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
SAMANTHA HILL, *Plaintiff,* v. NOVO NORDISK A/S, NOVO NORDISK, INC., and ELI LILLY AND COMPANY, *Defendant.*	COMPLAINT AND JURY DEMAND CIVIL ACTION NO.: 2:25-cv-989

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 Western District of North Carolina as Plaintiff's designated venue ("Original Venue"). Plaintiff makes this selection based upon one (or more) of the following factors (check the appropriate box(es)):

X Plaintiff currently resides in Gastonia, NC (City/State).

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

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

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)):
Western District of North Carolina.

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

__ Other reason (please explain): _____.

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiff, SAMANTHA HILL, who was severely injured as a result of Plaintiff's use of Ozempic and Trulicity injectable prescription medications, and Rybelsus an oral prescription medication, that are used to control blood sugar in patients with type 2 diabetes, to reduce cardiovascular risks, and to manage weight.

2. Ozempic is also known as semaglutide.

3. Rybelsus is also known as a semaglutide.

4. Trulicity is also known as dulaglutide.

5. Ozempic, Rybelsus and Trulicity work by stimulating insulin production and reducing glucose production in the liver helping to lower blood sugar levels.

6. Ozempic, Rybelsus and Trulicity belong to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

7. Defendants acknowledge that gastrointestinal events are well known side effects of the GLP-1RA class of drugs.[1] However, Defendants have downplayed the severity of the gastrointestinal events caused by their GLP-1RAs, never, for example, warning of the risk of gastroparesis ("paralyzed stomach") and its sequelae.

8. 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 cause nausea, vomiting (including vomiting of undigested food), abdominal pain,

[1] *See, e.g.*, CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601 (visited on 9/26/23).

abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, undigested food hardening and remaining 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.[2]

PARTY PLAINTIFF

9. Plaintiff, SAMANTHA HILL, is a citizen of the United States, and is a resident of the State of North Carolina.

10. Plaintiff is 27 years old.

11. Plaintiff used Ozempic from approximately September 2021 to March 2023.

12. Plaintiff used Rybelsus in approximately December 2022.

13. Plaintiff used Trulicity from approximately November 2021 to February 2022.

14. Plaintiff's physician(s) ("prescribing physician(s)") prescribed the Ozempic, Rybelsus and Trulicity that were used by Plaintiff.

15. As a result of using Ozempic, Rybelsus and Trulicity, Plaintiff was caused to suffer from gastroparesis and its sequelae and, as a result, sustained severe and permanent personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

16. As a result of using Ozempic, Rybelsus and Trulicity, Plaintiff was caused to suffer from gastroparesis and its sequelae, which resulted in, for example, nausea, severe vomiting, and requiring emergency medical treatment foir severe vomiting.

PARTY DEFENDANTS

17. Defendant Novo Nordisk Inc. is a Delaware corporation with a principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey.

[2] *Gastroparesis*, Mayo Clinic (June 11, 2022), available at https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787 (visited on 9/26/23).

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

19. Defendants Novo Nordisk A/S and Novo Nordisk Inc. are identified on Ozempic's and Rybelsus' labels.[3]

20. Defendants Novo Nordisk Inc., and Novo Nordisk are referred to collectively herein as "Novo Nordisk."

21. Novo Nordisk designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic and Rybelsus. Alternatively, Novo Nordisk has acquired the entity/entities who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Ozempic and Rybelsus and is, thus, the successor to such entity/entities.

22. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation with a principal place of business at 893 S. Delaware St., Indianapolis, Indiana.

23. Eli Lilly designed, researched, manufactured, tested, labeled, advertised, promoted, marketed, sold, and/or distributed Trulicity and is identified on its label.[4]

24. Novo Nordisk and Eli Lilly are collectively referred to herein as "Defendants".

FACTUAL BACKGROUND

A. FDA's Approval of Ozempic

25. On December 5, 2016, Novo Nordisk announced submission of a new drug application (NDA) to the FDA for regulatory approval of once-weekly injectable semaglutide, a

[3] Ozempic prescribing information, available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=adec4fd2-6858-4c99-91d4-531f5f2a2d79 (visited on 9/26/23).
[4] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).

new glucagon-like peptide-1 (GLP-1) medication for treatment of type 2 diabetes. In the announcement, Novo Nordisk represented that in clinical trials "once-weekly semaglutide had a safe and well tolerated profile with the most common adverse event being nausea."[5]

26. On December 5, 2016, Defendant Novo Nordisk Inc. submitted NDA 209637, requesting that the FDA grant it approval to market and sell Ozempic (semaglutide) 0.5 mg or 1 mg injection in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On December 5, 2017, the FDA approved NDA 209637.[6]

27. On March 20, 2019, Defendant Novo Nordisk Inc. submitted supplemental new drug application (sNDA) 209637/S-003 for Ozempic (semaglutide) 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.[7] On January 16, 2020, the FDA approved sNDA 209637/S-003.[8]

28. On May 28, 2021, Defendant Novo Nordisk Inc. submitted sNDA 209637/S-009, requesting approval for a higher 2 mg dose of Ozempic (semaglutide) injection. On March 28, 2022, the FDA approved sNDA 209637/S-009.[9]

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[5] Novo Nordisk, *Novo Nordisk files for regulatory approval of once-weekly semaglutide in the US and EU for the treatment of type 2 diabetes* (Dec. 5, 2016), available at https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183 (last visited 9/26/23).

[6] FDA Approval Letter for NDA 209637 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf (visited on 9/26/23).

[7] *Novo Nordisk files for US FDA approval of oral semaglutide for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes*, Cision PR Newswire (March 20, 2019), available at https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html (visited on 9/26/23).

[8] FDA Supplement Approval Letter for NDA 209637/A-003 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf (visited on 9/26/23).

[9] FDA Supplement Approval Letter for NDA 209637/S-009 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209637Orig1s009ltr.pdf (visited on 9/26/23).

B. FDA's Approval of Rybelsus

29. On March 20, 2019, the Novo Nordisk Defendants announced the submission of a new drug application (NDA) to the FDA for regulatory approval for oral semaglutide, under the brand name Rybelsus, the first once-daily glucagon-like peptide-1 receptor agonist for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes.[10]

30. On March 20, 2019, Defendant Novo Nordisk Inc. submitted NDA 213051, requesting that the FDA grant it approval to market and sell Rybelsus (oral semaglutide) in both 7 mg and 14 mg oral doses in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.[11] On September 20, 2019, the FDA approved NDA 213051.[12]

31. On December 10, 2019, Defendant Novo Nordisk Inc. submitted a supplemental new drug application (NDA 213051/S-001) for Rybelsus (semaglutide) asking "for the addition of efficacy and safety information to the prescribing information based on clinical data from the PIONEER 6 cardiovascular outcomes trial entitled, 'A trial investigating the cardiovascular safety of oral semaglutide in subjects with type 2 diabetes.'"[13] On January 16, 2020, the FDA approved NDA 213051/S-001.[14]

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[10] *Novo Nordisk files for US FDA approval of oral semaglutide for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes,* Cision PR Newswire (Mar. 20, 2019), available at https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html (last visited on 9/20/23).

[11] Clinical Review for NDA 213051 (Rybelsus), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/213051Orig1s000MedR.pdf (last visited on 9/22/23).

[12] FDA Approval Letter for NDA 213051 (Rybelsus), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/213051Orig1s000ltr.pdf (last visited on 9/20/23).

[13] FDA Approval Letter available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213182Orig1s000Approv.pdf (last visited on 9/22/23).

[14] FDA Approval Letter for NDA 213051/S-001 (Rybelsus), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/213182Orig1s000,%20213051Orig1s001ltr.pdf (last visited on 9/21/23).

