harm associated with the use of Ozempic and Wegovy. Failing to design and manufacture Ozempic and Wegovy so as to ensure the drugs were at least as safe and effective as other similar products;
- k. Failing to ensure that Ozempic and Wegovy were accompanied by proper and accurate warnings about the risk of severe gastrointestinal problems including gastroparesis.
- l. Failing to ensure that Ozempic and Wegovy were accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Ozempic and Wegovy and that use of Ozempic and Wegovy created a high risk of severe injuries; and
- m. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Ozempic and Wegovy.

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

245. As a direct and proximate result of Defendants' negligent testing, monitoring, and pharmacovigilance of Ozempic and Wegovy, Defendants introduced a drug into this Commonwealth that they knew or should have known would cause serious and severe gastrointestinal issues in people including gastroparesis, an incurable condition, and Plaintiff has been injured catastrophically and sustained severe and permanent pain, suffering, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

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

247. As a direct and proximate result of one or more of the above-stated negligent acts by Defendants, Plaintiff suffered bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

248. Defendants are liable in tort to Plaintiff for their negligence to warn pursuant to Pennsylvania common and statutory law.

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 as triable as a matter of right.

COUNT II: NEGLIGENCE - FAILURE TO WARN

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

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

251. 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.

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

253. Defendants advertised and promoted Ozempic and/or Wegovy for the purpose of weight loss and diabetes control, and their extensive marketing scheme led to rampant off-label usage.

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

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

256. Defendants knew or had reason to know of facts establishing that Ozempic and/or Wegovy posed a significant risk of gastroparesis, gastroenteritis, intestinal obstruction, malnutrition, hospitalization, and death and deliberately proceeded to act, or failed to act, in conscience disregard of, or indifference, to that risk.

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

258. In disregard of its duty to timely warn consumers of health risks associated with Ozempic and/or Wegovy, Defendants 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 lasting and permanent gastrointestinal injuries;
- b. Failing to timely disclose to Plaintiff and Plaintiff's treating physicians the risks of gastrointestinal injuries, including gastroparesis and intestinal obstruction, associated with Ozempic and/or Wegovy in the product's labeling;
- c. Failing to timely warn Plaintiff and Plaintiff's treating physicians that a detailed lab work and patient history should be obtained before starting Ozempic and/or Wegovy.

259. The labels for Ozempic and/or Wegovy are inadequate because they did not warn and/or adequately warn of all possible adverse side effects associated with the use of Ozempic and/or Wegovy, including the increased risk of severe gastrointestinal events (e.g., gastroparesis, gastroenteritis, intestinal blockage, and malnutrition) and the need to permanently stay on the drug or the weight will be regained.

260. The labels for Ozempic and/or Wegovy are inadequate because they did not contain adequate instructions for use such that a physician and patient could make an informed prescribing decision, adequately monitor the patient while using, and mitigate potential harms from the use of Ozempic and/or Wegovy.

261. The labels for Ozempic and/or Wegovy are inadequate because they did not warn and/or adequately warn that Ozempic and/or Wegovy had not been sufficiently and/or

adequately tested for safety risks, including severe gastrointestinal events (e.g., gastroparesis, gastroenteritis, intestinal blockage, and malnutrition).

262. 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.

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

264. Communications made by Defendants to Plaintiff and her prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects associated with the use of Ozempic and/or Wegovy, including the increased risk of severe gastrointestinal events (e.g., gastroparesis, gastroenteritis, intestinal blockage, and malnutrition).

265. Communications made by Defendants to Plaintiff and her prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn that Ozempic and/or Wegovy had not been sufficiently and/or adequately tested for safety risks, including severe gastrointestinal events (e.g., gastroparesis and gastroenteritis, intestinal blockage, and malnutrition).

266. Defendants' failure to warn of the above was the proximate cause of Plaintiff's injuries, harm, and economic loss, from which Plaintiff continue to suffer.

