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

IN RE GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	MDL NO. 3094 THIS DOCUMENT RELATES TO ALL CASES JUDGE KAREN SPENCER MARSTON
MEGAN ROCHA Plaintiff, v. NOVO NORDISK INC. and NOVO NORDISK A/S Defendants.	COMPLAINT AND JURY DEMAND CIVIL ACTION NO.: 2:25-cv-00240

COMPLAINT AND DEMAND FOR JURY TRIAL

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

__X__ Plaintiff currently resides in Landenberg, PA

__X__ Plaintiff purchased and used Defendant(s)' products in Pennsylvania

_____The Original Venue is a judicial district in which Defendant Novo Nordisk, Inc. and/or Novo Nordisk A/S resides, and all Defendants are residents of the State in which the district is located (28 USC § 1391(b)(1)).

__X__ The Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, specifically (28 USC § 1391(b)(2)):

Defendants routinely market their products at issue and conduct business related to their products at issue in the Eastern District of Pennsylvania.

____There is no district in which an action may otherwise be brought under 28 USC § 1391, and the Original Venue is a judicial district in which Defendant is subject to the Court's personal jurisdiction with respect to this action (28 USC § 1931(b)(3)).

Plaintiff, MEGAN ROCHA, by Plaintiff's attorneys, Nigh Goldenberg Raso & Vaughn, PLLC, upon information and belief, at all times hereinafter mentioned, alleges as follows:

PARTIES

1. Plaintiff, MEGAN ROCHA is a citizen and resident of the State of Pennsylvania.

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

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

4. Collectively, Defendants will be referred to as the "Novo Nordisk Defendants" or "Defendants."

5. Upon information and belief, the Novo Nordisk Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic.

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

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

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §1332(a) as the matter in controversy exceeds the value of $75,000, exclusive of interest and costs and is between citizens of different states and/or a foreign state, as Plaintiff is a citizen of the State of Pennsylvania and each Defendant is neither incorporated nor has its principal place of business in the State of Pennsylvania.

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

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

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

12. Novo Nordisk has retained U.S. private contract manufacturer PCI Pharma Services to handle assembly and packaging of Wegovy, including putting together the self-injection pens to administer Wegovy.[1] The self-injection pens are required for a patient to use the drug and

[1] https://www.reuters.com/business/healthcare-pharmaceuticals/novo-nordisk-hires-private-us-firm-handle-

potentially suffer adverse effects underlying this complaint. PCI Pharma Services is headquartered in Philadelphia, PA.[2]

13. Novo Nordisk routinely recruits employees within Philadelphia related to diabetes care,[3] and recruits sales associates in Pennsylvania.[4] Novo Nordisk maintains employees in Philadelphia related to diabetes care.[5] The Philadelphia Department of Public Health released a report on "Drug Marketing Through Gifts of Meals to Physicians in Philadelphia," which showed Novo Nordisk's Ozempic was #8 in the "Top 20 Drugs Marketed in Philadelphia" in 2018 through February 2020.[6]

14. Novo Nordisk's marketing agency for Wegovy, Accenture Song (formerly Concentric Life), has multiple offices in Pennsylvania including Philadelphia.[7]

15. The marketing agency that leads the Wegovy account is now Accenture Song. Accenture Song has four Pennsylvania offices, including one in Philadelphia. The Wegovy marketing team was awarded the industry Launch award for the year, and specifically thanked "our partners at Novo Nordisk" whose dedication "made it possible."[8]

16. Novo Nordisk funds extensive research at University of Pennsylvania in Philadelphia and Penn Medicine specifically related to diabetes care and weight loss.[9] Moreover,

---

somewegovy-pen-assembly-source-2023-09-18/
[2] https://pci.com/contact/
[3] https://novonordisk.dejobs.org/philadelphia-pa/medical-liaison-liver-healthpa/EF6DC568FC1E45E4B180EE94A52DBB1C/job/
[4] https://novonordisk.dejobs.org/philadelphia-pa/medical-liaison-liver-health-pa/EF6DC568FC1E45E4B180EE94A52DBB1C/job/
[5] https://www.linkedin.com/in/lindsey-hunt-82911b55
[6] https://www.phila.gov/media/20200204150030/2020-drug-marketing-report_2_4_2020.pdf
[7] https://www.pm360online.com/elite-2023-marketing-team-wegovy-obesity-marketing-team-of-novo-nordisk-inc/ ; and see https://newsroom.accenture.com/news/2023/accenture-completes-acquisition-of-healthcare-marketingagency-concentriclife; and https://www.accenture.com/us-en/about/locations/office-details?loc=Pennsylvania
[8] https://www.newswire.com/news/concentric-health-experience-named-agency-of-the-year-at-the-2022-21695158
[9] See, e.g., https://www.nursing.upenn.edu/details/news.php?id=1522; https://www.pennmedicine.org/news/newsreleases/2020/march/newly-discovered-brain-response-to-obesity-drug-may-inform-future-treatments.

University of Pennsylvania Professors have received research funds on behalf of the University of Pennsylvania while also serving on the advisory board of Novo Nordisk on studies directly related to semaglutide and obesity.[10]

17. Novo Nordisk has funded Philadelphia community programs to address obesity and diabetes.[11] This includes Novo Nordisk serving as a "local sponsor" for the Philadelphia Walk from Obesity and Fun Run; targeting Philadelphia as its second city in its "Cities Changing Diabetes" initiative; and hosting a "Tackle Your Health" sweepstakes with the Philadelphia Eagles to educate Eagle fans on the risk factors associated with type 2 diabetes and obesity.[12]

BACKGROUND

I. An Accidental Blockbuster: The Development of Ozempic

18. In the early 1990s, Novo Nordisk researchers discovered that when they injected into rats a chemical compound known as liraglutide—a GLP-1 (glucagon-like peptide-1) agonist—the drug caused the rats to stop eating almost entirely.[13]

19. GLP-1 agonists are a class of medications that can help lower blood sugar levels and promote weight loss.[14] An agonist is a manufactured substance that attaches to a cell receptor and causes the same action as the naturally occurring substance.[15] Thus, GLP-1 agonists work by mimicking a naturally occurring GLP-1 hormone.

---

[10] https://onlinelibrary.wiley.com/doi/full/10.1002/oby.23946; https://www.med.upenn.edu/weight/wadden.html; https://wfpc.sanford.duke.edu/podcast_guest/wadden-thomas/

[11] https://hcifonline.org/tag/population-health/

[12] https://bariatrictimes.com/walk-from-obesity-raising-funds-in-philadelphia-summer-2019/; *see also* https://www.citieschangingdiabetes.com/network/philadelphia.html https://static.clubs.nfl.com/image/upload/v1666020341/eagles/mp3pn3smy1yf2sj3cyrp.pdf

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

[14] https://my.clevelandclinic.org/health/articles/13901-glp-1-agonists (last visited Sept. 17, 2023).