32. On March 28, 2022, the FDA notified Defendant Novo Nordisk, Inc. of new safety information that it determined should be included in the labeling for GLP-1RA products pertaining to the risk of acute gallbladder disease. On April 27, 2022, Defendant Novo Nordisk, Inc. submitted a supplemental new drug application (NDA 213051/S-011) and amendments for Rybelsus (semaglutide) tablets incorporating the FDA's required safety modifications to the label. On June 10, 2022, the FDA provided supplemental approval for NDA 213051/S-011.[15]

33. On July 15, 2022, Defendant Novo Nordisk Inc. submitted a supplemental new drug application (NDA 123051/S-012) for Rybelsus to remove the "Limitation of Use" statement "Not recommended as first-line therapy for patients inadequately controlled on diet and exercise" in the "Prescribing Information and Medication Guide" ("PI"). The following updates were also made to the PI information: a) addition of Pancreatitis and Diabetic Retinopathy Complications to the Other Adverse Reactions subsection in section 6.1, Clinical Trials Experience; b) updating the Immunogenicity section and moving it from section 6.2 to section 12.6; c) adding "Gastrointestinal: ileus" to section 6.2, Postmarketing Experience; d) revising section 7.1, Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with insulin; and e) other minor grammatical changes. The FDA approved NDA 123051/S-012 on January 12, 2023.[16]

34. On January 12, 2023, the Novo Nordisk Defendants announced the FDA's approval of NDA 123051/S-012 for the label update described above. In the press release, the Novo Nordisk Defendants emphasized that "Rybelsus has been prescribed to hundreds of thousands of patients to help improve glycemic control[,]" and they disclosed Important Safety Information about

[15] FDA Approval Letter for NDA 123051/S-011 (Rybelsus) available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/213051Orig1s011ltr.pdf (last visited on 9/20/23).
[16] *Novo Nordisk announces FDA approval of label update for Rybelsus® (semaglutide) allowing use as a first-line option for adults with type 2 diabetes,* Cision PR Newswire (Jan. 12, 2023), available at https://www.prnewswire.com/news-releases/novo-nordisk-announces-fda-approval-of-label-update-for-rybelsus-semaglutide-allowing-use-as-a-first-line-option-for-adults-with-type-2-diabetes-301720965.html (last visited on 9/20/23).

Rybelsus and provided links to its Medication Guide and Prescribing Information, but gastroparesis was not identified as a side effect or risk.[17]

C. FDA's Approval of Trulicity

35. On September 18, 2014, the FDA approved Eli Lilly's Biologics License Application ("BLA") for dulaglutide "as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus" to be marketed as Trulicity in "single dose pre-filled syringes and pre-filled pens." As initially approved, the recommended dose for Trulicity was 1.5 mg per week.[18]

36. On April 19, 2019, Eli Lilly submitted supplemental BLA 125469/S-033, requesting approval to expand its marketing of Trulicity by adding an indication for reduction of major cardiovascular events in adults with type 2 diabetes. On February 21, 2020, the FDA approved the request.[19]

37. On November 4, 2019, Eli Lilly submitted BLA 125469/S-036, seeking approval for higher doses (3 mg per week and 4.5 per week) of Trulicity. On September 3, 2020, the FDA approved that request.[20]

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[17] Novo Nordisk, *Novo Nordisk announces FDA approval of label update for Rybelsus® (semaglutide) allowing use as a first-line option for adults with type 2 diabetes* (Jan. 12, 2023), available at https://www.novonordisk-us.com/media/news-archive/news-details.html?id=154651 (last visited on 9/21/23).

[18] FDA Approval Letter for BLA 125469/0 (Sept. 18, 2014), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/125469Orig1s000ltr.pdf (last visited Nov. 8, 2023).

[19] FDA Approval Letter for BLA 125469/S-033 (Feb. 21, 2020), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/125469Orig1s033ltr.pdf (last visited Nov. 8, 2023).

[20] *See News Release: FDA approves additional doses of Trulicity (dulaglutide) for the treatment of type 2 diabetes,* Eli Lilly (Sept. 3, 2020) available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-additional-doses-trulicityr-dulaglutide-treatment (last visited Nov.15, 2023).

38. On May 17, 2022, Eli Lilly submitted BLA 125469/S-051, seeking to add an indication for a new patient population: "pediatric patients 10 years of age and older with type 2 diabetes mellitus." On November 17, 2022, the FDA approved the drug for pediatric use.[21]

39. At all times, Trulicity's label has indicated that Trulicity delays gastric emptying and that the delay in gastric emptying "diminishes with subsequent doses." However, Trulicity's label has never warned that Trulicity can cause gastroparesis or its sequelae.

D. Novo Nordisk's Marketing and Promotion of Ozempic

40. On December 5, 2017, Novo Nordisk announced the FDA's approval of Ozempic (semaglutide) 0.5 mg or 1 mg injection in a press release stating that: "Novo Nordisk expects to launch OZEMPIC® in the U.S. in Q1 2018, with a goal of ensuring broad insurance coverage and patient access to the product. OZEMPIC® will be priced at parity to current market-leading weekly GLP-1RAs and will be offered with a savings card program to reduce co-pays for eligible commercially-insured patients. Additionally, as part of the access strategy, Novo Nordisk is working with appropriate health insurance providers to establish innovative contracting solutions."[22]

41. On February 5, 2018, Novo Nordisk announced that it had started selling Ozempic in the United States and touted the medication as a "new treatment option[]" that "addresses the concerns and needs of people with diabetes[.]" Novo Nordisk offered an "Instant Savings Card to reduce co-pays to as low as $25 per prescription fill for up to two years."[23]

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[21] FDA Approval Letter for BLA 125469/S-051 (Nov. 17, 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/125469Orig1s051ltr.pdf (last visited Nov. 15, 2023).

[22] *Novo Nordisk Receives FDA Approval of OZEMPIC® (semaglutide) Injection For the Treatment of Adults with Type 2 Diabetes*, Cision PR Newswire (December 05, 2017), available at https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-ozempic-semaglutide-injection-for-the-treatment-of-adults-with-type-2-diabetes-300567052.html (visited on 9/26/23).

[23] *Novo Nordisk Launches Ozempic® and Fiasp®, Expanding Treatment Options for Adults with Diabetes*, Cision PR Newswire (February 05, 2018), available at

42. Novo Nordisk promoted the safety 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, and through other public outlets.

43. On July 30, 2018, Novo Nordisk launched its first television ad for Ozempic, to the tune of the 1970s hit pop song "Magic" by Pilot, wherein Novo Nordisk advertised that "adults lost on average up to 12 pounds" when taking Ozempic, even though it is not indicated for weight loss.[24]

44. On March 28, 2022, Novo Nordisk announced the FDA's approval of sNDA 209637/S-009 for a higher 2 mg dose of Ozempic (semaglutide) injection. In the press release, Novo Nordisk represented Ozempic as having "proven safety" and advertised that "plus it can help many patients lose some weight."[25]

45. Since 2018, Novo Nordisk has spent more than $884,000,000 on television ads in the United States to promote its semaglutide drugs (Ozempic, Wegovy and Rybelsus) with the majority of the spending allocated specifically to advertising Ozempic.[26]

46. In 2022, Novo Nordisk spent $180.2 million on Ozempic ads, including an estimated $157 million on national television ads for Ozempic, making Ozempic the sixth most

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https://www.prnewswire.com/news-releases/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment-options-for-adults-with-diabetes-300592808.html (visited on 9/26/23).

[24] *Ozempic TV Spot, 'Oh!'*, iSpot.tv (July 30, 2018), available at https://www.ispot.tv/ad/d6Xz/ozempic-oh (visited on 9/26/23).

[25] *Novo Nordisk receives FDA approval of higher-dose Ozempic® 2 mg providing increased glycemic control for adults with type 2 diabetes*, Cision PR Newswire (March 28, 2022), available at 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 (visited on 10/16/23).

[26] Ritzau, *Novo Nordisk runs TV ads in US for multimillion-dollar sum*, MedWatch (April 26, 2023), available at https://medwatch.com/News/Pharma___Biotech/article15680727.ece (visited on 9/26/23).

advertised drug that year. As a result of its GLP-1RA treatments, including Ozempic, Novo Nordisk forecasts sales growth of 13% to 19% for 2023.[27]

47. On July 6, 2023, it was reported that Novo Nordisk had spent $11 million in 2022 on food and travel for doctors "as part of its push to promote Ozempic and other weight loss-inducing diabetes drugs."[28] The spending bought more than 457,000 meals for almost 12,000 doctors while also flying doctors to places like London, Paris, Orlando, and Honolulu.[29]

48. In an article published on July 21, 2023, the President and CEO of the Alliance of Community Health Plans described Novo Nordisk's spending on meals for doctors as "outrageous" and suggested that the millions Novo Nordisk spent marketing its drugs to prescribers would be better used furthering research about potential side effects and long-term effectiveness. The author cited research published in the spring of 2023 showing an increased risk of intestinal obstruction as a result of using GLP-1RA drugs.[30]

49. As a result of Novo Nordisk's advertising and promotion efforts, Ozempic has been widely used throughout the United States. 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

