UNITED STATES DISTRICT COURT NOTHERN DISTRICT OF NEW YORK

JENNY A. BRYANT

Plaintiff,

v.

NOVO NORDISK A/S, NOVO NORDISK NORTH AMERICA OPERATIONS A/S NOVO NORDISK US HOLDINGS INC., NOVO NORDISK US COMMERICAL HOLDINGS INC., NOVO NORDISK INC., NOVO NORDISK RESEARCH CENTER SEATTLE INC., NOVO HOLDINGS A/S, NOVO HOLDINGS EQUITY US INC., NOVO VENTURES US, INC., and NOVO VENTURES US, INC., and NOVO NORDISK PHARMACEUTICAL INDUSTRIES LP. Case No.: 1:24-cv-00561 (AMN/MJK)

COMPLAINT AND JURY DEMAND

Defendants.

COMPLAINT AND JURY DEMAND

COMES NOW, the Plaintiff, JENNY BRYANT, by and through undersigned counsel and submits this Complaint and Jury Demand against Defendants Novo Nordisk A/S, et. al. for negligence, failure to warn, defective design and deceptive and unfair marketing practices of Ozempic and Wegovy, Defendants' injectable prescription medication that is approved for weight loss. As a direct and proximate result of Defendants' conduct, Plaintiff was prescribed and used Ozempic and Wegovy, and suffered resulting injuries, for which we request compensatory and punitive damages, and such other relief deemed just and appropriate. In support, Plaintiffs allege the following:

I. <u>NATURE OF THE ACTION</u>

1. This case involves claims of negligence, failure to warn, design defect, negligent misrepresentation and marketing, and violations of the unfair and deceptive trade practices by Defendants in designing, distributing, marketing, supplying, warranting, and/or selling Ozempic and Wegovy by the Defendants directly or through their agents, apparent agents, servants, and/or employees.

2. For approximately a decade, Defendants advertised and marketed Ozempic and Wegovy, their once weekly injections of semaglutide, a GLP-1 (glucagon-like peptide-1) agonist, as safe and effective to treat obesity and diabetes while concealing the true and dangerous side effects of these products from prescribing physicians and consumers. Wegovy and Ozempic are chemically identical and primarily differ based upon dosage.

3. An agonist is a manufactured substance that attaches to a cell receptor and causes the same action as the naturally occurring substance.¹ GLP-1 agonists bind to GLP receptors to trigger the effects or roles of the GLP-1 hormone, a hormone in the lower gastrointestinal tract which helps to control insulin response levels after eating and slows gastric emptying.²

4. GLP-1 agonists are able to trigger the effects of the GLP-1 hormone, making them the active ingredient in a class of medications that can help lower blood sugar levels and promote weight loss.³

5. The higher the dose of the GLP-1 agonist, the more extreme the effects.⁴

³ <u>https://my.clevelandclinic.org/health/treatments/13901-glp-1-agonists</u> (last visited Feb. 28, 2024)

 ¹ <u>https://www.cancer.gov/publications/dictionaries/cancer-terms/def/agonist</u> (last visited March 4, 2024).
 ² <u>https://pubmed.ncbi.nlm.nih.gov/9840447/#:~:text=Glucagon%2Dlike%20peptide%201%20(GLP%2D1)%20is%20a.glucose%20administration%20in%20normal%20humans</u>. (last visited March 4, 2024).

⁴ Id.

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6. Defendants did not warn about the true and dangerous side effects including but not limited to acute and chronic gastrointestinal issues, deep vein thrombosis, sarcopenia, malnutrition, compromised body composition, hospitalization, and death.

7. Defendants did not warn about the true and dangerous side effects including but not limited to increased weight gain after cessation of medication.

8. Defendants did not warn about the true and dangerous side effects including alteration of fat, muscle and body composition.

9. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of Ozempic and Wegovy, Defendants designed and brought the products to market and continued to market the drug when there were safer alternatives available, including but not limited to alternate dosing and reduced exposure.

10. Despite Defendant's knowledge of these dangerous side effects, Defendant failed to warn the public and the medical community, including Plaintiff and Plaintiff's health care providers, of these risks, while also continuing to over-promote the medications and spend millions of dollars per year to market the medications as safe and effective.

11. Defendants' affirmative misrepresentations and omissions regarding the true and dangerous side effects of Ozempic and Wegovy, concealed from Plaintiff and Plaintiff's healthcare providers information necessary to properly weigh the benefits and risks associated with Ozempic and Wegovy, and to properly consider alternative treatment options.

12. As a result of Defendants' failure to properly warn the public and medical community of the actual risks of Ozempic and Wegovy, as well as Defendants' aggressive marketing of Ozempic and Wegovy, consumers have suffered and continue to suffer from acute

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injuries, such as intestinal blockages and deep vein thrombosis, as well as chronic injuries, such as gastroparesis, sarcopenia, and compromised body composition.

13. Plaintiff brings this action for personal injuries suffered as a proximate result of her Ozempic use. Plaintiff accordingly seeks compensatory and punitive damages, and all other available remedies provided to Plaintiffs under the law as a result of injuries.

II. <u>PARTIES</u>

14. At all times relevant hereto, Plaintiff Jenny A. Bryant was and is a resident and citizen of Ulster County, New York.

15. Defendant Novo Nordisk Inc. is a Delaware corporation with its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08538. Novo Nordisk has conducted business and derived substantial revenue from within the State of New York, including within the area covered by the Northern District of New York (hereinafter the "District"), and generated substantial revenue as a result.

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

17. Defendant Novo Nordisk US Commercial Holdings, Inc. is a Delaware corporation with its principal place of business at 103 Foulk Road, Wilmington, Delaware 19803, and is wholly owned by Defendant Novo Nordisk US Holdings Inc.

18. Defendant Novo Nordisk US Holdings Inc. is a Delaware corporation with its principal place of business at 103 Foulk Road, Wilmington, Delaware 19803, and is wholly owned by Defendant Novo Nordisk A/S.

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

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

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

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

23. 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."⁵ Upon information and belief, this refers to Novo Nordisk's manufacturing facility in Clayton, North Carolina, operated by Novo Nordisk Pharmaceutical Industries LP.

24. 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.⁶

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

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

27. Defendant Novo Ventures (US) Inc. is a Massachusetts corporation with its principal place of business at 501 2nd Street Suite 300 San Franciso, California 94107.

⁵ <u>https://www.novonordisk-us.com/about/who-we-are/north-carolina.html</u> (last visited March 5, 2024).

⁶ <u>https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=adec4fd2-6858-4c99-91d4-531f5f2a2d79</u> (last visited March 5, 2024).

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28. The aforementioned Novo Nordisk entities, subsidiaries and affiliates are collectively referred to herein as "Defendants" and "Novo Nordisk" and "Novo Nordisk Defendants."

III. JURISDICTION AND VENUE

29. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a) because there is complete diversity between Plaintiff and Defendants, and because the amount in controversy exceeds Seventy-Five Thousand Dollars (\$75,000) exclusive of interest and costs. Plaintiff was and is a resident of New York State. Each Defendant is neither incorporated nor has its principal place of business in New York.

30. This Court has personal jurisdiction over Defendants under one or more provisions of CPLR § 302(a)(1) because at all relevant times Defendants have engaged in substantial business activities in the State of New York. At all relevant times, Defendants transacted, solicited, and conducted business within the State of New York. Plaintiff's claims arise out of Defendants' transaction of business and their tortious acts within New York State, from which they realized pecuniary benefit.

31. Venue is proper under 28 U.S.C. § 1391 because Plaintiff is a citizen and resident of Ulster County, New York.

IV. FACTS COMMON TO ALL COUNTS

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

32. In the early 1990s, Novo Nordisk researchers discovered that injecting rats with chemical compound liraglutide, a GLP-1 (glucagon-like peptide-1) agonist, caused the rats to stop eating almost entirely.⁷

⁷ <u>https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html</u> (last visited Feb. 28, 2024).