[15] *Id.*

20. To describe the process in other words, GLP-1 medications bind to GLP receptors to trigger the effects (or roles) of the GLP-1 hormone. The higher the dose of the GLP-1 agonist, the more extreme the effects.[16]

21. "These rats, they starved themselves," said one Novo Nordisk scientist, Lotte Bjerre Knudsen, in a video series released by the Novo Nordisk Foundation, "so we kind of knew there was something in some of these peptides that was really important for appetite regulation."[17]

22. Later testing in human subjects revealed that those who received an intravenous drip of GLP-1 agonist ate 12% less at a lunch buffet than those who got a placebo.[18]

23. Consequently, Novo Nordisk decided to study liraglutide as not only a diabetes drug which had been shown to lower blood sugars, but also as a drug to treat obesity.[19]

24. Years later, in 2010, liraglutide was approved for the treatment of diabetes by the FDA under Novo Nordisk's brand name Victoza,[20] at which point Novo Nordisk moved forward with studying the drug for weight loss.[21]

25. After clinical trials, in 2014 the FDA approved liraglutide for treatment of obesity under Novo Nordisk's brand name Saxenda as a daily injectable.[22]

26. Saxenda's effects on weight loss, however, were modest; patients lost about 5% of their weight.[23]

---

[16] *Id*.
[17] https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html (last visited Sept. 17, 2023).
[18] *Id*.
[19] *Id*.
[20] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2957743/#:~:text=The%20incretin%20mimetic%20liraglutide%20(Victoza,adults%20with%20type%2D2%20diabetes.&text=Liraglutide%20is%20also%20approved%20in%20Europe%20and%20Japan (last visited Sept. 18, 2023).
[21] https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html (last visited Sept. 17, 2023).
[22] *Id*.
[23] *Id*.

27. In an effort to find ways to make a longer-lasting a GLP-1 agonist so patients would not have to inject themselves every day, Novo Nordisk created a new molecule with the chemical name semaglutide.[24]

28. Novo Nordisk branded semaglutide as Ozempic, and on December 5, 2016, the Novo Nordisk Defendants announced submission of Ozempic's new drug application (NDA) to the FDA for regulatory approval of once-weekly injectable in 0.5 mg or 1 mg for treatment of Type 2 diabetes. In the announcement, Defendants represented that in clinical trials "once-weekly" Ozempic had a safe and well-tolerated profile, and Defendants represented that the most common adverse event was nausea.[25]

29. On December 5, 2017, the FDA approved the application and granted premarket approval as NDA 209637.[26]

30. In addition to diabetic control, Ozempic also caused 15% weight loss, which was three times the loss caused by its predecessor, Saxenda.[27]

31. Just one year after Ozempic's approval for diabetes, Defendants started a clinical trial in patients who were overweight or suffered from obesity.[28]

32. The results of the trial demonstrated that for participants who were overweight or obese, 2.4 mg of semaglutide once weekly plus lifestyle intervention was associated with sustained, clinically relevant reduction in body weight.[29]

---

[24] *Id*.
[25] https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183 (last visited Sept. 17, 2023).
[26] https://www.accessdata.fda.gov/Ozempicatfda_docs/appletter/2017/209637s000ltr.pdf (last visited Sept. 17, 2023).
[27] https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html (last visited Sept. 17, 2023).
[28] *Id*.
[29] https://www.nejm.org/doi/full/10.1056/NEJMoa2032183 (last visited Sept. 17, 2023).

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

34. By March of 2021, Defendants had completed the clinical trial studying semaglutide for weight loss, and its results were published March 18, 2021.[30]

35. In addition to the results, the published study, which was funded by Defendants, argued: "Obesity is a chronic disease and global public health challenge."[31]

36. On March 20, 2019, Defendant Novo Nordisk Inc. submitted supplemental a new drug application for Ozempic 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.[32] On January 16, 2020, the FDA approved this new indication.[33]

37. Then, on May 28, 2021, Defendant Novo Nordisk Inc. submitted another sNDA requesting approval for a higher 2 mg dose of Ozempic injection. On March 28, 2022, the FDA approved this request.[34]

38. In their press release, Defendants represented Ozempic as having "proven safety and efficacy" and they continued to advertise that "it can help many patients lose some weight."[35] As with its prior press releases, Defendants disclosed Important Safety Information and provided

[30] https://www.nejm.org/doi/full/10.1056/NEJMoa2032183 (last visited Sept. 17, 2023).
[31] *Id*.
[32] https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html (last visited on Sept. 17, 2023).
[33] https://www.accessdata.fda.gov/Ozempicatfda_docs/appletter/2020/209637Orig1s003ltr.pdf (last visited Sept. 17, 2023).
[34] https://www.accessdata.fda.gov/Ozempicatfda_docs/appletter/2022/209637Orig1s009ltr.pdf (last visited Sept. 17, 2023).
[35] https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-higher-dose-ozempic-2-mg-providing-increased-glycemic-control-for-adults-with-type-2-diabetes-301512209.html (last visited Sept. 17, 2023).

link to the Medication Guide and Prescribing Information. However, severe gastrointestinal events, including gastroparesis and gastroenteritis, were not identified as risks.

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

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

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

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

42. Defendants also fail to disclose in their label and patient brochure for Ozempic that in order to maintain any weight loss, the patient must stay on the drug permanently or most patients will regain most of the weight within one year and virtually all the weight will be regained within five years.[36]

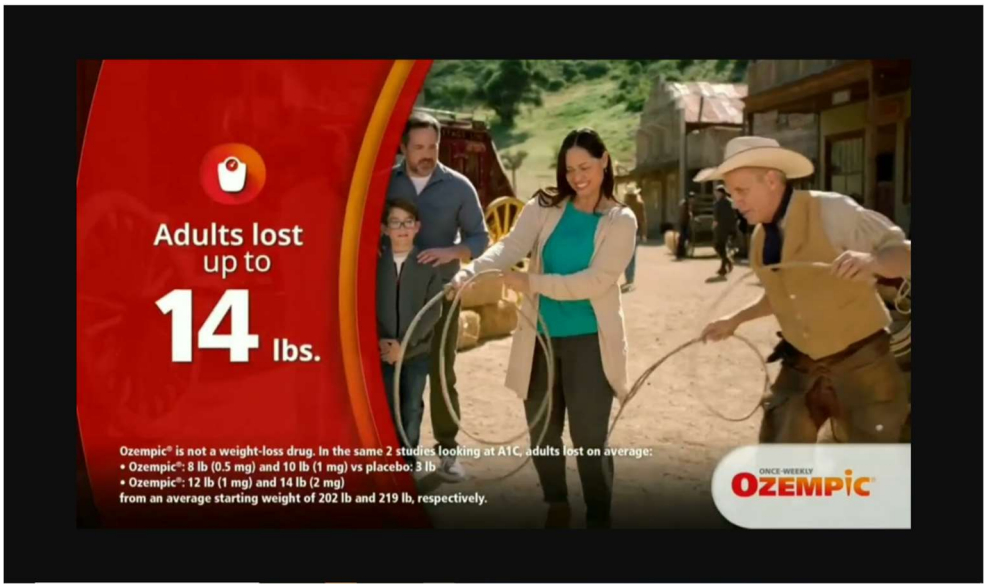
43. When the Novo Nordisk Defendants announced that they had started selling Ozempic in the United States, they touted the medication as a "new treatment option[]" that "addresses the concerns and needs of people with diabetes[.]" The Novo Nordisk Defendants offered an "Instant Savings Card to reduce co-pays to as low as $25 per prescription fill for up to two years."

[36] https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html; https://pubmed.ncbi.nlm.nih.gov/35441470/.

44. Indeed, some patients will regain even more weight after stopping the drug, so that they end up heavier than before starting Ozempic.[37] This is also not disclosed in the label or patient brochure.

45. Novo Nordisk was not permitted to market Ozempic for weight loss without F.D.A. approval for that specific indication,[38] but before Ozempic ever received separate approval for treatment of weight loss, Novo Nordisk had already begun mentioning weight loss in their Ozempic commercials.[39]

46. On July 30, 2018, the Novo Nordisk Defendants launched their first television ad for Ozempic to the tune of the 1970s hit pop song "Magic" by Pilot, wherein the Novo Nordisk Defendants advertised that "adults lost on average up to 14 pounds" when taking Ozempic.[40]



[37] https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html.
[38] https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html (last visited Sept. 18, 2023).
[39] *Id.*
[40] https://www.ispot.tv/ad/d6Xz/ozempic-oh (last visited Sept. 18, 2023).