[27] Adams B, Fierce Pharma, *The top 10 pharma drug ad spenders for 2022*, https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022 (visited on 9/26/23).
[28] Nicolas Florko, *Novo Nordisk bought prescribers over 450,000 meals and snacks to promote drugs like Ozempic*, National Center for Health Research (July 5, 2023), available at https://www.center4research.org/novo-nordisk-gave-doctors-450000-meals-ozempic/ (visited on 9/26/23).
[29] Nicolas Florko, *Novo Nordisk bought prescribers over 450,000 meals and snacks to promote drugs like Ozempic*, National Center for Health Research (July 5, 2023), available at https://www.center4research.org/novo-nordisk-gave-doctors-450000-meals-ozempic/ (visited on 9/26/23).
[30] Erin Prater, *Ozempic manufacturer Novo Nordisk spent $11 million last year 'wining and dining' doctors. Experts slam the move as a breach of doctor-patient trust,* Fortune Well (July 21, 2023), available at https://fortune.com/well/2023/07/21/ozempic-novo-nordisk-meals-travel-prescribing-doctors/ (visited on 9/26/23); *see also* Erin Prater, *Weight-loss drugs like Ozempic and Wegovy may put certain people at risk of serious complications, researchers warn*, Fortune Well (March 7, 2023), available at https://fortune.com/well/2023/03/07/ozempic-wegovy-elevated-risk-intestinal-obstruction-later-type-2-diabetes-weight-loss-drug/ (visited on 10/18/23).

prescriptions.[31] In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.[32]

50. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,[33] and currently has over 1.3 billion views.[34]

51. On June 15, 2023, NBC News published a report about the "thousands of weight-loss ads on social media for the drugs Ozempic and Wegovy." While many of those ads were found to be from online pharmacies, medical spas, and diet clinics, as of June of 2023, Novo Nordisk was still running online social-media ads for its semaglutide products, despite claiming in May that it would stop running ads due to a shortage of the drug.[35]

52. 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."[36]

53. At all relevant times, Novo Nordisk was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Ozempic.

E. Novo Nordisk's Marketing and Promotion of Rybelsus

54. On September 20, 2019, the Novo Nordisk Defendants announced the FDA's approval of Rybelsus (semaglutide) tablets 7 mg or 14 mg in a press release stating that: "Rybelsus

[31] Choi A, Vu H, *Ozempic prescriptions can be easy to get online. Its popularity for weight loss is hurting those who need it most*, CNN (March 17, 2023), available at https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/ (visited on 9/26/23).
[32] Gilbert D, *Insurers clamping down on doctors who prescribe Ozempic for weight loss*, The Washington Post (June 12, 2023), available at https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance/ (visited on 9/26/23).
[33] Blum D, *What is Ozempic and Why Is It Getting So Much Attention?,* The New York Times (published Nov. 22, 2022, updated July 24, 2023), available at https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html (visited on 9/26/23).
[34] https://www.tiktok.com/tag/ozempic (visited on 11/14/23).
[35] Ingram D, *More than 4,000 ads for Ozempic-style drugs found running on Instagram and Facebook*, NBC News (June 15, 2023), available at https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602 (visited on 9/26/23).
[36] Bain P, *Ozempic was 2023's Buzziest Drug*, AdAge (July 10, 2023), available at https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571 (visited on 9/26/23).

… will be available in the U.S. beginning in Q4 2019…. Initial supply of Rybelsus will come from manufacturing facilities in Denmark; however, future supply for Rybelsus will come from … a new manufacturing facility in Clayton, NC to prepare for the future demand of Rybelsus." The Novo Nordisk Defendants further stated that they were "working with health insurance providers with a goal of ensuring broad insurance coverage and patient access to the product. A savings card program will be available at the time of launch for eligible commercially-insured patients to keep out of pocket costs down to as little as $10 a month." The Novo Nordisk Defendants acknowledged that the most common side effects associated with the use of Rybelsus included nausea, stomach (abdominal) pain, diarrhea, decreased appetite, vomiting, and constipation. While the Novo Nordisk Defendants listed possible thyroid tumors (including cancer), inflammation of the pancreas, changes in vision, low blood sugar, kidney problems, and serious allergic reactions as "serious side effects", they failed to list gastroparesis.[37]

55. On January 16, 2020, the Novo Nordisk Defendants announced FDA approval of Rybelsus (semaglutide) tablets 7 mg and 14 mg prescribing information based on clinical data from the PIONEER 6 cardiovascular outcomes. In their announcement, the Novo Nordisk Defendants acknowledged that the most common side effects of Rybelsus are "nausea, stomach (abdominal) pain, diarrhea, decreased appetite, vomiting, and constipation." While the Novo Nordisk Defendants listed possible thyroid tumors (including cancer), inflammation of the pancreas, changes in vision, low blood sugar, kidney problems (kidney failure), and serious

[37] *FDA approves Rybelsus (semaglutide), the first GLP-1 analog treatment available in a pill for adults with type 2 diabetes,* Cision PR Newswire (September 20, 2019), available at https://www.prnewswire.com/news-releases/fda-approves-rybelsus-semaglutide-the-first-glp-1-analog-treatment-available-in-a-pill-for-adults-with-type-2-diabetes-300922438.html (last visited on 9/20/23).

allergic reactions as "serious side effects", they failed to list severe gastrointestinal events, including gastroparesis.[38]

56. On January 12, 2023, the Novo Nordisk Defendants announced FDA approval of a label update for Rybelsus (semaglutide) allowing its use as a first-line option for adult with type 2 diabetes. The update removed the previous limitation that Rybelsus could not be used as an initial therapy option for treating patients with type 2 diabetes. The announcement reiterated that the Novo Nordisk Defendants "work[] with health insurance providers to ensure broad insurance coverage and patient access to Rybelsus. Eligible, commercially insured patients may pay as little as $10 for a one- to three-month prescription of this medicine." The Novo Nordisk Defendants acknowledged that the most common side effects of Rybelsus are "nausea, stomach (abdominal) pain, diarrhea, decreased appetite, vomiting, and constipation." While the Novo Nordisk Defendants listed possible thyroid tumors (including cancer), inflammation of the pancreas, changes in vision, low blood sugar, kidney problems (kidney failure), serious allergic reactions, and gallbladder problems as "serious side effects", they did not list gastroparesis as a side effect or risk, nor did they otherwise mention it.[39]

57. The Novo Nordisk Defendants promoted the safety and sale of Rybelsus 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, and through other public outlets.

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[38] *FDA approves Ozempic for cardiovascular risk reduction in adults with type 2 diabetes and known heart disease, updates Rybelsus label,* Cision PR Newswire (January 16, 2020), available at https://www.prnewswire.com/news-releases/fda-approves-ozempic-for-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-and-known-heart-disease-updates-rybelsus-label-300988672.html (last visited on 9/20/23).

[39] *Novo Nordisk announces FDA approval of label update for Rybelsus (semaglutide) allowing use as first-line option for adults with type 2 diabetes*, Cision PR Newswire (January 23, 2023), available at https://www.prnewswire.com/news-releases/novo-nordisk-announces-fda-approval-of-label-update-for-rybelsus-semaglutide-allowing-use-as-a-first-line-option-for-adults-with-type-2-diabetes-301720965.html (last visited on 9/20/23).

58. On September 22, 2020, the Novo Nordisk Defendants launched their first television ad for Rybelsus featuring an upbeat cover version of "You Are My Sunshine" by Simon Ravenhall. In the ad, the Novo Nordisk Defendants advertised that "people taking Rybelsus lost up to 8 pounds", even though it is not a weight loss drug.[40] Also, the Novo Nordisk Defendants identified only one "serious side effect" of taking Rybelsus in the ad, pancreatitis.

59. From 2018 until present, the Novo Nordisk Defendants have spent $884,000,000 on running television ads in the United States to promote their semaglutide drugs (Ozempic, Wegovy and Rybelsus).[41]

60. In 2021, the Novo Nordisk Defendants spent $307.6 million on Rybelsus ads, making it the No. 2 top spender that year.[42] In 2022, the Novo Nordisk Defendants spent $167.2 million on Rybelsus advertisements, making it the No. 7 top spender last year.[43] In 2022, the Novo Nordisk Defendants spent an estimated $123.9 million on Rybelsus television ads alone.[44] More than 60% of the Novo Nordisk Defendants' television advertisement budget was for a single ad "Down With Rybelsus" that sought to make the case for switching from other GLP-1RA's to Rybelsus.[45] The commercial featured an actor playing a physician with a voice-over stating that Rybelsus lowered A1C better than "a leading branded pill", referring to Merck & Co.'s diabetes drug, Januvia.[46] The television ad identified only one "serious side effect" of taking Rybelsus,