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33. The Novo Nordisk Foundation released a video wherein Lotte Bierre Knudsen, a Novo Nordisk scientist stated, "These rats, they starved themselves... so we kind of knew there was something in some of these peptides that was really important for appetite regulation."⁸

34. 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 received a placebo.⁹

35. Consequently, Novo Nordisk decided to study liraglutide not only as a diabetes drug to lower blood sugar, but also as a drug to treat obesity.¹⁰

36. In 2010, liraglutide was approved for the treatment of diabetes by the FDA under Novo Nordisk's brand name Victoza,¹¹ at which point Novo Nordisk moved on to studying liraglutide for weight loss.¹²

37. In 2014, after clinical trials, the U.S. Federal Drug Administration (FDA) approved Novo Nordisk's daily injectable Saxenda, with liraglutide as active ingredient, as an obesity treatment.¹³

38. However, Saxenda's effects on weight loss were modest, with patients loosing about 5% of their weight.¹⁴

39. Thereafter, Novo Nordisk investigated how to make a longer-lasting GLP-1 agonist so patients would not have to inject themselves daily. The investigation led to the discovery of a new molecule with the chemical name semaglutide.¹⁵

⁸ Id.

⁹ Id.

 $^{^{10}}$ *Id*.

¹¹<u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2957743/#:~:text=The%20incretin%20mimetic%20liraglutide%20</u> <u>0(Victoza,adults%20with%20type%2D2%20diabetes.&text=Liraglutide%20is%20also%20approved%20in%20Europe%20and%20Japan</u> (last visited Feb 28, 2024).

 $^{^{12}}$ *Id.* at 5. 13 *Id.*

 $^{^{14}}$ Id.

 $^{^{15}}$ Id.

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40. On December 5, 2016, Defendants' announced submission of a new drug application (NDA) for semaglutide, a once-weekly injectable medication, in either a 0.5 mg or 1 mg dose, as a treatment of Type 2 diabetes. In the announcement, Defendants represented that in clinical trials "once-weekly semaglutide had a safe and well-tolerated profile with the most common adverse event being nausea."¹⁶

41. On December 5, 2017, the FDA approved the application and granted premarket approval for Ozempic (semaglutide) injection as NDA 209637.¹⁷

42. In addition to controlling diabetes, Ozempic's users had as much as a 15% weight loss, which was three times the loss following use of Saxenda, Ozempic's predecessor.¹⁸

43. One year after Ozempic was FDA approved for diabetes treatment, Defendants started a clinical trial in patients who were overweight or suffered from obesity.¹⁹

44. The results of the trial demonstrated that overweight or obese participants taking 2.4 mg of semaglutide once weekly with lifestyle intervention sustained clinically relevant body weight reduction.²⁰

45. The trial data also showed a greater number of participants in the semaglutide group than in the placebo group discontinued treatment due to gastrointestinal events (59 [4.5%] vs. 5 [0.8%] of the 1,961 participants).²¹

¹⁶ <u>https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183</u> (last visited Feb 28, 2024).

 ¹⁷ <u>https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf</u> (last visited Feb 29, 2024).
 ¹⁸ *Id.* at 5.

¹⁹ Id.

 ²⁰ John, P.H., et al, Once-Weekly Semaglutide in Adults with Overweight or Obesity. *The New England Journal of Medicine*. 384:989-1002 (March 19, 2021). Access here: <u>https://www.nejm.org/doi/full/10.1056/NEJMoa2032183</u> (last visited Feb. 28, 2024)
 ²¹ Id.

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46. By March of 2021, Defendants had completed the clinical trial studying semaglutide for weight loss, and its results were published March 18, 2021.²²

47. The opening section of the published study, which was supported and funded, at least in part, by Defendants', states "Obesity is a chronic disease and global public health challenge."²³

48. On March 20, 2019, Defendant Novo Nordisk Inc. submitted a supplemental a new drug application (sNDA) for Ozempic 0.5 mg or 1 mg injection. Defendants also requested to expand Ozempic's indication to include that it reduces the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.²⁴ On January 16, 2020, the FDA approved this new indication.²⁵

49. On May 28, 2021, Defendant Novo Nordisk Inc. submitted another sNDA requesting approval for a 2 mg dose of Ozempic injection. On March 28, 2022, the FDA approved this request.²⁶

50. In their March 28, 2022 press release, Defendants represented Ozempic as having "proven safety and efficacy" and advertised that "it can help many patients lose some weight."²⁷ As with its prior press releases, Defendants disclosed Important Safety Information and provided links to the Medication Guide and Prescribing Information. However, severe gastrointestinal events, including gastroparesis and gastroenteritis, were not identified as risks.²⁸

²² Id.

²³ Id.

²⁴<u>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 Feb. 28, 2024).</u>

 ²⁵ <u>https://www.accessdata.fda.gov/Ozempicatfda_docs/appletter/2020/209637Orig1s003ltr.pdf</u> (last visited Feb. 28, 2024).
 ²⁶ Id

 ²⁷<u>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 Feb. 28, 2024).
 ²⁸ Id.
</u>

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51. On June 4, 2021, the FDA approved Wegovy, a once-weekly 2.4 mg semaglutide dose, for chronic weight management in obese (BMI > 30) or overweight (BMI > 27) adults, with at least one chronic weight related condition, including but not limited to high blood pressure, type 2 diabetes, or high cholesterol.²⁹

52. We govy was the first FDA drug approved for weight loss since Saxenda in 2014.³⁰

53. 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.³¹

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

54. After discovering that GLP-1 agonists could lead to weight loss, Defendants began advertising, marketing, and lobbying to change the medical consensus as it relates to obesity.

55. Traditional evidence-based approaches to obesity focus on lifestyle, including eating whole nutrition-rich 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 through Defendants' medications, which cost users over \$1,000 per month.

56. Throughout their extensive marketing, Defendants fail to disclose the dangerous side effects of Ozempic and Wegovy, including but not limited to acute and chronic gastrointestinal issues, deep vein thrombosis, sarcopenia, malnutrition, compromised body composition, hospitalization, and death.

²⁹https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weightmanagement-first-2014 (last visited Feb. 28, 2024)

³⁰ Id.

³¹ <u>https://www.novonordisk-us.com/media/news-archive/news-details.html?id=151389</u> (last visited Feb. 29, 2024).

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57. Defendants Ozempic and Wegovy labels and patient brochures also fail to disclose that unless patients continue to take the drug indefinitely, they are at risk of regaining some of the weight they lost within one year and regaining all of the weight they lost within five years.^{32, 33}

58. In Defendants' 2018 announcement that Ozempic was now available in U.S. pharmacies, Defendants marketed the drug as a "new treatment option[]" that "addresses the concerns and needs of people with diabetes[.]" The brochure offered an "Instant Savings Card to reduce co-pays to as low as \$25 per prescription fill for up to two years."³⁴

59. On July 30, 2018, Defendants launched their first television advertisement for Ozempic stating that, "adults lost on average up to 14 pounds" when taking Ozempic. The advertisement played the 1970s hit pop song "Magic" by Pilot in the background.³⁵



³²https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-theystop-medication.html (last visited Feb. 28, 2024).

³³ <u>https://pubmed.ncbi.nlm.nih.gov/35441470/</u> (last visited Feb. 28, 2024).

³⁴<u>https://www.prnewswire.com/news-releases/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment-options-for-adults-with-diabetes-</u>

^{300592808.}html#:~:text=Ozempic%C2%AE%20is%20priced%20at,for%20up%20to%20two%20years.(Last visited Feb. 29, 2024).

³⁵ <u>https://www.ispot.tv/ad/d6Xz/ozempic-oh</u> (last visited Feb. 28, 2024).