47. Over the next five years, the Novo Nordisk Defendants spent $884,000,000 on running television ads in the United States to promote its semaglutide Ozempic, Wegovy, and another of its lesser known GLP-1 agonist, Rybelsus, with most advertisements allocated towards Ozempic.[41]

48. By 2021, Defendants' aggressive marketing of the weight loss benefits of Ozempic, sophisticated use of social media, and America's socially ingrained desire to be thin had reached a tipping point.[42]

49. Defendants' aggressive marketing includes a number of different platforms, including over 4,000 marketing advertisements for Ozempic and similar weight-loss medications that have been placed on Facebook and Instagram.[43]

50. According to open payments data, Novo Nordisk spent $33,927,336.42 on marketing/consulting/travel/food and beverage/etc. to physicians in 2022 alone.[44]

51. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,[45] and currently has over 1.2 billion views.[46]

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

53. Novo Nordisk partnered directly with Meta and Instagram to run marketing campaigns. One diabetes marketing campaign achieved a dramatic 28% direct engagement rate with their polls.[47] This was a lauded result presented in a case study by Meta.

---

[41] https://medwatch.com/News/Pharma___Biotech/article15680727.ece (last visited Sept. 18, 2023).
[42] https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html (last visited Sept. 18, 2023).
[43] https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602 (last visited Sept. 18, 2023).
[44] https://openpaymentsdata.cms.gov/company/100000000144 (last visited Sept. 18, 2023).
[45] https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html (last visited Sept. 18, 2023).
[46] https://www.tiktok.com/tag/ozempic (last visited on August 1, 2023).
[47] https://business.instagram.com/success/novo-nordisk (last visited Sept. 17, 2023).

54. 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."[48]

55. Novo Nordisk reportedly spent approximately one hundred million dollars advertising Ozempic last year.[49] 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.[50]

56. In 2023, over $491 million was spent advertising "diabesity" drugs, including Ozempic.[51]

57. Jimmy Kimmel joked about Ozempic at the Oscars.[52]

58. Howard Stern has joked and discussed Ozempic.[53] Interestingly, Stern notes that the "catchy" theme song "distracts" the listener from actually hearing any of the listed side effects.[54]

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

60. Novo Nordisk has partnered directly with other celebrities as paid spokespersons, including Queen Latifah.[56]

---

[48] https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571 (last visited on Sept. 17, 2023).
[49] https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin (last visited Sept. 17, 2023).
[50] https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571?utm_source=exchange&utm_medium=email&utm_campaign=t5687390.
[51] https://www.mmm-online.com/home/channel/spending-on-ozempic-wegovy-surges/.
[52] https://www.usatoday.com/story/life/health-wellness/2023/03/13/ozempic-sweeping-hollywood-celebrities-weight-loss/11428801002/ (last accessed Sept. 17, 2023).
[53] https://www.youtube.com/watch?v=QD-nCQn1Ads (last visited on Sept. 17, 2023).
[54] *Id*.
[55] https://www.insider.com/ozempic-celebrities-denied-semaglutide-wegovy-weight-loss-drugs-khloe-kardashian-2023-3#chelsea-handler-said-she-was-on-semaglutide-without-realizing-it-7 (last visited on Sept. 18, 2023).
[56] https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor (last visited Sept. 17, 2023).

61. As part of overall campaigns to target Black, Brown, and Hispanic consumers with their marketing campaigns and social media partnerships with influencers, in addition to Queen Latifah Novo Nordisk has compensated Yvette Nicole Brown to serve as a paid spokesperson.[57]

62. In 2021, Novo Nordisk even gave between $100,000 and $399,999 to the Congressional Black Caucus Foundation.[58]

63. Novo Nordisk combined with Eli Lilly are spending roughly ten million dollars annually on lobbying.[59]

64. A primary focus of that lobbying is the proposed Treat and Reduce Obesity Act, which has been introduced in congressional sessions annually since 2012. The Treat and Reduce Obesity Act would require Medicare to cover, among other treatments, chronic-weight-management drugs.[60]

65. Defendants and their competitors have promoted the message that "obesity is a disease" and largely due to "genetics" and "not a choice," in addition to promoting the message that coverage of pharmaceutical drugs for obesity is a step toward health equity.[61] What is not promoted is that this message directly impacts Defendants' pocketbooks by encouraging insurance to cover their drugs. Defendants' messaging encourages patients and prescribers to forgo lifestyle changes – long the cornerstone of healthy weight loss – in favor of powerful, dangerous, and

[57] https://www.essence.com/health-and-wellness/yvette-nicole-brown-fighting-obesity/ (last visited on Sept. 18, 2023).
[58] https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor (last visited Sept. 17, 2023).
[59] https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor (last visited Sept. 17, 2023).
[60] https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin (last visited Sept. 17, 2023); https://www.fiercepharma.com/pharma/novo-nordisk-eli-lilly-and-boehringer-get-behind-lawmakers-bill-enable-obesity-drug-coverage (accessed Sept. 17, 2023).
[61] https://www.statnews.com/2022/01/06/recognizing-obesity-as-a-disease-is-a-step-toward-health-equity/ (last visited on Sept. 18, 2023); https://www.womenshealthmag.com/health/a42679413/causes-of-obesity-genetics-lifestyle/ (last visited on Sept. 18, 2023).

expensive drugs.

66. Anticipating the passage of this bill within the next few years, Morgan Stanley forecasts that U.S. revenue from such drugs will increase four-hundredfold by the end of the decade. Obesity looks "set to become the next blockbuster pharma category," it declared in a report last year, which also predicted that social media and word of mouth will create an "exponential virtuous cycle" around the new medications: a quarter of people with obesity will seek treatment from physicians, up from the current seven per cent, and more than half of those who do will begin taking medicine.[62]

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

68. This includes the website "The Truth about Weight."[63]

69. This website includes headings such as "my weight, my culture," with these "my weight, my culture" hashtags appearing on Instagram with an apparent focus to target Black, Brown, and Hispanic individuals.[64]

70. Defendants also own and operate the website "It's Bigger Than Me."[65] This advertising campaign website promotes the message that obesity is a chronic health condition that requires pharmaceutical drugs to manage.[66]

71. The hashtag #itsbiggerthan also reveals paid social media influencers promoting

[62] https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin (last visited on Sept. 18, 2023).
[63] https://www.truthaboutweight.com/ (last visited on Sept. 18, 2023).
[64] https://www.truthaboutweight.com/understanding-excess-weight/my-weight-my-culture.html (last visited on Sept. 18, 2023).
[65] https://www.itsbiggerthan.com (last accessed Sept. 18, 2023).
[66] *Id*.

"body positivity" and linking back to Novo Nordisk's website (and ultimately to their weight loss drugs).

72. Novo Nordisk's presentation on capital markets day makes it clear that these campaigns are designed to "activate more people to seek treatment for obesity."[67]

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

74. This includes the American Board of Obesity Medicine. The former Director of the American Board of Obesity Medicine who served from 2017 to November of 2021 received payments by Novo Nordisk during her time as director of the American Board of Obesity Medicine.[68]

75. This former director of the American Board of Obesity Medicine currently promotes their GLP-1 agonists for weight loss as part of their telehealth company and continues to receive payments.[69]

76. At least one member of the American Board of Obesity Medicine that helped write the guidelines for obesity management has received payments directly from Novo Nordisk according to Open Payments Data during the same time he wrote those guidelines.[70]

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

---

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

[68]https://joinfound.com/pages/medication-biology (last visited on Sept. 18, 2023); https://openpaymentsdata.cms.gov/physician/1294300 (last visited on Sept. 18, 2023); https://www.linkedin.com/in/rekha-kumar-m-d-m-s-70b481237/ (last visited on Sept. 18, 2023).