[40] *Ozempic TV Spot,* "Wake Up", iSpot.tv (September 2020), available at https://www.ispot.tv/ad/nvgx/rybelsus-wake-up (last visited on 9/20/23).
[41] Ritzau, *Novo Nordisk runs TV ads in US for multimillion-dollar sum*, MedWatch (April 26, 2023), available at https://medwatch.com/News/Pharma___Biotech/article15680727.ece (last visited on 9/20/23).
[42] Adams B, Fierce Pharma, *The top 10 pharma drug ad spenders for 2022*, https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022 (last visited on 9/20/23).
[43] Adams B, Fierce Pharma, *The top 10 pharma drug ad spenders for 2022*, https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022 (last visited on 9/20/23).
[44] Adams B, Fierce Pharma, *The top 10 pharma drug ad spenders for 2022*, https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022 (last visited on 9/20/23).
[45] *Down With RYBELSUS*, https://www.ispot.tv/ad/btuw/rybelsus-down-with-rybelsus (last visited on 9/20/23).
[46] *Down With RYBELSUS*, https://www.ispot.tv/ad/btuw/rybelsus-down-with-rybelsus (last visited on 9/20/23).

pancreatitis.[47] As a result of its GLP-1RA treatments, including Rybelsus, the Novo Nordisk Defendants forecast sales growth of 13% to 19% for 2023.[48]

61. On July 5, 2023, it was reported that the Novo Nordisk Defendants had spent $11,000,000 on food and travel for doctors as part of their efforts to promote their GLP-1 medications, including Rybelsus. In 2022 alone, the Novo Nordisk Defendants bought more than 457,000 meals to educate doctors and other prescribers about its GLP-1, with nearly 12,000 doctors receiving more than 50 meals and snacks from the Novo Nordisk Defendants. In 2022, the Novo Nordisk Defendants also spent $2 million flying doctors to London, Paris, Orlando, and Honolulu related to its GLP-1s.[49]

62. On July 21, 2023, it was reported that Novo Nordisk had purchased more than 457,000 meals—at a total price of more than $9 million—to educate prescribers about its GLP-1s. The president and CEO of the Alliance of Community, who was interviewed for the article, described the expenditures as "outrageous" and suggested that the millions Novo Nordisk spent marketing its drugs to prescribers would be better used furthering research about their potential side effects and long-term effectiveness. The author pointed out that research published in spring 2023 "suggested that GLP-1s could put patients at an elevated risk of a potentially fatal gastrointestinal condition that requires surgery."[50]

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[47] *Down With RYBELSUS*, https://www.ispot.tv/ad/btuw/rybelsus-down-with-rybelsus (last visited on 9/20/23).
[48] Adams B, Fierce Pharma, *The top 10 pharma drug ad spenders for 2022*, https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022 (last visited on 9/20/23).
[49] Florko, N, *Novo Nordisk bought prescribers over 450,000 meals and snacks to promote drugs like Ozempic,* National Center for Health Research (July 5, 2023), available at https://www.center4research.org/novo-nordisk-gave-doctors-450000-meals-ozempic (last visited on 9/20/23).
[50] Erin Prater*, Ozempic manufacturer Novo Nordisk spent $11 million last year 'wining and dining' doctors. Experts slam the move as a breach of doctor-patient trust,* Fortune Well (July 21, 2023), available at https://fortune.com/well/2023/07/21/ozempic-novo-nordisk-meals-travel-prescribing-doctors/ (last visited on 9/19/23).

63. As a result of the Novo Nordisk Defendants' advertising and promotion efforts, Rybelsus has been widely used throughout the United States. In its inaugural year alone, Rybelsus "defied full-year sales expectations in 2020" topping $350 million. Over 80% of these Rybelsus prescriptions were from patients new to the GLP-1RA class, not significantly dipping into the Novo Nordisk Defendants' already strong market position with Ozempic.[51]

64. On TikTok, there are currently over 54.5M views on #rybelsus-review, 46 million views on #rybelsus, and 44.1M views on #rybelsus-experience.[52]

65. On June 15, 2023, NBC News published a report about the thousands of weight loss advertisements on social media for Defendants' drugs, including Rybelsus. While many of those ads were found to be from online pharmacies, medical spas, and diet clinics, as of June of 2023 the Novo Nordisk Defendants were still running online social-media ads for their semaglutide products, despite claiming in May that they would stop running ads due to a shortage of the drug.[53]

66. On June 25, 2023, NBC News reported that the Novo Nordisk Defendants anticipate filing for FDA approval for Rybelsus for weight loss in people who are obese or overweight, and do not have type 2 diabetes. ADA chief scientist, Dr. Robert Gabbay, called the development "a game changer."[54]

67. At all relevant times, Novo Nordisk was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Rybelsus.

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[51] *Novo Nordisk's Rybelsus launch defied 2020 full-year sales expectations, despite the economic impacts of the Covid-19 pandemic*, Pharmaceutical Technology (February 12, 2001), available at https://www.pharmaceutical-technology.com/comment/novo-nordisk-rybelsus-launch-sales (last visited on 9/20/23).

[52] https://www.tiktok.com/discover/rybelsus-review; https://www.tiktok.com/discover/rybelsus; https://www.tiktok.com/discover/rybelsus-experience (last visited on 9/22/23).

[53] Ingram D, *More than 4,000 ads for Ozempic-style drugs found running on Instagram and Facebook*, NBC News (June 15, 2023), available at https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602 (last visited on 9/19/23).

[54] Lovelace, B, *Effective pills for weight loss, including an oral version of Ozempic, are on the horizon,* NBC News (June 25, 2023), available at https://www.nbcnews.com/health/health-news/effective-pills-weight-loss-oral-version-ozempic-are-horizon-rcna90981 (last visited on 9/20/23).

F. Eli Lilly's Marketing and Promotion of Trulicity

68. Trulicity has been the top earning product for Eli Lilly for the past several years, with the drug bringing in more than $5.6 billion in revenue in 2022 in the United States alone. The demand for Trulicity is largely driven by Eli Lilly's advertising, which costs the company more than $1 billion annually. Indeed, Eli Lilly advertises Trulicity through its websites, press releases, in-person presentations, the drug's label, print materials, social media, and other public outlets. Eli Lilly's advertisements tout the health benefits of Trulicity, without warning of the risk of gastroparesis or its sequelae.[55]

69. Upon the approval of Trulicity on September 18, 2014, an Eli Lilly spokesperson indicated that Trulicity "has demonstrated proven glycemic control, only has to be taken once weekly, and comes in an easy-to-use pen."[56] Although a press release accompanying Trulicity's approval acknowledged that "nausea," "vomiting" abdominal pain" were among the most common adverse reactions reported with use of Trulicity, the press release did not indicate that those common adverse reactions were symptoms of gastroparesis or warn of the risk of gastroparesis or its sequelae. Instead, the press release merely indicated that "Trulicity has not been studied in patients with ... [pre-existing] gastroparesis."[57]

[55] Eli Lilly and Company 2022 Annual Report, available at https://investor.lilly.com/static-files/2f9b7bb1-f955-448d-baa2-c4343d39ee62 (last visited Nov. 15, 2023).
[56] *Lilly's Trulicity (dulaglutide) Now Available in U.S. Pharmacies,* PR Newswire (Nov. 10, 2014), available at https://www.prnewswire.com/news-releases/lillys-trulicity-dulaglutide-now-available-in-us-pharmacies-282138401.html (last visited Nov. 15, 2023).
[57] *News Release: FDA Approves Trulicity (dulaglutide), Lilly's Once-Weekly Therapy for Adults with Type 2 Diabetes,* Eli Lilly (Sept. 18, 2014), available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-trulicitytm-dulaglutide-lillys-once-weekly-therapy (last visited Nov. 15, 2023).

70. Following the FDA's approval of Trulicity in September 2014, Eli Lilly launched its direct-to-consumer ad campaign in 2015, with print and digital ads first appearing in September 2015 and the first Trulicity television ad launching on October 19, 2015.[58]

71. On November 5, 2018, in a press release announcing Trulicity's "superiority in reduction of cardiovascular events," as shown by an internal clinical trial, Eli Lilly acknowledged that "[t]he safety profile of Trulicity ... was generally consistent with the GLP-1 receptor agonist class." Although the press release included a section titled "Important Safety Information for Trulicity," the press release did not warn that Trulicity can cause gastroparesis or its sequelae.[59]

72. In a February 21, 2020, press release announcing Trulicity's new indication for reduction of cardiovascular risk, Eli Lilly touted Trulicity's ability to reduce the risk of major adverse cardiovascular events, including heart attack and stroke, even in adults without established cardiovascular disease.[60] In the press release, Eli Lilly again indicated that "Trulicity's safety profile [is] consistent with the GLP-1 receptor agonist (RA) class," but despite warning of certain risks, the press release did not warn of the risk of gastroparesis, or its sequelae, associated with GLP-1RAs.