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60. Novo Nordisk was not permitted to market Ozempic for weight loss without FDA approval for that specific indication.³⁶ However, before receiving separate FDA approval for weight loss for semaglutide or Ozempic, Ozempic's 2018 commercial highlighted that Ozempic would help people lose weight.³⁷

61. This 2018 patient brochure and 2018 commercial both failed to warn users that upon stopping Ozempic they are at risk for regaining more weight than they previously lost.³⁸

62. Over the next five years, Defendants paid \$884,000,000 for television advertisements in the United States to promote semaglutide products, including Ozempic, Wegovy, and another of its lesser known GLP-1 agonists, Rybelsus. Most advertisements were allocated toward Ozempic.³⁹

63. Defendants also marketed to medical professionals, paying for their consulting, travel and food.

64. According to open payments data, in 2022 alone, Novo Nordisk spent \$33,927,336.42 marketing Ozempic to medical professionals.⁴⁰

65. According to a Reuters report, over the past decade, Novo Nordisk spent at least \$25.8 million to market Wegovy and Saxenda, drugs approved specifically for obesity, to U.S. medical professionals.⁴¹

66. Reuters also reported that over the past decade at least 57 U.S. physicians each accepted at least \$100,000 from Novo Nordisk in payments associated with Wegovy or Saxenda.

 ³⁶ <u>https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html</u> (last visited Feb. 28, 2024).
 ³⁷ Id.

³⁸https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-theystop-medication.html (last visited Feb. 28, 2024).

³⁹ <u>https://medwatch.com/News/Pharma</u>Biotech/article15680727.ece (last visited Feb. 28, 2024).

⁴⁰ <u>https://openpaymentsdata.cms.gov/company/100000000144</u> (last visited Feb. 28, 2024).

⁴¹<u>https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/</u> (last visited Feb 29, 2024).

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Forty-one of these physicians were obesity specialists who ran weight-management clinics, worked at academic hospitals, wrote obesity-treatment guidelines, or held top positions at medical societies.⁴²

67. Reuters also reported that Dr. Donna Ryan, a Louisiana researcher and former president of The Obesity Society, accepted over \$1 million from Novo Nordisk over the last decade, including \$600,691 related to Wegovy and Saxenda, and was instrumental in persuading the U.S. Office of Personnel Management to cover Wegovy and similar drugs for millions of federal workers.⁴³

In 2022, Novo Nordisk reportedly spent approximately \$100 million advertising
 Ozempic.⁴⁴

69. Defendants' aggressive marketing includes placing over 4,000 marketing advertisements for Ozempic and similar weight-loss medications on Facebook and Instagram.⁴⁵

70. Novo Nordisk partnered with Meta and Instagram to run interactive marketing campaigns. One diabetes marketing campaign, which included interactive polls, achieved a dramatic 28% direct engagement rate and enabled Defendants to reach over 1.5 million people.⁴⁶

71. The TikTok hashtag #Ozempic had 273 million views as of November 22, 2022,⁴⁷ and currently has over 1.4 billion views.⁴⁸

⁴² Id.

⁴³ Id.

⁴⁴<u>https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin</u> (last visited March 1, 2024).

⁴⁵ <u>https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602</u> (last visited Feb. 28, 2024).

⁴⁶ <u>https://business.instagram.com/success/novo-nordisk</u> (last visited March 1, 2024).

⁴⁷ <u>https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html</u> (last visited Feb. 28, 2024). ⁴⁸ <u>https://www.tiktok.com/tag/ozempic?lang=en</u> (last visited March 4, 2024).

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72. The TikTok hashtag #wegovyweightloss has 183.9 million views as of March 4, 2024.⁴⁹

73. 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."⁵⁰

74. 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 2023.⁵¹

75. According to a MediaRadar study, in 2023, over \$491 million was spent advertising "diabesity" drugs, including Novo Nordisk's Ozempic, Wegovy, and Rybelsus, as well as Boehringer Ingelheim's Jardiance.⁵²

76. Jimmy Kimmel joked about Ozempic at the Oscars.⁵³

77. Howard Stern has joked and discussed Ozempic's 2018 commercial, noting that the "catchy" theme song "distracts" the listener from actually hearing any of the listed side effects.⁵⁴

78. Elon Musk and Chelsea Handler are among the celebrities who have admitted to using the drug for weight loss.⁵⁵

79. Novo Nordisk has partnered directly with other celebrities as paid spokespersons.

80. Novo Nordisk hired Queen Latifah to collaborate on US marketing.⁵⁶

⁵¹<u>https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-</u>2023/2500571?utm_source=exchange&utm_medium=email&utm_campaign=t5687390 (last visited March 1, 2024).
 ⁵² <u>https://www.usatoday.com/story/life/health-wellness/2023/03/13/ozempic-sweeping-hollywood-celebrities-weight-loss/11428801002/</u> (last visited March 1, 2024).

 ⁴⁹ <u>https://www.tiktok.com/tag/wegovyweightloss?lang=en</u> (March 4, 2024).
 ⁵⁰ <u>https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571</u> (last visited March 1, 2024).

⁵⁴ Id.

 ⁵⁵<u>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 March 1, 2024).
 ⁵⁶<u>https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor</u> (last visited March 1, 2024).
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81. Novo Nordisk hired Yvette Nicole Brown to launch the "It's Bigger Than Me" platform.⁵⁷

82. Novo Nordisk has spent a considerable amount of money lobbying for health equity and to gain Medicare's favor.

83. Since 2014, Novo Nordisk has spent over \$30 million lobbying congress and other federal officials.⁵⁸ In 2021 alone, Novo Nordisk spent \$3.2 million on lobbying, which is a 24% increase from the amount spent in 2020.⁵⁹

84. Defendants push the message that "obesity is a disease," largely due to "genetics," and "not a choice," to claim that coverage of pharmaceutical drugs for obesity is a step toward health equity.^{60,61,62}

85. Per year, Defendants and Eli Lilly together spend approximately 10 million dollars on lobbying. A consistent subject of the lobbying is the proposed Treat and Reduce Obesity Act, which has been introduced in congressional sessions annually since 2012.

86. The Treat and Reduce Obesity Act would require Medicare to cover, among other treatments, chronic-weight-management drugs.⁶³

 ⁵⁷ <u>https://www.essence.com/health-and-wellness/yvette-nicole-brown-fighting-obesity/</u> (last visited March 1, 2024).
 ⁵⁸ *Id.*

⁵⁹ <u>https://www.statnews.com/2022/01/25/insulin-giants-eli-lilly-and-novo-nordisk-boosted-their-lobbying-spending-as-democrats-eyed-pricing-reform/</u> (last visited March 4, 2024).

⁶⁰ <u>https://www.statnews.com/2022/01/06/recognizing-obesity-as-a-disease-is-a-step-toward-health-equity/</u> (last visited on Sept. 18, 2023).

⁶¹ <u>https://www.womenshealthmag.com/health/a42679413/causes-of-obesity-genetics-lifestyle/</u> (last visited on Sept. 18, 2023)

⁶² *Id.* at 57.

⁶³ <u>https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin</u> (last visited March 4, 2024); <u>https://www.fiercepharma.com/pharma/novo-nordisk-eli-lilly-and-boehringer-get-behind-lawmakers-bill-enable-obesity-drug-coverage</u> (last visited March 4, 2024)

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87. In 2021, Novo Nordisk contributed between \$100,000 and \$399,999 to the Congressional Black Caucus Foundation, a non-profit affiliated with the Congressional Black Caucus, a powerful group of lawmakers on Capitol Hill.⁶⁴

88. In 2022, Novo Nordisk sponsored a panel at the Congressional Black Caucus Foundation where, Dr. Fatima Cody Stanford, an Obesity Medicine Physician at Harvard Medical School, who frequently speaks on behalf of Novo Nordisk, is featured on Novo Nordisk's website, and has received payments from Novo Nordisk, explained to the audience that obesity is a "real disease."⁶⁵

89. NPR stated, "Pharmaceutical giant Novo Nordisk has turned to influential Black Americans in pursuit of what would be a lucrative victory: having Medicare cover a new class of weight loss drugs, including the company's high sought Wegovy, which can cost patients more than \$1,000 a month."⁶⁶

90. Morgan Stanley forecasts that The Treat and Reduce Obesity Act will pass within the next few years and United States revenue from weight loss drugs will increase four-hundredfold by the end of the decade. Morgan Stanley states that obesity is "set to become the next blockbuster pharma category" and predicts that social media and word of mouth will create an "exponential virtuous cycle" around the new medications. Currently, 7% of people who are obese seek treatment. Morgan Stanley predicts that this number will increase to 25% and half of these people will begin taking medicine.⁶⁷

 ⁶⁴<u>https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor</u> (last visited March 5, 2024).
 ⁶⁵ Id.