[69]https://joinfound.com/pages/medication-biology (last visited on Sept. 18, 2023); https://openpaymentsdata.cms.gov/physician/1294300 (last visited on Sept. 18, 2023); https://www.linkedin.com/in/rekha-kumar-m-d-m-s-70b481237/ (last visited on Sept. 18, 2023).

[70]https://openpaymentsdata.cms.gov/physician/1379381 (last visited Sept. 18, 2023); see also https://www.abom.org/karl-nadolsky/.

contributing $10,000 to Dr. Kaplan – a physician who has received over $1 million dollars from Novo Nordisk over the past decade – popular education course on obesity treatment.[71]

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

79. The American Board of Obesity Medicine lists public health "partners" on their website.[72]

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

81. This includes Obesity in Action Coalition, to which Novo Nordisk contributes more than $500,000 annually.[73] Novo Nordisk has been a partner since 2013, before any of its drugs were approved for weight loss.

82. Novo Nordisk also serves on the Corporate Council of American Society for Metabolic and Bariatric Society, another public health partner of the American Board of Obesity Medicine.[74]

83. Novo Nordisk is also a corporate member and directly financially contributes to Stop Obesity Alliance, yet another public health partner of the American Board of Obesity Medicine.[75]

84. 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.

---

[71] https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/.
[72] https://www.abom.org/ (last visited on Sept. 18, 2023).
[73] https://www.obesityaction.org/corporate-partners/ (last accessed Sept. 18, 2023).
[74] https://asmbs.org/corporate-council (last visited Sept. 18, 2023).
[75] https://stop.publichealth.gwu.edu/membership (last visited on Sept. 18, 2023).

85. This includes the Obesity Care Advocacy Network, which lobbies for legislation to expand access to Novo Nordisk's drugs.[76]

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

87. For example, the Milken Institute is a think tank focused on accelerating measurable progress on the path to a meaningful life.[77]

88. As early as 2019, before Ozempic or Wegovy was approved for weight loss, Defendants were publishing articles on the Milken Institute about the "untold story of obesity."[78]

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

90. For example, Novo Nordisk's drugs were the subject of an investigative report on 60 Minutes that aired New Year's Day of 2023.[79]

91. Complaints have been filed alleging that the "news" piece was in reality "deceptive marketing" in which all physicians interviewed had received payments by Novo Nordisk. [80]

92. The financial relationship between the physicians speaking about Ozempic and Novo Nordisk was not explicitly disclosed.[81] The reporter stated that the physicians had *advised* Novo Nordisk, but failed to state they had been compensated by the company.[82]

93. The nonprofit public health advocacy group the Physicians Committee issued a

---

[76] https://assets.obesitycareadvocacynetwork.com/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0.pdf (last visited on Sept. 18, 2023).
[77] https://milkeninstitute.org/about (last visited on Sept. 18, 2023).
[78] https://milkeninstitute.org/article/untold-story-obesity-collaborating-across-sectors-make-care-happen (last visited on Sept. 18, 2023).
[79] https://www.cbsnews.com/news/wegozy-ozempic-explainer-60-minutes-2023-01-01/ (last visited Sept. 18, 2023).
[80] https://www.fiercepharma.com/marketing/health-group-lambasts-novo-nordisk-60-minutes-paid-news-program-weight-loss-med-wegovy (last visited Sept. 18, 2023).
[81] https://fair.org/home/60-minutes-weight-loss-tip-dont-bite-the-hand-that-feeds-you/ (last visited on Sept. 18, 2023).
[82] *Id.*

formal complaint that a recent CBS "60 Minutes" segment was a promotion for Novo Nordisk's obesity drugs that was dressed up as a news segment.[83]

94. The Washington, D.C.-based group has filed a complaint with federal bodies alleging that the CBS "60 Minutes" segment that aired on New Year's Day breached the FDA's "fair balance" rules for drug ads.[84]

95. The Physician's Committee said in a release that the feature failed to talk about alternatives to the drug or about other weight-loss methods; that only experts "paid by Novo" were used in the program; and that the piece used overly promotional language.[85]

96. The FDA is currently investigating the marketing practices of Novo Nordisk.[86]

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

98. For example, Novo Nordisk spent over $33,000,000 in 2022 on traditional physician marketing and detailing according to Open Payments Data. [87]

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

100. This includes a 2019 direct partnership between Novo Nordisk and Noom, a leading behavior weight loss company.[88] After Saxenda was approved for weight loss, Noom joined with Novo Nordisk again to develop custom programs to accompany this weight loss medication.[89]

---

[83] *Id*.
[84] *Id*.
[85] *Id*.
[86] https://www.pcrm.org/news/news-releases/fda-confirms-investigation-novo-nordisk-ad-posited-60-minutes-story-about-weight (last visited Sept. 18, 2023).
[87] https://openpaymentsdata.cms.gov/company/100000000144 (last visited Sept. 18, 2023).
[88] https://www.prnewswire.com/in/news-releases/novo-nordisk-and-noom-to-partner-around-digital-health-solutions-to-help-people-with-obesity-lose-weight-and-keep-it-off-811725389.html (last visited on Sept. 18, 2023).
[89] https://www.noom.com/blog/in-the-news/noom-announces-two-new-studies-on-impact-of-mobile-coaching-on-binge-eating-disorder-and-obesity/ (last visited on Sept. 18, 2023).

101. In 2021, Novo Holdings participated in a $540 million round of financing with Noom.[90] At that time, Novo Holdings tweeted that it "is pleased to note that it has participated in the $540 million Series F round in @noom, a leading digital health platform…".[91]

102. Novo Holdings currently lists on its website that is has "venture investments" in Noom.[92]

103. Noom Med now provides to consumers, using physicians hired by Noom, prescriptions for weight loss directly to patients.[93]

104. Noom Med promotes off label usage of these weight loss drugs on its website.[94]

105. Noom currently has over 45 million users.[95]

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

107. This includes Weight Watchers, who purchased telehealth startup Sequence for $132,000,000 in order to provide weight loss medications to its subscribers.[96]

108. There are currently over 3.5 million Weight Watchers subscribers.[97]

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

---

[90] https://www.businesswire.com/news/home/20210525005492/en/Noom-Announces-540-Million-in-Growth-Funding-to-Further-Accelerate-Expansion-of-its-Digital-Health-Platform.
[91] https://twitter.com/novoholdings/status/1397170264702599171.
[92] https://novoholdings.dk/investments/noom/.
[93] https://abcnews.go.com/GMA/Wellness/noom-joins-weight-watchers-offering-medications-wegovy-weight/story?id=99841160 (last visited on Sept. 18, 2023).
[94] https://www.noom.com/med/ (last visited on Sept. 18, 2023).
[95] https://exitsandoutcomes.com/free-excerpt-from-the-noom-report-a-45-million-moat/ (last visited Sept. 18, 2023).
[96] https://www.usatoday.com/story/news/health/2023/03/07/weightwatchers-sequence-wegovy-obesity-weight-loss-drugs/11415201002/ (last visited on Sept. 18, 2023).
[97] https://finance.yahoo.com/news/ww-international-inc-announces-first-200100340.html#:~:text=%E2%80%9CWe%20expect%20to%20end%202023,including%203.5%20million%20WeightWatchers%20subscribers. (last visited on Sept. 18, 2023).