267. Defendants' 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.

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

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

270. Defendants is liable in tort to Plaintiff for its wrongful conduct pursuant to Pennsylvania.

271. As a direct, foreseeable and proximate result of Defendants' failure to warn of the significant risks associated with Ozempic and/or Wegovy, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above. As a consequence of Defendants' misconduct, Plaintiff' physicians lacked adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) that Defendants provided to physicians for Ozempic and/or Wegovy. Plaintiff suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income and disability, and punitive damages.

272. Defendants are liable in tort to Plaintiff for their negligent failure to warn pursuant to Pennsylvania common and statutory law.

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 as triable as a matter of right.

COUNT III: NEGLIGENCE - DESIGN DEFECT

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

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

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

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

(a) Failing to use ordinary care in designing, testing, and manufacturing Ozempic and/or Wegovy;

(b) Failing to design Ozempic and/or Wegovy as to properly minimize the adverse effects to the gastrointestinal and immune system;

(c) Failing to counteract in the design the known adverse effects on the gastrointestinal and immune system;

(d) Designing a product where the benefits were greatly outweighed by the risks gastroparesis, gastroenteritis, intestinal obstruction, malnutrition, hospitalization, and death;

(e) Designing a product without taking into consideration the proper dosage that could avoid gastroparesis, gastroenteritis, intestinal obstruction, malnutrition, hospitalization, and death.

277. Furthermore, Ozempic and/or Wegovy was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

278. At all reasonable times, given their lack of efficacy and increased safety risks, Ozempic and/or Wegovy did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff, or in the alternative, her medical providers.

279. Ozempic and/or Wegovy was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, more dangerous than an ordinary consumer would expect, and more dangerous than other similar drugs.

280. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of Ozempic and/or Wegovy at all times relevant, Defendants designed and brought the product to market and continued to market the drug when there were safer alternatives available, including but not limited to alternate dosing, reduced exposure, among others.

281. As a result of Defendants' negligent and reckless design, Plaintiff sustained severe and ongoing injuries.

282. As a direct and proximate result of one or more of the above-stated negligent acts by Defendants, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

283. Defendants are liable in tort to Plaintiff for their negligent design defect pursuant to Pennsylvania common and statutory law.

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 as triable as a matter of right.

COUNT IV: NEGLIGENT MISREPRESENTATION AND MARKETING

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

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

286. At all relevant times, Defendants negligently provided Plaintiff, her healthcare providers, the general medical community, and the public with false, fraudulent, and/or incorrect information or omitted or failed to disclose material information concerning Ozempic and/or Wegovy, including, but not limited to, misrepresentations and marketing regarding the long term effects of Ozempic and/or Wegovy, including, but not limited to the fact weight lost will be regained upon cessation of the drug.

287. The information distributed by Defendants to the public, the medical community, Plaintiff and her healthcare providers, including advertising campaigns, labeling materials, print advertisements, commercial media, and marketing that often promoted off-label usage was false and misleading, and contained omissions and concealment of truth about the dangers of Ozempic and/or Wegovy.

288. Defendants' 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.

289. Defendants had a duty to accurately and truthfully represent and market to the medical and healthcare community, medical pharmaceutical manufacturers, Plaintiff, her healthcare providers and the public, the known risks of Ozempic and/or Wegovy, including its propensity to cause gastroparesis, gastroenteritis, intestinal blockage/obstruction, and malnutrition.

290. Defendants 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 to cause gastroparesis, gastroenteritis, intestinal blockage/obstruction, and malnutrition.

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

292. Defendants 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 patients.

293. Defendants made the misrepresentations alleged herein with the intent to induce consumers, like Plaintiff, to take their weight-loss products.

294. In reliance upon the false, deceptive and negligent misrepresentations and omissions and marketing made by Defendants, Plaintiff and Plaintiff's healthcare providers were

induced to, and did use and prescribe Wegovy, and relied upon the affirmative misrepresentations and/or negligent omissions in doing so.

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

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

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

298. Plaintiff and their healthcare providers would not have used or prescribed Ozempic and/or Wegovy had the true facts not been concealed by Defendants.