 $^{^{66}}Id.$

⁶⁷ https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fatand-being-thin (last visited March 26, 2024).

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91. Lobbying for insurance coverage of weight loss drugs while encouraging patients and prescribers to forgo lifestyle changes in favor of dangerous, and expensive drugs, has a direct positive impact on Defendants' profits.

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

93. This includes the website "The Truth About Weight," which includes headings such as "my weight, my culture." ^{68,69}

94. This same language appears in Instagram hashtags, targeting Black, Brown, and Hispanic individuals.

95. The Truth About Weight website states, "Both the brain and these appetite hormones contribute to what, why, and how much you eat."⁷⁰ After educating readers on "hormones that effect appetite," including, *inter alia*, Peptide YY and GLP-1, the website states "Ask your health care provider how appetite hormones may play a role in your weight management plan."⁷¹

96. Defendants own and operate the website "It's Bigger Than Me," which states "We want the world to know that through science and understanding, obesity is a manageable health condition."⁷² The website proclaims "weight management is not just about will power. Many factors are also at play within our bodies, including genetics and biology."⁷³

17

⁶⁸ <u>https://www.truthaboutweight.com/</u> (last visited March 26, 2024).

⁶⁹ <u>https://www.truthaboutweight.com/understanding-excess-weight/my-weight-my-culture.html</u> (last visited March 26, 2024).

⁷⁰ <u>https://www.truthaboutweight.com/the-science-behind-weight-loss/how-hormones-affect-appetite.html</u> (last visited March 5, 2024).

⁷¹ Id.

 ⁷²<u>https://www.itsbiggerthan.com/about-the-movement/</u> (last visited March 5, 2024).
 ⁷³ Id.

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97. The hashtag #itsbiggerthan reveals paid social media influencers promoting "body positivity" and links to Novo Nordisk's website. Novo Nordisk also has an itsbiggerthan Instagram account.

98. By pushing the message that obesity is a chronic health condition caused by biology and genetics, Defendants' marketing scheme promotes the idea that obesity management is only obtainable with pharmaceutical drugs.

99. Novo Nordisk's presentation on capital markets day states that "there remains a large opportunity for activating more people with obesity to seek treatment."⁷⁴

100. Defendants spent significant resources aligning themselves and infiltrating their influence into physician and advocacy groups.

101. Doctor Rekha Kumar, Director of the American Board of Obesity Medicine from
 2017 to November of 2021, received payments by Novo Nordisk during her time as director.^{75,76,77}
 Doctor Kumar promotes Defendants' GLP-1 agonists on her telehealth company website.^{78,79}

102. At least one member of the American Board of Obesity Medicine who, while helping to write the guidelines for obesity management, received payments directly from Novo Nordisk, according to Open Payments.^{80,81,82}

103. Dr. Jamy Ard, of Wake Forest University, is the incoming president of The Obesity Society. In that role, he will oversee writing new "standards of care," which include the use Wegovy

⁷⁴ <u>https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/capital-markets-day-2022/P5-obesity-care.pdf</u> (last visited March 1, 2024).

⁷⁵<u>https://joinfound.com/pages/medication-biology</u> (last visited on March 1, 2024).

⁷⁶ <u>https://openpaymentsdata.cms.gov/physician/1294300</u> (last visited on March 1, 2024).

⁷⁷ <u>https://www.linkedin.com/in/rekha-kumar-m-d-m-s-70b481237/</u> (last visited on March 1, 2024).

 ⁷⁸<u>https://joinfound.com/pages/medication-biology</u> (last visited on March 1, 2024);
 ⁷⁹ *Id.* at 65.

⁸⁰<u>https://openpaymentsdata.cms.gov/physician/1379381</u> (last visited March 1, 2024).

⁸¹ <u>https://www.endocrinepractice.org/article/S1530-891X(23)00335-X/abstract</u> (last visited March 5, 2023).

⁸² <u>https://www.abom.org/karl-nadolsky/</u>. (last visited Feb 29, 2024).

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and similar therapies. Primary-care doctors often use standards of care is quick-reference guide for advice.⁸³ Dr. Ard has accepted more than \$200,000 from Novo Nordisk, according to Reuters.⁸⁴

104. Novo Nordisk contributes money directly to education courses used to satisfy continuing education requirements or to prepare for certification in obesity medicine.

105. Novo Nordisk has contributed \$10,000 to Dr. Lee Kaplan's popular education course on obesity treatment.⁸⁵ Doctor Kaplan, chief of obesity at Dartmouth College's medical school, has also received over \$1 million dollars from Novo Nordisk over the past decade.⁸⁶

106. Novo Nordisk serves the board and/or provides direct financial contributions to many public health advocacy groups.

107. The American Board of Obesity Medicine lists public health "partners" on their website.⁸⁷ Their list of partners includes the Obesity in Action Coalition. Annually, Novo Nordisk contributes over \$100,000 to the Obesity in Action Coalition, making Novo Nordisk a platinum-level supporter.^{88,89}

108. Novo Nordisk serves on the Corporate Council of American Society for Metabolic and Bariatric Society, another public health partner of the American Board of Obesity Medicine.⁹⁰

109. Novo Nordisk is a corporate member and financially contributes to Stop Obesity Alliance, another public health partner of the American Board of Obesity Medicine.⁹¹

⁸³ <u>https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/</u> (last visited Feb. 29, 2024).

⁸⁴ Id.

⁸⁵ Id.

⁸⁶ Id.

⁸⁷ <u>https://www.abom.org/</u> (last visited on March 1, 2024).

⁸⁸ <u>https://www.obesityaction.org/corporate-partners/</u> (last visited March 1, 2024).

⁸⁹ <u>https://www.obesityaction.org/novo-nordisk-renews-support-for-oac-chairmans-council-at-platinum-level/</u> (last visited March 4, 2024).

⁹⁰ <u>https://asmbs.org/corporate-council</u> (last visited March 1, 2024).

⁹¹ <u>https://stop.publichealth.gwu.edu/membership</u> (last visited March 1, 2024).

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110. 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.

111. This includes the Obesity Care Advocacy Network, which lobbies for legislation to expand access to Novo Nordisk's drugs.⁹²

112. 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 contribute to Wegovy treatments, a \$1,300-per-month-per-person proposition."⁹³

113. Novo Nordisk partnered with Milken Institute, a think tank with a stated mission of "accelerating measurable progress on the path to a meaningful life.⁹⁴ As early as 2019, before Ozempic or Wegovy was approved for weight loss, Defendants published articles on the Milken Institute website about the "untold story of obesity."⁹⁵

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

115. Novo Nordisk's drugs were the subject of an investigative report on "60 Minutes" that aired New Year's Day of 2023.⁹⁶

116. In response to the 60 Minutes segment, Physicians Committee for Responsible Medicine, a Washington, D.C.-based nonprofit public health advocacy group, issued a formal

⁹²https://assets.obesitycareadvocacynetwork.com/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_2224

⁹³https://www.fiercepharma.com/marketing/health-group-lambasts-novo-nordisk-60-minutes-paid-news-programweight-loss-med-wegovy (last visited March 1, 2024).

⁹⁴ <u>https://milkeninstitute.org/about</u> (last visited on March 1, 2024).

⁹⁵ <u>https://milkeninstitute.org/article/untold-story-obesity-collaborating-across-sectors-make-care-happen</u> (last visited March 1, 2024).

⁹⁶ <u>https://www.cbsnews.com/news/wegozy-ozempic-explainer-60-minutes-2023-01-01/</u> (last visited March 1, 2024).

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complaint with federal regulatory bodies that the broadcast violated the FDA's "fair balance" requirements for advertisements. The Physicians Committee argues that the segment was not news, but rather was effectively a pharmaceutical advertisement, excluding other points of review, other approaches to obesity, and used consultants paid by Novo Nordisk.^{97, 98, 99}

117. Doctor Cody Stanford appeared on the 60 minutes segment.^{100,101}



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

119. Novo Nordisk spent millions of dollars delivering their message to physicians, healthcare providers, and consumers. According to Open Payments Data, in 2022, Novo Nordisk spent over \$33,000,000 on traditional marketing.¹⁰³

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

⁹⁷ https://pcrm.widen.net/s/8gzbksl6cs/1.23-fda-complaint (last visited March 4, 2024).