73. When announcing the approval of higher weekly doses of Trulicity in September 2020, Eli Lilly's press release indicated that "with the 3.0 and 4.5 [mg] doses available, people with type 2 diabetes who use Trulicity can benefit from additional A1C and weight loss as their

[58] Beth Snyder Bulik, *One year after FDA nod, Eli Lilly's Trulicity launches first consumer campaign,* Fierce Pharma (Oct. 19, 2015) https://www.fiercepharma.com/dtc-advertising/one-year-after-fda-nod-eli-lilly-s-trulicity-launches-first-consumer-campaign (last visited Nov. 15, 2023).
[59] *News Release: Trulicity (dulaglutide) demonstrates superiority in reduction of cardiovascular events for broad range of people with type 2 diabetes,* Eli Lilly (Nov. 5, 2018), available at https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-demonstrates-superiority-reduction (last visited Nov. 15, 2023).
[60] *News Release: Trulicity (dulaglutide) is the first and only type 2 diabetes medicine approved to reduce cardiovascular events in adults with and without established cardiovascular disease,* Eli Lilly (Feb. 21, 2020), available at https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-first-and-only-type-2-diabetes-medicine (last visited Nov. 15, 2023).

condition progresses."[61] Despite touting the off-label use of Trulicity for "weight loss," Eli Lilly did not warn of the associated risk of gastroparesis or its sequelae.

74. Around this same time, Robert H. Schmerling, MD, Senior Faculty Editor and Editorial Advisory Board Member at Harvard Health Publishing commented that the actors in the tv ads for Trulicity appeared notably thinner than the typical person with type 2 diabetes.[62]

75. In Summer 2021, in conjunction with Eli Lilly's sponsorship of the rescheduled Summer Olympics, Eli Lilly ran extensive television advertisements for Trulicity featuring Olympic gymnast Laurie Hernandez and her father, who has type 2 diabetes. The advertisement indicates that treatment with Trulicity is the "right choice" for people with type 2 diabetes but does not mention or warn about gastroparesis or its sequelae.[63]

76. In a similar January 2022 tv ad featuring Olympic figure skater Madison Chock and her mother, Eli Lilly again indicated that Trulicity was the "right choice" for people with type 2 diabetes. However, the ad did not warn that Trulicity can cause gastroparesis or its sequelae.[64]

77. In January 2022, the FDA determined that Eli Lilly's "10,800 Minutes" Instagram advertisement for Trulicity "ma[de] false or misleading claims and representations about the benefits and risks of Trulicity" and that the advertisement elicits "a misleading impression regarding the safety and effectiveness of Trulicity" that "minimizes the risks associated with the

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[61] *News Release: FDA approves additional doses of Trulicity (dulaglutide) for the treatment of type 2 diabetes,* Eli Lilly (Sept. 3, 2020) available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-additional-doses-trulicityr-dulaglutide-treatment (last visited Nov.15, 2023).
[62] Robert H. Schmerling, MD, *Harvard Health Ad Watch: A feel-good message about a diabetes drug,* Harvard Health Publishing (Sept. 18, 2020), available at https://www.health.harvard.edu/blog/harvard-health-ad-watch-a-feel-good-message-about-a-diabetes-drug-2020091620961 (last visited Nov. 15, 2023).
[63] *See* Trulicity TV advertisement, available at https://www.youtube.com/watch?v=eVA1vYV980w (last visited Nov. 15, 2023); Beth Snyder Bulik, *Lilly warms up for Olympics with Team USA athletes in ads for Trulicity, Emgality and Verzenio,* Fierce Pharma (July 7, 2021), available at https://www.fiercepharma.com/marketing/lilly-warms-up-for-olympics-team-usa-athletes-ads-for-trulicity-emgality-and-verzenio (last visited Nov. 15, 2023).
[64] *See* Trulicity TV advertisement (Madison Chock), available at https://www.ispot.tv/ad/q3ii/trulicity-shes-got-this-featuring-madison-chock (last visited Nov. 15, 2023).

use of Trulicity." In response to a letter from the FDA, Eli Lilly temporarily removed the Trulicity Instagram account.[65] The FDA citation is emblematic of Eli Lilly's willingness to mislead and omit important information, focusing on profit over safety, specifically with respect to Trulicity.

78. That same month, it was reported that Trulicity was the most advertised drug on United States television, with Eli Lilly spending an estimated $36.2 million on national television advertisements in January 2022 alone.[66]

79. In another Trulicity tv ad that premiered in February 2022, Eli Lilly boasted that Trulicity "can help you lose up to ten pounds," a use for which Trulicity is not indicated, but did not mention the risk of gastroparesis or its sequelae.[67]

80. Similarly, Eli Lilly's website used to promote Trulicity (Trulicity.com) states that people taking Trulicity "lost up to 10 lbs," without disclosing the risk of gastroparesis.[68]

81. By the end of 2022, the market was experiencing shortages of Trulicity due to "high demand" driven by Eli Lilly's advertising.[69]

G. The Medical Literature and Clinical Trials Gave Defendants Notice of Gastroparesis Being Causally Associated with GLP-1RAs.

82. As previously noted, Ozempic (semaglutide), Rybelsus (semaglutide), and Trulicity (dulaglutide) belong to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

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[65] Fraiser Kansteiner, *FDA chides Eli Lilly for 2nd misleading ad in 2 months, this time for diabetes blockbuster Trulicity,* Fierce Pharma (Jan. 25, 2022), available at https://www.fiercepharma.com/marketing/fda-chides-lilly-for-second-misleading-ad-2-months-time-for-diabetes-med-trulicity (last visited Nov. 15, 2023).
[66] Ben Adams, *Eli Lilly's Trulicity dethrones Dupixent, taking January's TV ad spending crown,* Fierce Pharma (Feb. 4, 2022), available at https://www.fiercepharma.com/marketing/sanofi-regeneron-s-dupixent-de-throned-as-lilly-s-trulicity-takes-crown-january-s-biggest (last visited Nov. 15, 2023).
[67] Trulicity TV advertisement ("Father-Son"), available at https://www.ispot.tv/ad/q4Kl/trulicity-father-son (last visited Nov. 15, 2023).
[68] *See* https://www.trulicity.com/what-is-trulicity#what-is-trulicity.
[69] https://www.fiercepharma.com/manufacturing/after-novos-wegovy-supply-woes-lillys-would-be-obesity-rival-tirzepatide-runs-scarce

83. Medications within the GLP-1RA class of drugs mimic the activities of physiologic GLP-1, which is a gut hormone that activates the GLP-1 receptor in the pancreas to stimulate the release of insulin and suppress glucagon.[70]

84. Because the risk of gastroparesis is common to the entire class of drugs, any published literature regarding the association between gastroparesis and *any* GLP-1RA (such as tirzepatide, exenatide, liraglutide, albiglutide, dulaglutide, lixisenatide, and semaglutide) should have put Defendants on notice of the need to warn patients and prescribing physicians of the risk of gastroparesis associated with these drugs.

85. In addition to pancreatic effects, the published medical literature shows that GLP-1 slows gastric emptying. As early as 2010, a study published in The Journal of Clinical Endocrinology & Metabolism indicated this effect.[71]

86. Defendants knew or should have known of this risk of gastroparesis from the clinical trials, medical literature, and case reports.

87. A 2016 trial funded by Novo Nordisk measuring semaglutide and cardiovascular outcomes in patients with type 2 diabetes found more gastrointestinal disorders in the semaglutide group than in the placebo group, including a severe adverse event report of impaired gastric emptying with semaglutide 0.5 mg together with other serious gastrointestinal adverse events such

[70] Hinnen D, *Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes*, 30(3) Diabetes Spectr., 202–210 (August 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556578/ (visited on 9/26/23).
[71] Deane AM et al., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia*, 95(1) J Clinical Endo Metabolism, 225-221 (January 1, 2010), available at https://academic.oup.com/jcem/article/95/1/215/2835243 (visited on 9/26/23); American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at 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 (visited on 9/26/23).

as abdominal pain (upper and lower), intestinal obstruction, change of bowel habits, vomiting, and diarrhea.[72]

88. Two subjects in a semaglutide trial pool by Novo Nordisk reported moderate adverse events of impaired gastric emptying and both subjects permanently discontinued treatment due to the adverse events. Three subjects also reported mild adverse events of impaired gastric emptying in the semaglutide run-in period of trial 4376. The cardiovascular outcomes trials included two cases of gastroparesis with the first subject being diagnosed with severe gastroparesis after one month in the trial and second subject being diagnosed with gastroparesis after approximately two months in the trial.