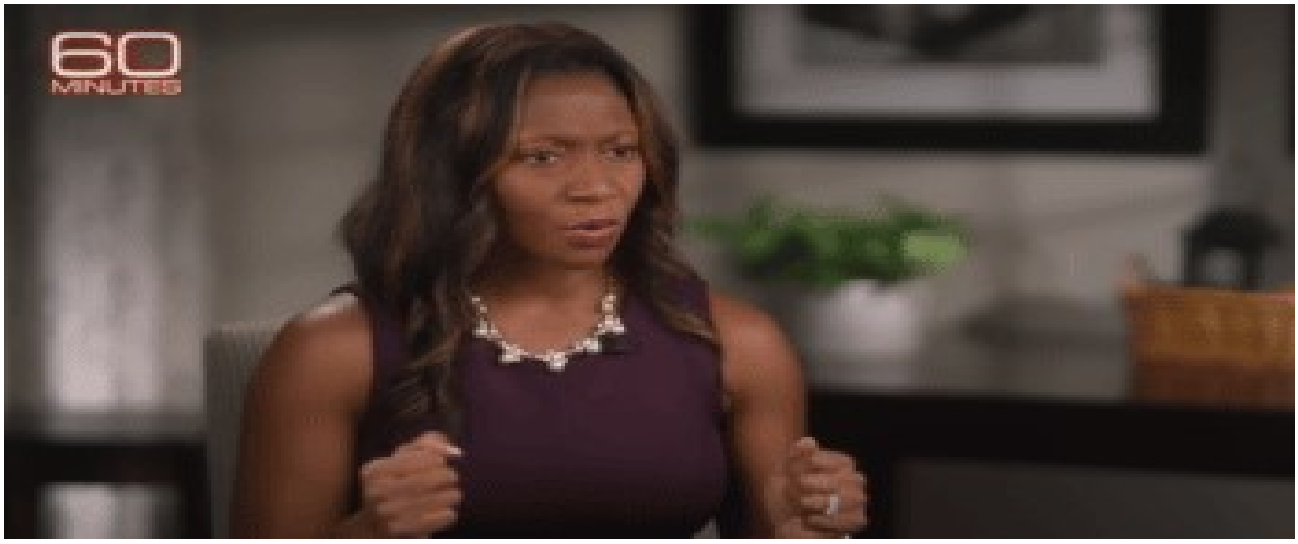
110. Calibrates' clinical advisory board includes Dr. Fatima Cody Stanford. [98]

111. Dr. Cody Stanford is an obesity specialist that frequently speaks on behalf of Novo Nordisk, is featured on Novo Nordisk's website, and has received payments directly from Novo Nordisk.[99] Upon information and belief, Dr. Cody Stanford is one of the highest paid key opinion leaders for Novo Nordisk.

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

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

[100]



News reports have recognized that such marketing, particularly with telehealth providers, is a "gray area."[101]

[98] https://www.joincalibrate.com/about-us (last visited on Sept. 18, 2023).
[99] https://openpaymentsdata.cms.gov/physician/807348 (last visited on Sept. 18, 2023); https://www.novonordisk-us.com/about/perspectives/changing-the-mindset-around-obesity.html (last visited on Sept. 18, 2023).
[100] https://mronline.org/2023/02/13/60-minutes-weight-loss-tip/ (last visited on Sept. 18, 2023).
[101] https://www.statnews.com/2023/04/06/weight-loss-drugs-wegovy-ro-telehealth-ozempic/?utm_campaign=morning_rounds&utm_medium=email&_hsmi=253265291&_hsenc=p2ANqtz-_6H01FfkCg2JOnqJnju52tvRlJrTnn-KTwSkzAv1qkbBHi4MR2mN8wdPsbzj6Csbzm5s5M56muD-1rjaA-

114. Dr. Fatima Cody Stanford is also included on Novo Nordisk's website, arguing that access to their weight loss drugs is an issue of equity and disparity for communities of color.[102]

115. Their full financial relationship is not disclosed on Defendants' website.

116. Nor has Dr. Stanford disclosed this relationship in other seemingly independent publications arguing that obesity is a chronic disease that necessitates weight loss medications.[103]

117. 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.[104]

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

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

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

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

IF60zzjN1A&utm_content=253265291&utm_source=hs_email (last visited on Sept. 18, 2023).

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

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

[104] https://www.statnews.com/2023/08/10/wegovy-ozempic-weight-loss-telehealth-prescriptions/.

121. As of August 10, 2023, Novo Nordisk reported that in the first six months of 2023 sales of Ozempic jumped 50% to more than $3.7 billion.[105]

122. In July of 2021, doctors in the US wrote 62,000 prescriptions a week for Ozempic.[106]

123. It has been reported that the huge demand created by extensive marketing has lead to rampant off-label usage and "gaming" the system to allow for insurance coverage.[107]

124. 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.[108]

125. 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.[109]

126. In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.[110]

127. 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.[111]

---

[105] 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. (last visited Sept. 18, 2023).

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

[107] *Id*.

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

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

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

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

128. There is now a shortage of Ozempic, including those for people who have diagnosed Type II diabetes.[112]

129. Ozempic has become so popular, Novo Nordisk has recently limited shipment to the US and paused advertising to address shortages.[113]

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

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

131. On June 14, 2023, the AMA adopted a new policy clarifying how body mass index should be used as a measure in medicine.[114]

132. The American Medical Association has urged doctors to deemphasize their use of body mass index (BMI) in determining healthy weights for patients.[115]

133. Due to significant limitations associated with the widespread use of BMI in clinical settings, the AMA suggests that it be used in conjunction with other valid measures of risk such as, but not limited to, measurements of visceral fat, body adiposity index, body composition, relative fat mass, waist circumference and genetic/metabolic factors.[116]

134. A recent study examined subjects' B.M.I. in relation to their blood pressure, cholesterol levels, and insulin resistance. Nearly a third of people with a "normal" B.M.I. had

[112] https://www.forbes.com/sites/brianbushard/2023/09/16/shortage-of-weight-loss-drugs-like-wegovy-and-ozempic-persist-and-could-for-some-years/?sh=191877ce631e (last visited Sept. 17, 2023)
[113] https://www.theatlantic.com/health/archive/2023/05/ozempic-teen-obesity-treatment-health-promises-risks/674204/ (last visited on Sept. 18, 2023).
[114] https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measure-medicine (last visited Sept. 18, 2023).
[115] *Id*.
[116] *Id*.

unhealthy metabolic metrics, and nearly half of those who were technically overweight were metabolically healthy. About a quarter of those who were classified as obese were healthy, too.[117]

135. In short, BMI is a poor indicator of health outcomes for an individual.[118]

136. Weight loss as the sole indicator of health has also been rejected by many clinicians in favor of improvements in other health outcomes and the assessing the whole health of an individual.[119]

137. These clinicians have cautioned that "a lower body weight does not always mean a person is healthier."[120]

138. It's recognized in the medical community that weight loss achieved by Ozempic is often a result of a significant loss of muscle mass.[121]

139. 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.[122]

140. Ongoing use of Ozempic for weight loss can lead to malnutrition and key vitamin deficiencies, such a vitamin B12, that can lead to poor health outcomes.[123]

---

[117] https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin (last access Sept. 18, 2023).
[118] https://newsroom.uw.edu/resource/why-body-mass-index-doesnt-give-whole-health-picture (last visited Sept. 18, 2023).
[119] https://link.springer.com/content/pdf/10.1007/s11606-022-07821-w.pdf?pdf=button (last visited on Sept. 18, 2023); https://newsroom.uw.edu/resource/why-body-mass-index-doesnt-give-whole-health-picture (last accessed Sept. 18, 2023).
[120] https://www.healthline.com/health-news/ozempic-muscle-mass-loss (last accessed Sept. 18, 2023).
[121] https://www.nbcnews.com/health/health-news/weight-loss-drugs-muscle-loss-rcna84936 (last accessed Sept. 18, 2023).
[122] https://www.healthline.com/health-news/ozempic-muscle-mass-loss (last accessed Sept. 18, 2023).
[123] https://www.nytimes.com/2023/04/21/well/eat/ozempic-side-effects-malnutrition.html (last accessed Sept. 18, 2023).