⁹⁸https://www.fiercepharma.com/marketing/health-group-lambasts-novo-nordisk-60-minutes-paid-news-programweight-loss-med-wegovy (last visited March 1, 2024).

⁹⁹ <u>https://fair.org/home/60-minutes-weight-loss-tip-dont-bite-the-hand-that-feeds-you/</u> (last visited March 1, 2024).

¹⁰⁰ <u>https://mronline.org/2023/02/13/60-minutes-weight-loss-tip/</u> (last visited March 1, 2024).

¹⁰¹ <u>https://www.linkedin.com/in/askdrfatima/</u> (last visited March 5, 2024).

¹⁰² <u>https://www.pcrm.org/news/news-releases/fda-confirms-investigation-novo-nordisk-ad-posited-60-minutes-story-about-weight</u> (last visited March 1, 2024)

¹⁰³ <u>https://openpaymentsdata.cms.gov/company/10000000144</u> (last visited March 1, 2024)

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121. In 2019, Novo Nordisk announced its collaboration with telehealth provider Noom, a leading behavior weight loss company, whose aim is to improve lives of people living with obesity.¹⁰⁴

122. 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 round of financing with Noom.¹⁰⁶ On May 25, 2021, 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 focused on behavior change...".¹⁰⁷

124. Novo Holdings currently lists on its website that it has "venture investments" in Noom.¹⁰⁸ Noom currently has over 45 million users.¹⁰⁹

125. Noom Med, a healthcare program through Noom, advertises "breakthrough medications, like GLP-1s, have revolutionized obesity care," and provides, using physicians hired by Noom, prescriptions for weight loss directly to patients.¹¹⁰

126. Noom Med's website disclaimer includes that medications may be prescribed off label. Noom Med's website includes that, *inter alia*, Wegovy can be prescribed with Noom Med.¹¹¹

¹⁰⁴<u>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 March 1, 2024).
 ¹⁰⁵<u>https://www.noom.com/blog/in-the-news/noom-announces-two-new-studies-on-impact-of-mobile-coaching-on-binge-eating-disorder-and-obesity/</u> (last visited March 1, 2024).
</u>

¹⁰⁶https://www.businesswire.com/news/home/20210525005492/en/Noom-Announces-540-Million-in-Growth-Funding-to-Further-Accelerate-Expansion-of-its-Digital-Health-Platform (last visited March 1, 2024)

¹⁰⁷ https://twitter.com/novoholdings/status/1397170264702599171 (last visited March 1, 2024)

¹⁰⁸ <u>https://novoholdings.dk/investments/noom/</u> (last visited March 1, 2024)

¹⁰⁹ <u>https://exitsandoutcomes.com/free-excerpt-from-the-noom-report-a-45-million-moat/</u> (last visited March 1, 2024).

¹¹⁰ <u>https://www.noom.com/med/</u> (last visited March 1, 2024).

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127. In 2023, Weight Watchers purchased telehealth startup Sequence for \$132,000,000 in order to provide weight loss medications, including Ozempic, to its subscribers.^{112, 113} Reuters stated that "[s]ince then, clinical subscribers at [Weight Watchers] have jumped 23%. . . Latching on to the Ozempic hype has helped boost shares by 60%."¹¹⁴

128. There are currently over 3.5 million Weight Watchers subscribers.¹¹⁵

129. Telehealth provider Calibrate prominently states on its website "Kickstart results with GLP-1 Medication."¹¹⁶

Calibrates' clinical advisory board includes obesity specialist Dr. Fatima Cody
 Stanford.¹¹⁷

The financial and professional conflict of interest between Novo Nordisk, Dr. Cody
 Stanford and Calibrate is not disclosed on Calibrates' website.

132. Upon information and belief, Doctor Cody Stanford was featured on Novo Nordisk's website, where she claimed that access to weight loss drugs is an issue of equity and disparity for communities of color.

133. A financial relationship between Dr. Stanford is not disclosed on Defendants' website.

¹¹²<u>https://www.usatoday.com/story/news/health/2023/03/07/weightwatchers-sequence-wegovy-obesity-weight-loss-drugs/11415201002/</u> (last visited March 1, 2024).

¹¹³https://abcnews.go.com/GMA/Wellness/noom-joins-weight-watchers-offering-medications-wegovyweight/story?id=99841160 (last visited on March 1, 2024).

¹¹⁴ <u>https://www.reuters.com/breakingviews/oprahs-weight-watchers-is-ozempic-as-a-platform-2023-12-15/</u> (last visited March 4, 2024).

¹¹⁵<u>https://finance.yahoo.com/news/ww-international-inc-announces-first-</u>200100340.html#:~:text=%E2%80%9CWe%20expect%20to%20end%202023,including%203.5%20million%20We

ightWatchers%20subscribers. (last visited March 1, 2024). ¹¹⁶https://www.joincalibrate.com/medication (last visited March 4, 2024).

¹¹⁷ https://www.joincalibrate.com/about-us (list visited March 4, 2024).

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134. Dr. Stanford has not disclosed her relationship Defendants in other seemingly independent publications arguing that obesity is a chronic disease that necessitates weight loss medications.¹¹⁸

135. 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 2022.¹¹⁹

136. STAT news stated that "promotions risk exploiting a regulatory gray area of directto-consumer drug advertising, for which there as are long-standing boundaries for drugmakers but less clarity for telehealth companies that are cropped up to prescribe their medicines."¹²⁰

137. Novo Nordisk Defendants have spent millions of dollars advertising on social media platforms, working with celebrity partnerships and telehealth providers, and lobbying governmental bodies to promote the safety, efficacy and, thus, the sale of Ozempic and Wegovy.

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

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

139. During only one week of July 2021, U.S. doctors wrote 94,000 Wegovy prescriptions 62,000 Ozempic prescriptions.¹²¹

ozempic/?utm_campaign=morning_rounds&utm_medium=email&_hsmi=253265291&_hsenc=p2ANqtz-6H01FfkCg2JOnqJnju52tvRJJrTnn-KTwSkzAv1qkbBHi4MR2mN8wdPsbzj6Csbzm5s5M56muD-1rjaA-

¹¹⁸<u>https://www.statnews.com/2022/01/06/recognizing-obesity-as-a-disease-is-a-step-toward-health-equity/</u> (last visited on March 1, 2024).

¹¹⁹ <u>https://www.statnews.com/2023/08/10/wegovy-ozempic-weight-loss-telehealth-prescriptions/</u> (last visited March 1, 2024)

¹²⁰https://www.statnews.com/2023/04/06/weight-loss-drugs-wegovy-ro-telehealth-

IF60zzjN1A&utm_content=253265291&utm_source=hs_email (last visited March 1, 2024).

¹²¹ <u>https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html</u> (last visited March 1, 2024).

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140. 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.¹²²

141. From September 2023 to December 2023, U.S. health care providers wrote over 9 million prescriptions for Ozempic, Wegovy and other obesity drugs. 65 percent of these prescriptions were for Ozempic, and it was primarily prescribed off label for weight loss.¹²³

142. 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.¹²⁴

143. Novo Nordisk has seen major increases in sales.

144. 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.¹²⁵

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

146. 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.¹²⁷

¹²² <u>https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/</u> (last visited on Sept. 18, 2023).

¹²³ <u>https://www.cnbc.com/2023/09/27/ozempic-wegovy-drug-prescriptions-hit-9-million.html</u> (last visited March 5, 2024).

¹²⁴ *Id.* at 122.

¹²⁵<u>https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin</u> (last accessed Sept. 18, 2023).

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

¹²⁷<u>https://www.cnbc.com/2023/09/09/big-pharma-blockbuster-obesity-drug-battle-is-headed-for-100-billion.html#:~:text=Novo%20traded%20earnings%20jabs%20with,to%20more%20than%20%243.7%20billion.</u> (last visited March 1, 2024).