89. A study published in 2017 evaluated the effect of GLP-1RAs on gastrointestinal tract motility and residue rates and explained that "GLP-1 suppresses gastric emptying by inhibiting peristalsis of the stomach while increasing tonic contraction of the pyloric region." The study authors concluded that the GLP-1RA drug liraglutide "exhibited gastric-emptying delaying effects" and "the drug also inhibited duodenal and small bowel movements at the same time."[73]

90. Another study in 2017 reviewed the survey results from 10,987 patients and 851 physicians and found that "GI-related issues were the top two patient-reported reasons for GLP-1RA discontinuation in the past 6 months, with 'Made me feel sick' as the most frequently reported reason (64.4%), followed by 'Made me throw up' (45.4%)."[74] As explained above, these are symptoms of gastroparesis.

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[72] Marso, SP, et al., Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes, N. Eng. J. Med. 375:1834-1844 (November 2016), available at https://www.nejm.org/doi/10.1056/NEJMoa1607141 (visited on 10/19/23).

[73] Nakatani Y et al., *Effect of GLP-1 receptor agonist on gastrointestinal tract motility and residue rates as evaluated by capsule endoscopy*, 43(5) Diabetes & Metabolism, 430-37 (October 2017), available at https://www.sciencedirect.com/science/article/pii/S1262363617301076 (visited on 9/26/23).

[74] Sikirica M et al., *Reasons for discontinuation of GLP1 receptor agonists: data from a real-world cross-sectional survey of physicians and their patients with type 2 diabetes*, 10 Diabetes Metab. Syndr. Obes., 403-412 (September 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5630073/

91. A 2019 study of the GLP-1RA drug dulaglutide identified adverse events for impaired gastric emptying and diabetic gastroparesis.

92. 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 drugs can exacerbate the symptoms of diabetic gastroparesis. ... Thus, GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis."[75]

93. In a September 2020 article funded and reviewed by Novo Nordisk, scientists affiliated with Novo Nordisk reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes. More patients permanently discontinued taking oral semaglutide (11.6%) than placebo (6.5%) due to adverse events. The most common adverse events associated with semaglutide were nausea (2.9% with semaglutide versus 0.5% with placebo), vomiting (1.5% with semaglutide versus 0.3% with placebo), and diarrhea (1.4% with semaglutide versus 0.4% with placebo). Injectable semaglutide had a discontinuation rate of 11.5-14.5% (versus 5.7-7.6% with placebo) over a two-year period. The authors acknowledged the potential for severe gastrointestinal events, warning that "[f]or patients reporting severe adverse gastrointestinal reactions, it is advised to monitor renal function when initiating or escalating doses of oral semaglutide." For patients with other comorbidities, the study warned that "patients should be made aware of the occurrence of gastrointestinal adverse events

[75] 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/ (visited on 9/26/23).

with GLP-1RAs." The study further identified as one "key clinical take-home point" that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs."[76]

94. A July 2021 article funded and reviewed by Novo Nordisk considered 23 randomized control trials conducted across the United States, Japan, and China and concluded that "gastrointestinal disturbances" were "well-known" side effects associated with semaglutide use. When compared with placebos, the subcutaneous (injection) form of the drug induced nausea in up to 20% of patients (versus up to 8% on the placebo group), vomiting in up to 11.5% of patients (versus up to 3% in the placebo group) and diarrhea in up to 11.3% of patients (versus up to 6% in the placebo group). Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for gastrointestinal related adverse events, with some trials experiencing 100% discontinuation due to gastrointestinal related adverse events. The mean value of gastrointestinal related adverse events that led to discontinuation averaged 57.75%. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"[77]

95. An October 2021 article in the Journal of Investigative Medicine ("JIM") concluded that because gastroparesis can be associated with several medications, "[i]t is crucial to identify the causative drugs as discontinuation of the drug can result in resolution of the symptoms[.]" In diabetics, making this determination can be particularly "tricky" because both diabetes and GLP-1RAs can cause delayed gastric emptying. As such, "the timeline of drug initiation and symptom onset becomes of the upmost importance." The authors reviewed two case reports (discussed

[76] Mosenzon O, Miller EM, & Warren ML, *Oral semaglutide in patients with type 2 diabetes and cardiovascular disease, renal impairment, or other comorbidities, and in older patients*, Postgraduate Medicine (2020), 132:sup2, 37-47, available at https://doi.org/10.1080/00325481.2020.1800286 (visited on 9/26/23).
[77] Smits MM & Van Raalte DH (2021), *Safety of Semaglutide*, Front. Endocrinol., 07 July 2021, doi: 10.3389/fendo.2021.645563, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8294388/ (visited on 9/26/23).

below) and concluded that history taking and making an accurate diagnosis of diabetic gastroparesis versus medication-induced gastroparesis is critical.[78]

96. Case Report #1 in JIM involved a 52-year-old female with long-standing (10 years) well-controlled, type 2 diabetes who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis symptoms. The patient was referred with a 7-month history of post-prandial epigastric pain, accompanied by fullness, bloating, and nausea. A gastric emptying study showed a 24% retention of isotope in the patient's stomach at four hours, indicative of delayed gastric emptying. The patient discontinued semaglutide and her symptoms resolved after six weeks. The case report authors concluded that "thorough history taking revealed the cause [of gastroparesis] to be medication induced."[79]

97. Case Report #2 in JIM involved a 57-year-old female with a long-standing (16 years) type 2 diabetes who had been taking weekly dulaglutide injections (another GLP-1RA) for 15 months and suffering from abdominal bloating, nausea, and vomiting for 12 of those months. A gastric emptying study showed 35% retention of isotope in the patient's stomach at four hours, indicating delayed gastric emptying. After discontinuing dulaglutide, the patient experienced a gradual resolution of symptoms over a four-week period.[80]

98. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[81]

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[78] 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/ (visited on 9/26/23).
[79] 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/ (visited on 9/26/23).
[80] 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/ (visited on 9/26/23).
[81] Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).

99. An October 2022 study analyzed 5,442 GLP-1RA adverse gastrointestinal events. 32% were serious, including 40 deaths, 53 life-threatening conditions, and 772 hospitalizations. The primary events were nausea and vomiting. There were also adverse events for impaired gastric emptying.[82]

100. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[83]

101. In February 2023, a longitudinal study of GLP-1RA (dulaglutide) reported adverse events for nausea and vomiting, and one adverse event of impaired gastric emptying.[84]

102. On March 28, 2023, a case study concluded that impaired gastric emptying is "a significant safety concern, especially since it is consistent with the known mechanism of action of the drug."[85]

103. On June 29, 2023, the American Society of Anesthesiologists ("ASA") warned that patients taking semaglutide and other GLP-1RAs should stop the medication at least a week before elective surgery because these medications "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." The ASA also

[82] Shu, *Gastrointestinal adverse events associated with semaglutide: A pharmacovigilance study based on FDA adverse event reporting system*, Front. Public Health (Oct. 20, 2022). (https://doi.org/10.3389%2Ffpubh.2022.996179).
[83] Mirsha, *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).
[84] Chin, *Safety and effectiveness of dulaglutide 0.75 mg in Japanese patients with type 2 diabetes in real-world clinical practice: 36 month postmarketing observational study*, J Diabetes Investig (Feb. 2023) (https://doi.org/10.1111%2Fjdi.13932).
[85] Klein, Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report, Can J. Anesth (Mar. 28, 2023) (https://doi.org/10.1007/s12630-023-02440-3).

warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[86]

104. News sources have identified the potential for serious side effects in users of Ozempic, including gastroparesis, leading to hospitalization.[87] For example, NBC News reported in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable, and one user said that five weeks into taking the medication she found herself unable to move off the bathroom floor because she had "vomited so much that [she] didn't have the energy to get up."[88] CNN reported in July that one Ozempic user diagnosed with gastroparesis vomits so frequently that she had to take a leave of absence from her teaching job.[89]

105. A July 25, 2023, article in Rolling Stone magazine—"*Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell*'"—highlighted three patients who have suffered severe gastrointestinal related events, including gastroparesis, as a result of their use of GLP-1RAs. Patient 1 (female, age 37) reported incidents of vomiting multiple times per day and being unable to eat. The patient's physician diagnosed her with severe gastroparesis and concluded that her problems were caused and/or exacerbated by her use of a GLP-1RA medication. Patient 2

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[86] American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at 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 (visited on 9/26/23).

[87] Penny Min, *Ozempic May Cause Potential Hospitalizations*, healthnews (June 26, 2023), available at https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/ (visited on 9/26/23); Elizabeth Laura Nelson, *These Are the 5 Most Common Ozempic Side Effects, According to Doctors*, Best Life (April 3, 2023), available at https://bestlifeonline.com/ozempic-side-effects-news/ (visited on 9/26/23); Cara Shultz, *Ozempic and Wegovy May Cause Stomach Paralysis in Some Patients*, People (July 26, 2023), available at https://people.com/ozempic-wegovy-weight-loss-stomach-paralysis-7565833 (visited on 9/26/23); CBS News Philadelphia, *Popular weight loss drugs Ozempic and Wegovy may cause stomach paralysis, doctors warn* (July 23, 2023), available at https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomach-paralysis/ (visited on 9/26/23).