141. Given these adverse effects on overall health, the National Institute of Care and Excellence (NICE) has recommended that people stop taking Ozempic after 2 years.[124]

142. The problem, of course, is that individuals immediately begin to gain the weight back once they stop taking Ozempic.[125]

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

144. Paradoxically, individuals may be lighter than they were initially but have a higher percentage of body fat.[126] 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.[127]

145. 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.

146. A trial published by Novo Nordisk showed that after a year participants had gained back two thirds of the weight lost after they stopped taking semaglutide.[128]

147. Novo Nordisk has publicly recognized that most individuals will regain all the weight back within five years of stopping Ozempic.[129]

148. Remarkably, Novo Nordisk has publicly stated that some individuals will regain even more weight after stopping Ozempic than they initially lost.[130]

---

[124] National Institute for Health and Care Excellence. (2023). Semaglutide for managing overweight and obesity. *NICE.* Retrieved from: https://www.nice.org.uk/guidance/ta875/chapter/1-Recommendations (last visited on Sept. 18, 2023).
[125] https://www.psychologytoday.com/ie/blog/the-neuroscience-of-eating-disorders/202303/ozempic-and-wegovy-is-semaglutide-a-miracle-weight (last visited on Sept. 18, 2023).
[126] https://www.afr.com/policy/health-and-education/lighter-but-fatter-the-ozempic-paradox-20230718-p5dp5w
[127] *Id*.
[128] https://dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.14725.
[129] https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-stop-medication.html.
[130] https://www.cnbc.com/2023/03/29/people-taking-obesity-drugs-ozempic-and-wegovy-gain-weight-once-they-

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

150. Ozempic is often marketed as part of a "metabolic reset."[131]

151. However, Novo Nordisk has recognized that GLP-1s do not rewire "your neural networks to really define a new body weight setpoint."[132]

152. 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).[133]

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

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

154. The Novo Nordisk Defendants have repeatedly failed to warn about the known dangerous side effects of Ozempic. This includes malnutrition, cyclical vomiting, and gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, esophageal and bowel injury,

---

stop-medication.html.

[131] https://www.joincalibrate.com/resources/how-long-does-it-take-to-lose-weight-on-ozempic.

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

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

DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, and intraoperative aspiration. All of these conditions can, and have, lead to hospitalization and/or death in patients across America.

155. Some doctors estimate that as many as 10% of patients discontinue use of these drugs due to the severity of side effects.[134]

156. Thousands of adverse event reports have been filed by the public with the FDA Adverse Event Reporting System. As of June 2022, the FDA has posted an alert that Ozempic had potential safety signals for intestinal blockage.[135]

157. On September 22, 2023, FDA updated the label for Ozempic to include "ileus," the medical term for blocked intestines.[136]

158. As early as 2014, Defendants knew that Saxenda (liraglutide), Ozempic's predecessor, caused serious side effects and warned the end user of same.[137]

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

160. 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.[138]

---

[134] https://www.cbsnews.com/news/ozempic-side-effects-weight-loss-drugs-wegovy-mounjaro-doctors-warn/ (last visited Sept. 18, 2023).
[135] https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/april-june-2022-potential-signals-serious-risksnew-safety-information-identified-fda-adverse-event (last visited Sept. 18, 2023).
[136]https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=2183; https://www.healthline.com/health-news/fda-updates-ozempic-label-to-include-blocked-intestines-as-potential-side-effect#:~:text=Ozempic%20Label%20Updated%20to%20Include%20Blocked%20Intestines%20as%20Potential%20Side%20Effect&text=The%20FDA%20is%20warning%20patients,serious%20and%20potentially%20fatal%20condition.
[137] https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206321orig1s000lbl.pdf (last visited on Sept. 18, 2023).
[138] https://www.novo-pi.com/rybelsus.pdf (last visited on Sept. 18, 2023).

161. According to the FDA Adverse Event Reporting System, Defendants were aware of reports of intestinal obstruction no later than 2019 for Ozempic.[139] These reports to the FDA also stated that many of these patients reporting intestinal obstruction or blockage were hospitalized.[140]

162. 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."[141] 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.

163. 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.

164. 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

[139] https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis (last access Sept. 18, 2023).
[140] *Id.*
[141] https://www.novo-pi.com/ozempic.pdf (last visited on Sept. 18, 2023).

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.[142]

165. 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.[143] Its symptoms include vomiting, nausea, diarrhea, stomach cramps, muscle aches, headaches, and fever.[144] Notably, vomiting and diarrhea can cause dehydration, which is the main complication of gastroenteritis, and which can lead to death.[145]

166. At all relevant time periods, 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.

167. At all relevant time periods, 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.

168. 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

[142] https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787 (last visited on Sept. 18, 2023).
[143] https://www.merckmanuals.com/home/digestive-disorders/gastroenteritis/drug-related-gastroenteritis-and-chemical-related-gastroenteritis (last visited on Sept. 18, 2023).
[144] https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847 (last visited on Sept. 18, 2023).
[145] https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847 (last visited on Sept. 18,2023).

effect in the gut that was verified in healthy volunteers…". [146] It is explicitly noted that GLP-1s have slow down gastric emptying.[147]

169. A similar published article in 2013 found that after a review of PubMed articles it was evident that GLP-1s inhibit gastric emptying; notably, they separately found that delayed gastric emptying could lead to malnutrition.[148]

170. 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."[149]

171. In August of 2020, medical literature advised that some "patients do not know they have diabetic gastroparesis until they are put on a glucagon-like peptide 1 (GLP-1) receptor agonist such as ... semaglutide ... to manage their blood glucose." The article went on to explain that "[t]his class of Ozempic can exacerbate the symptoms of diabetic gastroparesis. ... Thus, GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis."[150]

172. In 2021, a case report was published regarding a 52-year-old female who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis

---

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

[147] *Id*.

[148] 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. Aliment Pharmacol Ther. 2013 Sep;38(6):573-83. doi: 10.1111/apt.12421. Epub 2013 Jul 23. PMID: 23879699. (last visited Sept. 18, 2023).

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

[150] Young CF, Moussa M, Shubrook JH, *Diabetic Gastroparesis: A Review*, Diabetes Spectr. 2020 Aug; 33(3): 290–297, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/ (last visited on Sept. 18, 20230.

symptoms. The case report authors concluded that "thorough history taking revealed the cause [of gastroparesis] to be medication induced."[151]

173. A second case report also published in 2021 involved a 57-year-old female who had been taking weekly dulaglutide injections (another GLP-1 receptor agonist) for 15 months and suffering from bloating, nausea and vomiting for 12 of those months. Testing revealed delayed gastric emptying which improved with cessation of dulaglutide.[152]

174. In 2022 a large, population-based study indicated that the use of GLP-1 RAs was associated with an increased risk of intestinal obstruction.[153]

175. In addition, in March of 2022, the FDA modified the warning label of Ozempic to include a specific warning about the risk of gallbladder disease associated with the drug.[154] Gallbladder disease has been associated with surgery and other complications.

176. 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."[155]

---

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

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

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

[154] https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209637s009lbl.pdf.

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

177. 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[.]"[156]

178. Case reports continue to be published regarding the use of semaglutide and intraoperative aspirations.[157]

179. In June 2021, a comprehensive meta-analysis showed nearly a four-fold increased risk of DVT when taking semaglutide.[158] DVT, or deep vein thrombosis, is associated with pulmonary embolism and other serious complications, including death.

180. At all relevant time periods, the Novo Nordisk Defendants made, distributed, marketed, and/or sold Ozempic and/or Wegovy without adequate warning to Plaintiff's prescribing physician(s) and/or Plaintiff that Ozempic and/or Wegovy was associated with and/or could cause severe gastrointestinal issues including gastroparesis, gastroenteritis, and intestinal blockage or obstruction, ileus, malnutrition, esophageal and bowel injury, DVT, intraoperative aspiration, and death.