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147. 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.¹²⁸

148. Novo Nordisk's spokeswoman Ambre James-Brown reported that Wegovy hit such a high demand that the company was not able to make enough.¹²⁹

149. There is now a shortage for the drugs, including those for people who have diagnosed Type 2 diabetes.¹³⁰

150. Ozempic and Wegovy have become so popular, Novo Nordisk has recently limited shipment to the US and paused advertising to address shortages.¹³¹

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

151. Defendants incorrectly rely on body mass index (BMI) to market Ozempic and Wegovy as health promoting drugs.

152. On June 14, 2023, the American Medical Association (AMA) adopted a new policy

clarifying how BMI should be used as a measure in medicine, urging doctors to deemphasize their

use of BMI in determining a patient's healthy weight.¹³²

153. The AMA suggests that due to BMI's significant clinical limitations, it be used in

conjunction with other valid measures of risk such as, but not limited to, measurements of visceral

wegovy.html?action=click&pgtype=Article&state=default&module=styln-weight-loss-

¹²⁸https://www.nytimes.com/2023/08/28/business/denmark-ozempic-

<u>drugs&variant=show®ion=MAIN_CONTENT_1&block=storyline_top_links_recirc</u> (last visited March 5, 2024). ¹²⁹ <u>https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html</u> (last visited March 5, 2024).

¹³⁰ <u>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</u> (last visited March 5, 2024)

¹³¹<u>https://www.theatlantic.com/health/archive/2023/05/ozempic-teen-obesity-treatment-health-promises-risks/674204/</u> (last visited March 4, 2024).

¹³²https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measuremedicine (last visited Sept. 18, 2023).

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fat, body adiposity index, body composition, relative fat mass, waist circumference and genetic/metabolic factors.¹³³

154. A recent study examined BMI in relation to blood pressure, cholesterol levels, and insulin resistance. Nearly a third of people with a "normal" BMI had unhealthy metabolic metrics, and nearly half of those who were "overweight" were metabolically healthy. About a quarter of those who were classified as "obese" were also metabolically healthy.¹³⁴

155. BMI is a poor indicator of health outcomes for an individual.¹³⁵

156. Some clinicians offer a different approach, adopting a "weight-skeptical approach" to patient-centered care, where BMI is not the sole indicator of health.¹³⁶

157. Other clinicians have cautioned that "a lower body weight does not always mean a person is healthier."¹³⁷

158. Weight loss achieved by Ozempic and Wegovy is not always due to loss of fat, but rather due to loss of lean mass. An NBC news article states, "lean mass loss is generally from muscle . . . lean mass is healthier and associated with better metabolism, so when we lose lean mass, we may lose some of that function."¹³⁸

159. 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

¹³³ *Id*.

¹³⁴ https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fatand-being-thin (last visited March 1, 2024).

¹³⁵ Body Mass Index - PMC (nih.gov) (last visited March 11, 2024).

¹³⁶ <u>https://link.springer.com/content/pdf/10.1007/s11606-022-07821-w.pdf?pdf=button</u> (last visited March 1, 2024).

¹³⁷ <u>https://www.healthline.com/health-news/ozempic-muscle-mass-loss</u> (last visited March 1, 2024).

¹³⁸ <u>https://www.nbcnews.com/health/health-news/weight-loss-drugs-muscle-loss-rcna84936</u> (last visited March 1, 2024).

¹³⁹ <u>https://www.healthline.com/health-news/ozempic-muscle-mass-loss</u> (last visited March 1, 2024).

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160. 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

161. 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 However, individuals immediately begin to gain the weight back when they stop taking Ozempic and Wegovy.¹⁴²

162. Studies show that weight rebounds once individuals stop taking Ozempic and Wegovy and that weight gain is predominantly fat rather than muscle.

163. 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

164. 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.

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

¹⁴⁰ <u>https://www.nytimes.com/2023/04/21/well/eat/ozempic-side-effects-malnutrition.html</u> (last visited March 1, 2024).

¹⁴¹ National Institute for Health and Care Excellence. (2023). Semaglutide for managing overweight and obesity. *NICE*. Retrieved from: <u>https://www.nice.org.uk/guidance/ta875/chapter/1-Recommendations</u> (last visited March 1, 2024).

¹⁴² <u>https://www.psychologytoday.com/ie/blog/the-neuroscience-of-eating-disorders/202303/ozempic-and-wegovy-is-semaglutide-a-miracle-weight</u> (last visited March 1, 2024).

¹⁴³ <u>https://www.afr.com/policy/health-and-education/lighter-but-fatter-the-ozempic-paradox-20230718-p5dp5w</u> (last visited March 1, 2024).

¹⁴⁴ Id.

 ¹⁴⁵ John, P.H., Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension.
 24:8 *Diabetes Obesity and Metabolism. (Aug. 2022).* Accessed here: <u>https://dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.14725</u> (last visited March 1, 2024).

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

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

168. 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. The label and marketing material does not warn that once an individual stops taking the drug, they may gain even more weight back than they lost and ultimately weigh more than before they started taking the drug.

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

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

171. 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

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

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

¹⁴⁶ <u>https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html</u> (last visited March 1, 2024).

https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-theystop-medication.html (last visited March 1, 2024).

¹⁴⁸ <u>https://www.joincalibrate.com/resources/how-long-does-it-take-to-lose-weight-on-ozempic</u> (last visited March 5, 2024).

¹⁴⁹https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-theystop-medication.html (last visited March 5, 2024).

¹⁵⁰ <u>https://www.psychologytoday.com/ie/blog/the-neuroscience-of-eating-disorders/202303/ozempic-and-wegovy-is-semaglutide-a-miracle-weight</u> (last visited March 5, 2024).

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173. 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.

174. Some doctors estimate that at least 10% of patients discontinue use of these drugs due to the severity of side effects.¹⁵¹ Some patients reported malnutrition and severe GI-related issues, including gastroparesis.¹⁵²

175. 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 a posted alert that both Ozempic and Wegovy had potential safety signals for intestinal blockage.¹⁵³

176. As early as 2014, Defendants knew that Saxenda (liraglutide), Ozempic's predecessor, caused serious side effects and warned the end user of same.¹⁵⁴

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

178. 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.¹⁵⁵

179. 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.¹⁵⁶ These reports

¹⁵¹ <u>https://www.cbsnews.com/news/ozempic-side-effects-weight-loss-drugs-wegovy-mounjaro-doctors-warn/</u> (last visited March 5, 2024)

¹⁵² Id.

¹⁵³<u>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 March 5, 2024)</u>

https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206321orig1s000lbl.pdf (last visited March 5, 2024).
 https://www.novo-pi.com/rybelsus.pdf (last visited March 5, 2024).

¹⁵⁶ <u>https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis</u> (last access Sept. 18, 2023).

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to the FDA also stated that many of these patients reporting intestinal obstruction or blockage were hospitalized.¹⁵⁷

180. 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."¹⁵⁸ These statements do not disclose 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.

181. 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."¹⁵⁹ 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.

182. 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.

¹⁵⁷ Id.

¹⁵⁸<u>https://www.novo-pi.com/ozempic.pdf</u> (last visited on Sept. 18, 2023).

¹⁵⁹ <u>https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215256s000lbl.pdf</u> (last visited on Sept. 18, 2023).

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183. 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.¹⁶⁰

184. 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.¹⁶¹ Its symptoms include vomiting, nausea, diarrhea, stomach cramps, muscle aches, headaches, and fever.¹⁶² Notably, vomiting and diarrhea can cause dehydration, which is the main complication of gastroenteritis, and which can lead to death.¹⁶³

185. 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.

¹⁶⁰ <u>https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787</u> (last visited March 26, 2024).

¹⁶¹ <u>https://www.merckmanuals.com/home/digestive-disorders/gastroenteritis/drug-related-gastroenteritis-and-chemical-related-gastroenteritis</u> (last visited March 26, 2024).

 ¹⁶²<u>https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847</u> (last visited March 26, 2024)
 ¹⁶³ Id.

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186. 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.

187. 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...".¹⁶⁴ It is explicitly noted that GLP-1s slow down gastric emptying.¹⁶⁵

188. A similar article, published 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.¹⁶⁶

189. 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."¹⁶⁷

190. 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

¹⁶⁴ 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 March 26, 2024).