[88] Bendix A, Lovelace B Jr., *What it's like to take the blockbuster drugs Ozempic and Wegovy, from severe side effects to losing 50 pounds*, NBC News (Jan. 29, 2023), available at https://www.nbcnews.com/health/health-news/ozempic-wegovy-diabetes-weight-loss-side-effects-rcna66493 (visited on 9/26/23).

[89] Brenda Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis/index.html (visited on 9/26/23).

(female) used Ozempic for one year and reported incidents of vomiting, including multiple times per day. The patient's physician diagnosed her with severe gastroparesis related to her Ozempic use. Patient 3 (female, age 42) experienced severe nausea both during and after she discontinued use of a GLP-1RA. In a statement to Rolling Stone, Novo Nordisk acknowledged that "[t]he most common adverse reactions, as with all GLP-1 RAs, are gastrointestinal related." Novo Nordisk further stated that while "GLP-1 RAs are known to cause a delay in gastric emptying, … [s]ymptoms of delayed gastric emptying, nausea and vomiting are listed as side effects." Novo Nordisk did not claim to have warned consumers about gastroparesis, or other severe gastrointestinal issues.[90]

106. On July 25, 2023, CNN Health reported that patients taking Ozempic have 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." Another patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.[91]

107. On July 26, 2023, a New York hospital published an article to its online health blog section "What You Need to Know About Gastroparesis" entitled "Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines." It was reported that a growing number of gastroparesis cases had been seen in people taking GLP-1RAs. The article noted that the weight-loss drugs can delay or decrease the contraction of muscles that mix and propel contents in the gastrointestinal tract leading to delayed gastric emptying. One concern raised was that patients and

[90] CT Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601 (visited on 9/26/23).
[91] Brenca Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed,* CNN Health (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis (last visited on 9/26/23).

doctors often assume the symptoms of gastroparesis are reflux or other gastrointestinal conditions, meaning it may take a long time for someone to be diagnosed correctly.[92]

108. In an October 5, 2023, Research Letter published in the Journal of the American Medical Association ("JAMA"), the authors examined gastrointestinal adverse events associated with GLP-1RAs used for weight loss in clinical setting and reported that use of GLP-1RAs compared with use of bupropion-naltrexone was associated with increased risk of pancreatitis, gastroparesis, and bowel obstruction.[93] The study found that patients prescribed GLP-1RAs were at 4.22 times higher risk of intestinal obstruction and at 3.67 times higher risk of gastroparesis.

109. The medical literature listed above is not a comprehensive list, and several other case reports have indicated that GLP-1RAs can cause gastroparesis and impaired gastric emptying.[94]

110. Defendants knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae, but they ignored the causal association. Defendants' actual and constructive knowledge derived from their clinical studies, case reports, medical literature, including the medical literature and case reports referenced above in this Complaint.

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[92] *Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines*, Montefiore Health Blog article (released July 26, 2023), available at https://www.montefiorenyack.org/health-blog/what-you-need-know-about-gastroparesis (last visited on 9/26/2023).

[93] Mohit Sodhi, et al., *Risk of Gastrointestinal Adverse Events Associated with Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss*, JAMA (published online October 5, 2023), available at https://jamanetwork.com/journals/jama/fullarticle/2810542 (last visited 10/19/23).

[94] Cure, *Exenatide and Rare Adverse Events*, N. Eng. J. Med. (May 1, 2008) (https://doi.org/10.1056/nejmc0707137); Rai, *Liraglutide-induced Acute Gastroparesis*, Cureus (Dec. 28, 2018) (https://doi.org/10.7759%2Fcureus.3791); Guo, *A Post Hoc Pooled Analysis of Two Randomized Trials*, Diabetes Ther (2020) (https://doi.org/10.1007%2Fs13300-020-00869-z); Almustanyir, *Gastroparesis With the Initiation of Liraglutide: A Case Report*, Cureus (Nov. 28, 2020) (https://doi.org/10.7759/cureus.11735); Ishihara, *Suspected Gastroparesis With Concurrent Gastroesophageal Reflux Disease Induced by Low-Dose Liraglutide*, Cureus (Jul. 16, 2022) (https://doi.org/10.7759/cureus.26916); Preda, *Gastroparesis with bezoar formation in patients treated with glucagon-like peptide-1 receptor agonists: potential relevance for bariatric and other gastric surgery*, BJS Open (Feb. 2023) (https://doi.org/10.1093%2Fbjsopen%2Fzrac169).

111. On information and belief, Defendants not only knew or should have known that their GLP-1RAs cause delayed gastric emptying, resulting in risks of gastroparesis, but they may have sought out the delayed gastric emptying effect due to its association with weight loss. For example, a recent study published in 2023 notes that "it has been previously proposed that long-acting GLP-1RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying,]" and the study authors suggested "further exploration of peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake."[95]

H. Defendants Failed to Warn of the Risk of Gastroparesis from Ozempic, Rybelsus, and Trulicity

112. The Prescribing Information for Ozempic (the "label") discloses "Warnings and Precautions" and "Adverse Reactions" but does not adequately warn of the risk of gastroparesis and its sequelae.[96]

113. The Ozempic label lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Ozempic patients, but it does not include these adverse reactions in its "Warnings and Precautions" section, nor does it warn that these adverse reactions are symptoms of more severe conditions, including gastroparesis. In fact, gastroparesis is not mentioned at all in the label.

114. Instead of properly disclosing gastrointestinal risks, the label discloses delayed gastric emptying in the "Drug Interaction" section and notes that Ozempic "may impact absorption of concomitantly administered oral medications." Similarly, in the "Mechanism of Action"

[95] Jensterle M et al., *Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity*, 25(4) Diabetes Obes. Metab. 975-984 (April 2023), available at https://dom-pubs.onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944 (visited on 9/26/23).
[96] https://www.novo-pi.com/ozempic.pdf

section, the label minimizes gastrointestinal risks by stating that "[t]he mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase." These statements only describe the drug's mechanism of action and do not disclose gastroparesis as a ***risk*** of taking Ozempic, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Ozempic.

115. Similarly, Novo Nordisk's main promotional website for Ozempic (ozempic.com) includes a variety of information about the benefits of Ozempic relating to blood sugar, cardiovascular health, and weight loss, as well as "Important Safety Information" – however, Novo Nordisk does not disclose the risk of gastroparesis within the "Important Safety Information" section of its promotional website.[97]

116. In January 2020, Novo Nordisk removed the "Instructions" portion from Section 17 "Patient Counseling Information" of the Ozempic label, which had instructed prescribers to "[a]dvise patients that the most common side effects of Ozempic are nausea, vomiting, diarrhea, abdominal pain and constipation." These instructions were present in the 2017 and 2019 labels.

117. The 2017 and 2019 labels for Ozempic also instructed physicians that "vomiting … decreases over time in the majority of patients." As a result, a physician would not only fail to appreciate vomiting as a symptom of gastroparesis but, even worse, would encourage a patient to continue using Ozempic despite symptoms of gastroparesis.

118. In its section on "Females and Males of Reproductive Potential," the Ozempic label advises female users to discontinue Ozempic at least 2 months before a planned pregnancy due to the long washout period for semaglutide. This demonstrates that Novo Nordisk knew or should

[97] *See* Ozempic.com (visited on 10/16/23).

have known that symptoms, such as continuous and violent vomiting, can linger long after the drugs are discontinued and shows the need to warn of gastroparesis and its sequelae.

119. From the date Novo Nordisk received FDA approval to market Ozempic until the present time, Novo Nordisk made, distributed, marketed, and/or sold Ozempic without adequate warning to Plaintiff's prescribing physician(s) and/or Plaintiff that Ozempic was causally associated with and/or could cause gastroparesis and its sequelae.

120. Novo Nordisk's failure to disclose information that they possessed regarding the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae, rendered the warnings for Ozempic inadequate.

121. The Prescribing Information for Rybelsus (the "Rybelsus label") discloses warnings, precautions, and adverse reactions, but it does not disclose the risk of gastroparesis. Instead, it discloses delayed gastric emptying under the "Drug Interactions" heading and notes that Rybelsus "has the potential to impact the absorption of other 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."[98] These statements do not disclose gastroparesis or delayed gastric emptying as ***risks*** of taking Rybelsus, nor do they disclose gastroparesis as a side effect or condition that can result as a consequence of taking Rybelsus.