181. Defendants knew of the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues including gastroparesis, gastroenteritis, and intestinal blockage or obstruction, ileus, malnutrition, esophageal and bowel injury, DVT, intraoperative aspiration, and death. Defendants' knowledge derived from their clinical studies,

---

[156] https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-Ozempic-gastroparesis/index.html (last visited Sept. 18, 2023).
[157] https://pubmed.ncbi.nlm.nih.gov/36977934/ (last visited Sept. 18, 2023).
[158] Yin DG, Ding LL, Zhou HR, Qiu M, Duan XY. Comprehensive analysis of the safety of semaglutide in type 2 diabetes: a meta-analysis of the SUSTAIN and PIONEER trials. Endocr J. 2021 Jun 28;68(6):739-742. doi: 10.1507/endocrj.EJ21-0129. Epub 2021 May 22. PMID: 34024887.

case reports, and the medical literature, including the medical literature and case reports referenced above in this Complaint.

182. 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, gastroenteritis, and intestinal blockage or obstruction, ileus, malnutrition, esophageal and bowel injury, DVT, intraoperative aspiration, and death.

183. 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, gastroenteritis, and intestinal blockage or obstruction, ileus, malnutrition, esophageal and bowel injury, DVT, intraoperative aspiration, and death, rendered the warnings for this medication inadequate.

184. 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.

185. Defendants also fail to provide adequate instructions for use and warnings and precautions for Ozempic, 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 severe gastrointestinal issues including

gastroparesis, gastroenteritis, and intestinal blockage or obstruction, ileus, malnutrition, esophageal and bowel injury, DVT, intraoperative aspiration, and death.

VI. The Dark Side of Ozempic

186. 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.[159]

187. 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."[160]

188. Strikingly, Novo Nordisk's own hired spokesperson and consultant has stated on national television that "[d]octors do not understand obesity."[161]

189. 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.

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

191. This includes the fact that female sex is an independent risk factor associated with an increased risk of adverse effects when taking GLP-1s.[162]

---

[159] https://www.vox.com/science/23683383/ozempic-pregnancy-risks-side-effect-semaglutide-wegovy.
[160] https://www.vox.com/science/23683383/ozempic-pregnancy-risks-side-effect-semaglutide-wegovy (last visited Sept. 18, 2023).
[161] https://www.cbsnews.com/news/weight-loss-obesity-drug-2023-01-01/ (last visited Sept. 18, 2023).
[162] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8950819/ ("In contrast, female sex appears to be a well-recognized independent factor linked to greater weight loss achievement after treatment with GLP-1 RAs. **This is also the case for adverse events resulting from the use of these medications**, which appear to manifest in higher percentages in women, mainly affecting the GI tract.") (emphasis added).

192. The Ozempic label does not warn that being female increases the risk of suffering adverse effects when taking these drugs.

193. Recently, news articles have begun to publicize the dark side of these drugs.[163]

194. Consumers of Ozempic are reporting major health problems, including gastroparesis, stomach paralysis, gastroenteritis, DVT (deep vein thrombosis), gallbladder problems necessitating surgery, intraoperative aspiration, and intestinal blockage or obstruction.[164]

195. Consumers are not aware that taking Ozempic can lead to severe malnutrition.[165]

196. Consumers are not aware that taking Ozempic can lead to severe muscle loss.[166]

197. Muscle loss (sarcopenia) can lead to death.[167]

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

199. 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.

200. Other industry experts, including physicians, believe that there needs to be greater awareness of the risks of Ozempic.[168]

201. Yet Defendants have continued selling Ozempic to a point where there are mass shortages and waitlists.[169]

---

[163] https://www.cnn.com/2023/06/07/opinions/ozempic-weight-loss-drug-diet-culture-wellness-carr-goldynia-sole-smith/index.html (last visited Sept. 18, 2023).
[164] https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis (last visited Sept. 18, 2023).
[165] An Extreme Risk of Taking Ozempic: Malnutrition – The New York Times (nytimes.com) (last visited Sept. 18, 2023).
[166] https://www.healthline.com/health-news/ozempic-muscle-mass-loss (last visited Sept. 18, 2023).
[167] https://my.clevelandclinic.org/health/diseases/23167-sarcopenia#:~:text=Sarcopenia%20affects%20your%20musculoskeletal%20system,risk%20of%20complications%20including%20death (last visited on Sept. 18, 2023).
[168] https://www.vox.com/science/23683383/ozempic-pregnancy-risks-side-effect-semaglutide-wegovy (last visited Sept. 18, 2023).
[169] https://www.nytimes.com/2023/08/28/business/denmark-ozempic-

202. 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.[170]

203. This is not the first time the FDA has cited a company for failures related to the manufacturing of Wegovy. 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.[171] 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."[172]

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

PARTY PLAINTIFF

205. Plaintiff, MEGAN ROCHA, is a citizen and resident of the state of Pennsylvania.

206. Plaintiff is 39 years old.

207. Plaintiff used Ozempic from approximately March 2022 until December 2022.

208. Plaintiff's physicians(s) ("prescribing physicians(s)") prescribed the Plaintiff Ozempic for weight loss.

209. As a result of using Ozempic, Plaintiff was diagnosed with Gastroparesis and suffered pain and incurred medical expenses.

---

wegovy.html?action=click&pgtype=Article&state=default&module=styln-weight-loss-drugs&variant=show&region=MAIN_CONTENT_1&block=storyline_top_links_recirc (last visited Sept. 18, 2023).

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

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

[172] *Id*.

210. At all times material to the above, the Ozempic label failed to adequately warn MEGAN ROCHA and her medical provider(s) of the true risks of taking Ozempic.

211. At all times material to the above, the Ozempic marketing and advertising failed to adequately warn MEGAN ROCHA and her medical providers of the true risks of taking Ozempic.

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

COUNT I: NEGLIGENCE

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

214. Defendants, directly or indirectly, caused Ozempic to be sold, distributed, packaged, labeled, marketed, promoted, and used by Plaintiff. At all relevant times, Defendants registered, researched, distributed, marketed, overpromoted, and sold Ozempic within the Commonwealth of Pennsylvania and throughout the United States.

215. At all relevant times, Defendants had a duty to exercise reasonable care in the manufacture, marketing, advertisement, supply, storage, transport, packaging, sale, and distribution of Ozempic products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that did not cause users to suffer from unreasonable, dangerous side effects without an adequate warning—when used alone or in foreseeable combination with other drugs.

216. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known of the hazards and dangers associated with Ozempic, and specifically that use of these drugs could cause malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, and death.

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

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

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

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

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

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

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Ozempic was safe for 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 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'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;

g. Advertising, marketing, and recommending the use of Ozempic, 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;

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

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

j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of Ozempic so as to avoid the risk of serious harm associated with the use of Ozempic. Failing to design and manufacture Ozempic so as to ensure the drugs were at least as safe and effective as other similar products;

k. Failing to ensure that Ozempic was accompanied by proper and accurate warnings about the risk of severe gastrointestinal problems including gastroparesis.

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

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

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

222. As a direct and proximate result of Defendants' negligent testing, monitoring, and pharmacovigilance of Ozempic, Defendants introduced a drug into this Commonwealth that they knew or should have known would cause serious and severe complications in people, including DVT, 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.

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

224. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania law.

225. 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

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

227. Ozempic is a product within the meaning of Pennsylvania products liability law.

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

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

230. Defendants advertised and promoted Ozempic for the purpose of weight loss and diabetes control.

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

232. A reasonable patient or consumer of Ozempic would expect the drug to be free of significant defects.

233. Defendants knew or had reason to know of facts establishing that Ozempic posed a significant risk of malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, intraoperative aspiration and death, and deliberately proceeded to act, or failed to act, in conscience disregard of, or indifference, to that risk.