 $^{^{165}}$ *Id*.

¹⁶⁶ Luttikhold J, de Ruijter FM, van Norren K, Diamant M, Witkamp RF, van Leeuwen PA, Vermeulen MA. Review article: the role of gastrointestinal hormones in the treatment of delayed gastric emptying in critically ill patients. <u>https://onlinelibrary.wiley.com/doi/10.1111/apt.12421</u>. (last visited March 26, 2024).

¹⁶⁷ 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 March 26, 2024).

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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."¹⁶⁸

191. In 2021, a case report was published regarding a 52-year-old female who began 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."¹⁶⁹

192. Another case report 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.¹⁷⁰

193. In 2022, a large population-based study indicated that the use of GLP-1 RAs was associated with an increased risk of intestinal obstruction.¹⁷¹

194. 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."¹⁷²

¹⁶⁸ Young CF, Moussa M, Shubrook JH, *Diabetic Gastroparesis: A Review*, Diabetes Spectr. 2020 Aug; 33(3): 290–297, available at <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/</u> (last visited March 26, 2024).

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

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (last visited March 26, 2024). ¹⁷⁰ Id.

¹⁷¹ 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. <u>https://doi.org/10.1002/cpt.2430</u> (last visited March 26, 2024).

¹⁷² <u>https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-</u> diabetes-and-weight-loss-should-stop-before-elective-surgery (last visited March 26, 2024).

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195. 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[.]"¹⁷³

196. Case reports continue to be published regarding the use of semaglutide and intraoperative pulmonary aspirations.¹⁷⁴

197. 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.

198. 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.

199. 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.

¹⁷³ <u>https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-Ozempic-gastroparesis/index.html</u> (last visited March 26, 2024).

¹⁷⁴ <u>https://pubmed.ncbi.nlm.nih.gov/36977934/</u> (last visited March 26, 2024)

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200. 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.

201. 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.

202. 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.

F. The Dark Side of Ozempic and Wegovy

203. 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.¹⁷⁵

¹⁷⁵ <u>https://www.vox.com/science/23683383/ozempic-pregnancy-risks-side-effect-semaglutide-wegovy(last visited March 24, 2024).</u>

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204. 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."¹⁷⁶

205. Strikingly, Novo Nordisk's own hired spokesperson and consultant has stated on national television that "[d]octors do not understand obesity."¹⁷⁷

206. 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.

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

208. This includes the fact that female sex is an independent risk factor associated with an increased risk of adverse effects when taking GLP-1s.¹⁷⁸

209. Neither the Ozempic and Wegovy label warns that being female increases the risk of suffering adverse effects when taking these drugs.

210. Recently, news articles have begun to publicize the dark side of these drugs.¹⁷⁹

211. Consumers of Ozempic and Wegovy are reporting major health problems, including gastroparesis, stomach paralysis, gastroenteritis, and intestinal blockage or obstruction.¹⁸⁰

¹⁷⁷ <u>https://www.cbsnews.com/news/weight-loss-obesity-drug-2023-01-01/</u> (last visited March 26, 2024).
 ¹⁷⁸ <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8950819/</u> ("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).

¹⁷⁶ Id.

 ¹⁷⁹ <u>https://www.cnn.com/2023/06/07/opinions/ozempic-weight-loss-drug-diet-culture-wellness-carr-goldynia-sole-smith/index.html</u> (last visited March 26, 2024).
 ¹⁸⁰ <u>https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349-</u>

¹⁸⁰ <u>https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349e5c41ed49f99/state/analysis</u> (last visited Sept. 18, 2023).

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212. Consumers are not aware that taking Ozempic or Wegovy can lead to severe malnutrition.¹⁸¹

213. Consumers are not aware that taking Ozempic and Wegovy can lead to severe muscle loss.¹⁸²

214. Muscle loss (sarcopenia) can lead to death.¹⁸³

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

216. 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.

217. Other industry experts, including physicians, believe that there needs to be greater awareness of the risks of Ozempic and Wegovy.¹⁸⁴

218. Yet Defendants have continued selling Ozempic and Wegovy to a point where there are mass shortages and waitlists.¹⁸⁵

219. 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.¹⁸⁶

¹⁸⁵https://www.nytimes.com/2023/08/28/business/denmark-ozempic-

wegovy.html?action=click&pgtype=Article&state=default&module=styln-weight-loss-

¹⁸¹ <u>An Extreme Risk of Taking Ozempic: Malnutrition – The New York Times (nytimes.com)</u> (last visited March 26, 2024).

 ¹⁸² <u>https://www.healthline.com/health-news/ozempic-muscle-mass-loss</u> (last visited March 26, 2024)
 ¹⁸³ <u>https://my.clevelandclinic.org/health/diseases/23167-</u>

sarcopenia#:~:text=Sarcopenia%20affects%20your%20musculoskeletal%20system,risk%20of%20complications%2 0including%20death (last visited March 26, 2024).

¹⁸⁴ <u>https://www.vox.com/science/23683383/ozempic-pregnancy-risks-side-effect-semaglutide-wegovy</u> (last visited March 26, 2024).

<u>drugs&variant=show®ion=MAIN_CONTENT_1&block=storyline_top_links_recirc_(last visited March 26, 2024).</u>

¹⁸⁶<u>https://www.investors.com/news/technology/novo-nordisk-stock-skids-as-report-finds-objectionable-conditions-at-wegovy-</u>

plant/#:~:text=Novo%20Nordisk%20(NVO)%20stock%20skidded,diabetes%20and%20weight%2Dloss%20drugs (last visited March 26, 2024).

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220. 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.¹⁸⁷ 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."¹⁸⁸

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

G. Plaintiff Specific Allegations

222. Plaintiff, Jenny Bryant, was born on November 6, 1975, and is 48 years old.

223. On or around April 2023, Dr. Sadia Hussain, Ms. Bryant's primary care provider, practicing at Optum Medical Care in Ulster County, prescribed Ms. Bryant once weekly injections of .25mg Wegovy to promote weight loss.

224. Ms. Bryant's dose increased according to the recommended dosing schedule, starting with a .25mg dose and increasing to a 2.4mg dose.

225. Ms. Bryant's Wegovy dose was then decreased to 1.7mg due to Ms. Bryant's symptoms.

226. For a few days after each injection, Ms. Bryant had been vomiting, feeling bloated, and had upper abdomen pain.

227. Dr. Hussain prescribed Ms. Bryant various nausea medications, including Zofran and Reglan to help with the vomiting.

¹⁸⁷<u>https://bioprocessintl.com/bioprocess-insider/regulations/fda-483-shows-7-observations-at-catalent-fill-finish-plant-in-belgium/</u> (last visited March 26, 2024); <u>https://www.fiercepharma.com/manufacturing/inside-catalent-fda-citation-allegedly-at-heart-novo-nordisk-s-wegovy-supply-hiccup</u> (last visited March 26, 2024).
¹⁸⁸ Id.

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228. In August 2023, Ms. Bryant stopped taking Wegovy. Ms. Bryant's symptoms continued.

229. In December 2023, Ms. Bryant saw Dr. Elizabeth Williams, a gastroenterologist, practicing at Premiere Medical Group in Poughkeepsie, NY, who ordered an endoscopy.

230. During the endoscopy, Ms. Bryant had a food bolus and the endoscopy had to be discontinued.

231. Because of Ms. Bryant's symptoms, including the food bolus, Dr. William's ordered a stomach emptying test.

232. In January 2024, Ms. Bryant underwent a stomach emptying test at Northern Dutchess Hospital in Rhinebeck, NY, which revealed her severe gastroparesis diagnosis.

233. Ms. Bryant continues to suffer from gastroparesis, vomiting, bloating and upper abdomen pain.

CAUSES OF ACTION

COUNT I: NEGLIGENCE (ALL DEFENDANTS)

234. Plaintiff re-alleges and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth therein.

235. At all times relevant to this action, including prior to when Plaintiff's physician prescribed Plaintiff Ozempic and throughout the period of time that Plaintiff used Ozempic, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, advertised, marketed, overpromoted, distributed and/or sold Ozempic to physicians and/or consumers, such as Plaintiff, in the State of New York and in the United States.