299. Defendants 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.

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

301. Defendants failed to exercise ordinary care in making representations concerning Ozempic and/or Wegovy while they were involved in their manufacture, design, sale, testing, quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate

commerce, because Defendants negligently misrepresented Ozempic and/or Wegovy's high risk of unreasonable and dangerous adverse side effects.

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

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

304. Defendants are liable in tort to Plaintiff for their negligent misrepresentation(s) and marketing pursuant to Pennsylvania statutory and common law.

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 as triable as a matter of right.

COUNT V: VIOLATION(S) OF UNFAIR AND DECEPTIVE TRADE PRACTICES AND OTHER CONSUMER PROTECTION LAWS

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

306. Defendants financed, assisted, supported and participated in the promotion and use of Ozempic and/or Wegovy in order to create a demand for the drug, including for off-label usage.

307. Defendants deliberately and/or negligently misrepresented the safety of Ozempic and/or Wegovy and concealed the risks attendant to use of the drugs. Through their

misrepresentations, Defendants' conduct had the tendency or capacity to deceive, and affected the decisions of consumer and their health care providers to purchase, prescribe and use Ozempic and/or Wegovy, and to exclude the options of not using a drug product for treatment.

308. All Defendants, while engaged in the conduct and practices identified above, committed one or more violations of state laws related to unfair or deceptive acts or practices, including, but not limited to, the following:

- a. Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of Ozempic and/or Wegovy;
- b. Representing that Ozempic and/or Wegovy have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have;
- c. Representing that Defendants' authors, key opinion leaders, consultants, and speakers do not have a sponsorship, approval, status, affiliation or connection that they do have;
- d. Representing that Ozempic and/or Wegovy are of a particular standard, quality or grade;
- e. Engaging in other fraudulent or deceptive conduct which creates likelihood of confusion or of misunderstanding, alleged in this Complaint.

309. All Defendants engaged in unconscionable, false, fraudulent, misleading, and/or deceptive acts while conducting trade or commerce in violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1, et seq., respectively.

310. Plaintiff has suffered injuries and damages as a direct and proximate result of Defendants' said conduct and in statements in the advertising and promotional activities to Plaintiff and Plaintiff's medical providers, as described above.

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 as triable as a matter of right.

COUNT VI: FRAUD

311. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

312. Defendants falsely and fraudulently have represented and continue to represent to the medical and healthcare community, Plaintiff and her physicians, and/or the public that Ozempic and/or Wegovy has been appropriately tested and was found to be safe and effective.

313. The representations made by the Defendants through labeling and their widespread marketing and advertisements scheme were, in fact, false. When the Defendants made their representations, they knew and/or had reason to know that those representations were false, and they willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of Ozempic and/or Wegovy.

314. These representations were made by the Defendants with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, Plaintiff's physicians, and/or the public, to recommend, prescribe, dispense, and purchase Ozempic and/or Wegovy for use as a treatment for diabetes and/or obesity while concealing the drug's known propensity to cause gastroparesis and the consequent injuries.

315. In representations to Plaintiff and/or to her healthcare providers, including Plaintiff's prescribing physician, Dr. Ross Del Fierro, the Defendants fraudulently concealed and

intentionally omitted the following material information from the Ozempic product labeling and advertisements in existence at the time Plaintiff was prescribed Ozempic in September 2021 and April 2022:

- (a) That Ozempic causes severe gastrointestinal issues, including gastroparesis and other potentially long-term and permanent injuries.
- (b) That Ozempic was known to increase the risk of severe gastroparesis and other potentially long-term or permanent injuries;
- (c) That Ozempic was not adequately tested following the Defendants' knowledge that the drug was causing gastroparesis at increased and alarming levels;
- (d) That Defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and either ignored, concealed and/or misrepresented those findings;
- (e) That there is a clinically important difference between mild or moderate temporary gastrointestinal issues and gastroparesis, the latter of which is a serious and often permanent harm caused by Ozempic use; and,

316. (f) That Ozempic causes severe gastrointestinal events, including gastroparesis, and its ability to cause debilitating and/or permanent injuries.

317. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, and/or her physicians through accurate labeling and advertisements and other marketing materials promoting directed to consumers.

318. Defendants knew or had reason to know that incidences of gastroparesis were not temporary, transient, or asymptomatic, as a result of information from case studies, clinical trials, literature, and adverse event reports available to the Defendants at the time of the development and sale of Ozempic and/or Wegovy, as well as at the time of Plaintiff's Ozempic prescription(s).

319. Defendants knew or had reason to know that Ozempic and/or Wegovy caused gastroparesis and related conditions as a result of information from case studies, clinical trials, literature, and adverse event reports available to the Defendants at the time of the development and sale of Ozempic and/or Wegovy, as well as at the time of Plaintiff's Ozempic prescription(s).

320. Defendants' concealment and omissions of material facts concerning the safety of the Ozempic and/or Wegovy were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff, Plaintiff's physicians, surgeons and healthcare providers and to induce them to purchase, prescribe, and/or use Ozempic.

321. At the time these representations were made by Defendants, and at the time Plaintiff and/or her physicians used Ozempic, Plaintiff and/or her physicians were unaware of the falsehood of these representations.

322. In reliance upon these false representations, Plaintiff was induced to, and did use Ozempic, thereby causing severe, debilitating, and potentially permanent personal injuries and damages to Plaintiff. The Defendants knew or had reason to know that the Plaintiff had no way to determine the truth behind the Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of Ozempic, as described in detail herein.

323. In comporting with the standard of care for prescribing physicians, Plaintiff's prescribing physician relied on the labeling for Ozempic in existence at the September 2021 and

April 2022 dates of prescription that included the aforementioned fraudulent statements and omissions.

324. These representations made by Defendants were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

325. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of the Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts about the Defendants' misrepresentations at the time when Ozempic was prescribed to her.

326. As a proximate result of the Defendants' fraudulent statements and omissions, Plaintiff has been seriously injured, and sustained severe and permanent injury, pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

327. The aforementioned fraudulent statements and omissions and wrongs done by the Defendants were aggravated by the kind of malice and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless

disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

328. Defendants are liable in tort to Plaintiff for their fraudulent conduct pursuant to Pennsylvania common and statutory law.

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 as triable as a matter of right.

COUNT VII – GROSS NEGLIGENCE

329. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

339. Defendants' aforementioned conduct was aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious disregard to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

340. Defendants ignored or disregarded years of data and reports on the relationship between Ozempic and/or Wegovy and severe gastrointestinal events, including but not limited to gastroparesis and gastroenteritis.

330. Defendants advertised and promoted Ozempic and/or Wegovy for the purpose of weight loss and diabetes control without that safety data, and their extensive marketing scheme led to rampant off-label usage.

341. Defendants' ignorance of the aforementioned safety data was ongoing through the date Plaintiff was prescribed and ingested Ozempic.

342. Given the Defendants' knowledge and awareness of the extensive body of information available on Ozempic and/or Wegovy's propensity to cause severe gastrointestinal events, Defendants' failure to ensure Ozempic and/or Wegovy was safe for recommended use amounts to gross negligence, malice, and a reckless disregard for the safety of Plaintiff and others.

343. Plaintiff and her physicians relied on the Defendants to introduce into the marketplace a safe and adequately tested drug, and Plaintiff suffered her catastrophic injuries because of Defendants' failure to do so.

344. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

345. Plaintiff will seek to assert claims for exemplary damages to the extent available under all applicable Pennsylvania laws.

346. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused Plaintiff's injuries. In that regard, Plaintiff will seek exemplary damages in an amount that would

punish Defendants for their conduct, and which would deter other manufacturers from engaging in such misconduct 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 as triable as a matter of right.

DEMAND FOR JURY TRIAL

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 Defendants awarding the following:

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 Defendants 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: December 19, 2023

Respectfully Submitted,

/s/ Michael G. Daly

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