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

235. In disregard of its duty to timely warn consumers of health risks associated with Ozempic, 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 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 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.

236. At all relevant times, the label for Ozempic is inadequate because it did not warn and/or adequately warn of all possible adverse side effects associated with the use of Ozempic, including the increased risk of severe gastrointestinal events (e.g., gastroparesis, gastroenteritis, intestinal blockage, ileus, bowel or esophageal injury, and malnutrition), DVT, intraoperative aspiration, gallbladder problems necessitating surgery, and/or death, as well as the need to permanently stay on the drug or the weight will be regained.

237. The label for Ozempic is inadequate because it did not contain adequate instructions for use such that a physician and patient could make an informed prescribing decision, adequately monitor the patient while using, and mitigate potential harms from the use of Ozempic.

238. At all relevant times, the label for Ozempic is inadequate because it did not warn and/or adequately warn that Ozempic had not been sufficiently and/or adequately tested for safety risks, including severe gastrointestinal events (e.g., gastroparesis, gastroenteritis, intestinal

blockage, ileus, bowel or esophageal injury, and malnutrition), as well as DVT, gallbladder problems necessitating surgery, intraoperative aspiration, and/or death.

239. The label for Ozempic was inadequate because it did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Ozempic.

240. The label for Ozempic was inadequate because it 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.

241. At all relevant times, communications made by Defendants to Plaintiff and her prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects associated with the use of Ozempic, including the increased risk of severe gastrointestinal events (e.g., gastroparesis, gastroenteritis, intestinal blockage, bowel/esophageal injury, and malnutrition), DVT, intraoperative aspiration, and/or death.

242. At all relevant times, communications made by Defendants to Plaintiff and her prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn that Ozempic had not been sufficiently and/or adequately tested for safety risks, including severe gastrointestinal events (e.g., gastroparesis and gastroenteritis, intestinal blockage, bowel/esophageal injury, and malnutrition), DVT, intraoperative aspiration, and/or death.

243. 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.

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

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

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

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

248. As a direct, foreseeable and proximate result of Defendants' failure to warn of the significant risks associated with Ozempic, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above. As a consequence of Defendants' misconduct, Plaintiff' physicians lacked adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) that Defendants provided to physicians for Ozempic. 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

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

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

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

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

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

(b) Failing to design 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 malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, intraoperative aspiration and death.

(e) Designing a product without taking into consideration the proper dosage that could avoid malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, intraoperative aspiration and death.

(f) 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.

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

254. 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.

255. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of 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.

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

257. 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

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

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

260. At all relevant times, Defendants negligently provided Plaintiff, her healthcare providers, the general medical community, and the public with false, fraudulent, and/or incorrect

information or omitted or failed to disclose material information concerning Ozempic, including, but not limited to, misrepresentations and marketing regarding the long term effects of Ozempic, including, but not limited to the fact weight lost will be regained upon cessation of the drug.

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

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

263. Defendants had a duty to accurately and truthfully represent and market to the medical and healthcare community, medical pharmaceutical manufacturers, Plaintiff, her healthcare providers and the public, the known risks of Ozempic, including its propensity to cause malnutrition, cyclical vomiting, and gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, and death

264. Defendants made continued omissions in the Ozempic labeling, including promoting it as safe and effective while failing to warn of its propensity to cause malnutrition, cyclical vomiting, and gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, and death.

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

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

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

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

269. 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.

270. 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.

271. 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.

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

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

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

275. Defendants failed to exercise ordinary care in making representations concerning 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 Ozempic's high risk of unreasonable and dangerous adverse side effects.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgement against Defendants on each of the above referenced claims and Causes of Action as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health care costs, medical monitoring, together with interest and costs as

provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendants, who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct
3. Awarding Plaintiff the costs of these proceedings; and
4. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

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

Dated: January 15, 2025

RESPECTFULLY SUBMITTED,

/s/ Daniel A. Nigh

Daniel A. Nigh (FL Bar No. 30905)
NIGH GOLDENBERG RASO & VAUGHN, PLLC
14 Ridge Square NW, Third Floor
Washington, D.C. 20016
Telephone: 202-792-7927
Facsimile: 202-792-7927
dnigh@nighgoldenberg.com
Attorney for Plaintiff

JS 44 (Rev. 08/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

MEGAN ROCHA

(b) County of Residence of First Listed Plaintiff Chester County, PA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Daniel A. Nigh; Nigh Goldenberg Raso & Vaughn, PLLC 14 Ridge Square NW Third Floor Washington, DC 20016

DEFENDANTS

NOVO NORDISK INC., NOVO NORDISK A/S

County of Residence of First Listed Defendant Middlesex County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	☒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

❒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ☒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332

Brief description of cause:
Products Liability

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Robert B. Kugler DOCKET NUMBER 19-2875

DATE 01/15/2025

SIGNATURE OF ATTORNEY OF RECORD /s/Daniel A. Nigh

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

Place of Accident, Incident, or Transaction: Landenberg, PA

RELATED CASE IF ANY: Case Number: MDL 3094 Judge: Karen Spencer Marston

1. Does this case involve property included in an earlier numbered suit? Yes ☐
2. Does this case involve a transaction or occurrence which was the subject of an earlier numbered suit? Yes ■
3. Does this case involve the validity or infringement of a patent which was the subject of an earlier numbered suit? Yes ☐
4. Is this case a second or successive habeas corpus petition, social security appeal, or pro se case filed by the same individual? Yes ☐
5. Is this case related to an earlier numbered suit even though none of the above categories apply? If yes, attach an explanation. Yes ☐

I certify that, to the best of my knowledge and belief, the within case ☐ **is** / ■ **is not** related to any pending or previously terminated action in this court.

Civil Litigation Categories

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts)
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Wage and Hour Class Action/Collective Action
- ☐ 6. Patent
- ☐ 7. Copyright/Trademark
- ☐ 8. Employment
- ☐ 9. Labor-Management Relations
- ☐ 10. Civil Rights
- ☐ 11. Habeas Corpus
- ☐ 12. Securities Cases
- ☐ 13. Social Security Review Cases
- ☐ 14. Qui Tam Cases
- ☐ 15. Cases Seeking Systemic Relief ***see certification below***
- ☐ 16. All Other Federal Question Cases. *(Please specify)*:_____

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury (*Please specify*):_____
- ✓ 7. Products Liability
- ☐ 8. All Other Diversity Cases: *(Please specify)*_____

I certify that, to the best of my knowledge and belief. that the remedy sought in this case ☐ **does** / ✓ **does not** have implications beyond the parties before the court and ☐ **does** / ✓ **does not** seek to bar or mandate statewide or nationwide enforcement of a state or federal law including a rule, regulation, policy, or order of the executive branch or a state or federal agency, whether by declaratory judgment and/or any form of injunctive relief.

ARBITRATION CERTIFICATION (CHECK ONLY ONE BOX BELOW)

I certify that, to the best of my knowledge and belief:

[✓] Pursuant to Local Civil Rule 53.2(3), this case is not eligible for arbitration either because (1) it seeks relief other than money damages; (2) the money damages sought are in excess of $150,000 exclusive of interest and costs; (3) it is a social security case, includes a prisoner as a party, or alleges a violation of a right secured by the U.S. Constitution, or (4) jurisdiction is based in whole or in part on 28 U.S.C. § 1343.

[ ] None of the restrictions in Local Civil Rule 53.2 apply and this case is eligible for arbitration.

NOTE: A trial de novo will be by jury only if there has been compliance with F.R.C.P. 38.