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236. At all times relevant to this action, including prior to when Plaintiff's physician prescribed Plaintiff Ozempic and throughout the period of time that Plaintiff used Ozempic, Defendants had a duty to exercise reasonable care in the in testing, studying, researching, designing, formulating, manufacturing, inspecting, labeling, packaging, promoting, advertising, marketing, distributing, and selling Ozempic and/or Wegovy to physicians and/or consumers, such as Plaintiff, in the State of New York and in the United States.

237. Defendants' duty to exercise reasonable care includes 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 whether the product is used alone or in foreseeable combination with other drugs.

238. At all times relevant to this action, Defendants knew, or in the exercise of reasonable care, should have known of the hazards and dangers associated with Ozempic and/or Wegovy. Specifically, that the use of Ozempic and/or Wegovy could cause gastroparesis, gastroenteritis, malnutrition, intestinal obstruction, hospitalization, sarcopenia, and death.

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

240. Despite the fact that Defendants knew, or in the exercise of reasonable care, should have known of the dangerous and unreasonable risks of Ozempic and/or Wegovy use, Defendants continue to manufacture and market the product to the medical community and the public.

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

- 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, 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.
- (k) 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;
- Failing to ensure that Ozempic and Wegovy were accompanied by proper and accurate warnings about the risk of severe gastrointestinal problems including gastroparesis.
- (m) 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
- (n) Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Ozempic and Wegovy.

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

243. As a direct and proximate result of Defendants' negligent testing, monitoring, and pharmacovigilance of Ozempic and Wegovy, Defendants introduced a drug into the State of New York 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.

244. 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

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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.

245. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to New York law.

246. 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.

COUNT II: NEGLIGENCE - FAILURE TO WARN (ALL DEFENDANTS)

247. Plaintiff re-alleges and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth therein.

248. Defendants are liable to Plaintiff for the injuries and damages sustained due to Defendants' failure to warn Plaintiff and consumers like Plaintiff of the true and dangerous risk of Wegovy and/or Ozempic.

249. At all times relevant to this action, including prior to when Plaintiff's physician prescribed Plaintiff Ozempic and throughout the period of time that Plaintiff used Ozempic, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, advertised, marketed, overpromoted, distributed and/or sold Ozempic to physicians and/or consumers, such as Plaintiff, in the State of New York and in the United States.

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250. 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.

251. Defendants advertised and promoted Ozempic and/or Wegovy for the purpose of weight loss and diabetes control.

252. At all times relevant, including at the time Defendants distributed, supplied, or sold their respective products, 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, and not known to ordinary physicians who would be expected to prescribe the drug to their patients.

253. 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.

254. The labels for Wegovy and/or Ozempic are inadequate because they did not warn and/or adequately warn of all possible adverse side effects associated with the use of Wegovy and/or Ozempic, 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.

255. The labels for Wegovy and/or Ozempic 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 Wegovy and/or Ozempic.

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256. The labels for Wegovy and/or Ozempic are inadequate because they did not warn and/or adequately warn that Wegovy and/or Ozempic had not been sufficiently and/or adequately tested for safety risks, including severe gastrointestinal events (e.g., gastroparesis, gastroenteritis, intestinal blockage, and malnutrition).

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

258. The labels for Wegovy and/or Ozempic 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.

259. 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 Wegovy and/or Ozempic, including the increased risk of severe gastrointestinal events (e.g., gastroparesis, gastroenteritis, intestinal blockage, and malnutrition).

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

261. 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' treating physicians that Wegovy and/or Ozempic 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' treating physicians the risks of gastrointestinal injurie, 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.

262. Defendants expected Ozempic and/or Wegovy to reach, and it 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.

263. At all times relevant, Ozempic and/or Wegovy was used by Plaintiff in a manner intended and/or foreseeable to Defendants.

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

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

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

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

268. 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.

269. Defendants is liable in tort to Plaintiff for its wrongful conduct pursuant to New York law.

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

COUNT III: NEGLIGENCE - DESIGN DEFECT (ALL DEFENDANTS)

271. Plaintiff re-alleges and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth therein.

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

273. 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 Wegovy and/or Ozempic. Defendants' duties included, but were not limited

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to, carefully and properly designing, testing, studying, and manufacturing Wegovy and/or Ozempic.

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

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

275. Furthermore, Wegovy and/or Ozempic 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.

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

277. Wegovy and/or Ozempic 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.

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278. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of Wegovy and/or Ozempic 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.

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

280. 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.

COUNT IV: NEGLIGENT MISREPRESENTATION AND MARKETING (ALL DEFENDANTS)

281. Plaintiff re-alleges and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth therein.

282. 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 Wegovy and/or Ozempic, including, but not limited to, misrepresentations and marketing regarding the safety, known risks, and long term effects of Wegovy and/or Ozempic.

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

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284. 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 Wegovy and/or Ozempic and induce the public and medical community, including Plaintiff and Plaintiff's healthcare providers to request, recommend, purchase, and prescribe Wegovy and/or Ozempic.

285. 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 Wegovy and/or Ozempic, including its propensity to cause gastroparesis, gastroenteritis, intestinal blockage/obstruction, and malnutrition, as well as that fact weight lost will be regained upon cessation of the drug.

286. Defendants made continued omissions in the Wegovy and/or Ozempic labeling, including promoting it as safe and effective while failing to warn of its propensity to cause gastroparesis, gastroenteritis, intestinal blockage/obstruction, and malnutrition.

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

288. Defendants misrepresented and overstated the benefits of Wegovy and/or Ozempic to Plaintiff, Plaintiff's treaters, and the medical community without properly advising of the known risks to patients.

289. Defendants made the misrepresentations alleged herein with the intent to induce consumers, like Plaintiff, to take Ozempic and/or Wegovy, and to induce health care providers to prescribe Ozempic and/or Wegovy.

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290. In reliance upon the false, deceptive and negligent misrepresentations and omissions and marketing made by Defendants, Plaintiff and Plaintiff's healthcare providers were induced to, and did use and prescribe Ozempic and/or Wegovy.

291. In reliance upon the affirmative misrepresentations and/or negligent omissions made by Defendants, Plaintiff and Plaintiff's healthcare providers were induced to, and did use and prescribe Ozempic and/or Wegovy.

292. 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.

293. 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.

294. 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.

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

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

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

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298. Defendants failed to exercise ordinary care in making representations concerning Wegovy and/or Ozempic 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 Wegovy and/or Ozempic's high risk of unreasonable and dangerous adverse side effects. 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 Wegovy and/or Ozempic. Plaintiff and Plaintiff's healthcare providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff' injuries.

COUNT V: CONSUMER FRAUD – VIOLATION OF GBL §§ 349 AND 350 (ALL DEFENDNATS)

299. Plaintiff re-alleges and incorporate by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

300. The Defendants acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including the Plaintiff herein and his physicians and medical providers, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of Ozempic and/or Wegovy, in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to prescribe the Ozempic and/or Wegovy for obesity and diabetes treatment, to patients/consumers such as the Plaintiff herein.

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301. By reason of the Defendants' unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff herein, were caused to suffer ascertainable loss of money and property and actual damages.

302. The Defendants engaged in consumer-oriented, commercial conduct by selling and advertising Ozempic and/or Wegovy.

303. The Defendants misrepresented and omitted material information regarding Ozempic and Wegovy by failing to disclose known risks.

304. The Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of Ozempic and/or Wegovy, in violation of New York General Business Law ("GBL") §§349 and 350.

305. The Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including the Plaintiff herein.

306. As a direct and proximate result of the Defendants' violations of GBL §§349 and 350, the Plaintiff has suffered damages, for which they are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

307. As a direct and proximate result of Defendants' conduct, the Plaintiff used Defendants' Ozempic and/or Wegovy and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

V. 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.

VI. <u>DEMAND FOR A JURY TRIAL</u>

Plaintiff hereby demands a trial by jury as to all claims in this action.

Dated: April 22, 2024

MAINETTI & MAINETTI, P.C.

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