122. The Rybelsus label lists nausea, abdominal pain, diarrhea, decreased appetite, vomiting and constipation as common adverse reactions reported in Rybelsus patients but does not

[98] Rybelsus prescribing information, available at http https://www.novo-pi.com/rybelsus.pdf (last visited on 9/20/23).

include vomiting in its "Warnings and Precautions" section, and it does not indicate a severity of risk.[99] Gastroparesis is not mentioned at all.

123. Similarly, the Novo Nordisk's main promotional website for Rybelsus (rybelsus.com) includes a variety of information about the benefits of Rybelsus relating to blood sugar and weight loss, as well as "Important Safety Information"; however, Novo Nordisk does not disclose any risks causally associated with gastroparesis within the "Important Safety Information" section or elsewhere on its promotional website.[100]

124. From the date Novo Nordisk received FDA approval to market Rybelsus until the present time, Novo Nordisk made, distributed, marketed, and/or sold Rybelsus without adequate warning to Plaintiff's prescribing physician(s) and/or Plaintiff that Rybelsus was causally associated with and/or could cause gastroparesis and its sequelae.

125. None of Novo Nordisk's additional advertising or promotional materials warned prescription providers or the general public of the risks of gastroparesis and its sequelae associated with Ozempic and Rybelsus.

126. Novo Nordisk's failure to disclose information that it possessed regarding the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae, rendered the warnings for Ozempic and Rybelsus inadequate

127. On information and belief, as a result of Novo Nordisk's inadequate warnings, the medical community at large, and Plaintiff's prescribing physician in particular, were not aware that Ozempic and Rybelsus can cause gastroparesis, nor were they aware that "common adverse reactions" listed on the labels might be sequelae of gastroparesis.

[99] Rybelsus prescribing information, available at http https://www.novo-pi.com/rybelsus.pdf (last visited on 9/20/23).
[100] *See* Rybelsus.com (last visited on 9/20/23).

128. On information and belief, had Novo Nordisk adequately warned Plaintiff's prescribing physician that Ozempic and Rybelsus are causally associated with gastroparesis and its sequelae, then the physician's prescribing decision would have changed by not prescribing Ozempic or Rybelsus, or by monitoring Plaintiff's health for symptoms of gastroparesis and discontinuing Ozempic and Rybelsus when the symptoms first started.

129. The Prescribing Information for Trulicity (the "label") discloses "Warnings and Precautions" and "Adverse Reactions" but does not adequately warn of the risk of gastroparesis and its sequelae.[101]

130. The Trulicity label lists nausea, vomiting, diarrhea, abdominal pain, and decreased appetite as the most common adverse reactions reported in Trulicity patients, but it does not include these adverse reactions in its "Warnings and Precautions" section, nor does it warn that these adverse reactions are symptoms of more severe conditions, including gastroparesis. While the Warnings and Precautions section indicates that "Use of TRULICITY may be associated with gastrointestinal adverse reactions, sometime severe," the warning is lacking in urgency and specificity.[102]

131. Instead of properly disclosing gastrointestinal risks, the label for Trulicity encourages prescribing physicians and patients to ignore the signs of gastroparesis and continue therapy with Trulicity because the Drug Interactions and Clinical Pharmacology sections of the label state that the delayed gastric emptying caused by Trulicity "is largest after the first dose and diminishes with subsequent doses."[103]

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[101] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).
[102] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).
[103] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).

132. Similarly, Eli Lilly's main promotional website for Trulicity (trulicity.com) includes a variety of information about the benefits of Trulicity relating to blood sugar, cardiovascular health, and weight loss, and includes a section about "Side Effects" and a sidebar containing a "SAFETY SUMMARY WITH WARNINGS." However, Eli Lilly does not disclose the risk of gastroparesis within either the "Side Effects" or "SAFETY SUMMARY WITH WARNINGS" sections of the website.[104]

133. Nothing in the label for Trulicity has ever disclosed gastroparesis as a ***risk*** of taking Trulicity.

134. Eli Lilly's failure to disclose information that it possessed regarding the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae, rendered the warnings for Trulicity inadequate.

135. On information and belief, as a result of Eli Lilly's inadequate warnings, the medical community at large, and Plaintiff's prescribing physician in particular, were not aware that Trulicity can cause gastroparesis, nor were they aware that "common adverse reactions" listed on the label might be sequelae of gastroparesis.

136. On information and belief, had Eli Lilly adequately warned Plaintiff's prescribing physician that Trulicity is causally associated with gastroparesis and its sequelae, then the physician's prescribing decision would have changed by not prescribing Trulicity, or by monitoring Plaintiff's health for symptoms of gastroparesis and discontinuing Trulicity when the symptoms first started.

137. None of Defendants' additional advertising or promotional materials warned prescription providers or the general public of the risks of gastroparesis and its sequelae.

[104] *See* Trulicity.com (last visited Nov. 15, 2023).

138. Defendants knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae. Defendants' actual and constructive knowledge derived from its clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced in this Complaint.

139. Upon information and belief, Defendants ignored the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae.

140. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from gastroparesis and its sequelae, which resulted in 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.

FIRST CAUSE OF ACTION
(NEGLIGENT FAILURE TO WARN –
AGAINST ALL DEFENDANTS)

141. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

142. North Carolina tort law imposes a duty on producers, manufacturers, distributors, lessors, and sellers of a product to exercise all reasonable care when producing, manufacturing, distributing, leasing, and selling their products.

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

144. Ozempic, Rybelsus and Trulicity were expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendants.

145. At all relevant times, and at the times Ozempic, Rybelsus and Trulicity left Defendants' control, Defendants knew or should have known that Ozempic, Rybelsus and Trulicity were unreasonably dangerous because Defendants did not adequately warn of the risk of gastroparesis and its sequelae, especially when used in the form and manner as provided by Defendants.

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

147. Despite the fact that Defendants knew or should have known that Ozempic, Rybelsus and Trulicity caused unreasonably dangerous injuries, Defendants continued to market Ozempic, Rybelsus and Trulicity to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

148. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of their failure to provide adequate warnings, as set forth herein.

149. At all relevant times, given its increased safety risks, Ozempic, Rybelsus and Trulicity were not fit for the ordinary purpose for which they were intended.

150. At all relevant times, given its increased safety risks, Ozempic, Rybelsus and Trulicity did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

151. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Ozempic, Rybelsus and Trulicity into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as gastroparesis and its sequelae.

152. At all relevant times, Defendants expressly warranted to Plaintiff and Plaintiff's prescribing physician(s) that Ozempic, Rybelsus and Trulicity were safe as an adjunct to diet and exercise to improve glycemic control and to reduce cardiovascular risks in adults with type 2 diabetes mellitus.

153. The Ozempic, Rybelsus and Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate warnings or instructions, as Defendants knew or should have known that the products created a risk of serious and dangerous injuries, including gastroparesis and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendants failed to adequately warn of said risk.

154. The Ozempic, Rybelsus and Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including gastroparesis and its sequelae, as well as other severe and permanent health consequences from Ozempic, Rybelsus and Trulicity, Defendant failed to provide adequate warnings to users and/or prescribers of the product, and

continued to improperly advertise, market and/or promote their products, Ozempic, Rybelsus and Trulicity.

155. The labels for Ozempic, Rybelsus and Trulicity were inadequate because they did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic, Rybelsus and Trulicity, including the increased risk of gastroparesis and its sequelae.

156. The labels for Ozempic, Rybelsus and Trulicity were inadequate because they did not warn and/or adequately warn that Ozempic, Rybelsus and Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae.

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

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

159. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic, Rybelsus and Trulicity, including the increased risk of gastroparesis and its sequelae.

160. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn that Ozempic, Rybelsus and Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae.

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

162. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and his/her/their reliance upon Defendant's warnings was reasonable.

163. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risks of gastroparesis and its sequelae, which are causally associated with Ozempic, Rybelsus and Trulicity, then the prescribing physician would not have prescribed Ozempic, Rybelsus and Trulicity and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic, Rybelsus and Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic, Rybelsus and Trulicity.

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

165. If Plaintiff had been warned of the increased risks of gastroparesis and its sequelae, which are causally associated with Ozempic, Rybelsus and Trulicity, then Plaintiff would not have used Ozempic, Rybelsus and Trulicity and/or suffered from gastroparesis and its sequelae.

166. If Plaintiff had been warned that Ozempic, Rybelsus and Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, then

Plaintiff would not have used Ozempic, Rybelsus and Trulicity and/or suffered gastroparesis and its sequelae.

167. If Plaintiff had been warned of the increased risks of gastroparesis and its sequelae, which is causally associated with Ozempic, Rybelsus and Trulicity, then Plaintiff would have informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Ozempic, Rybelsus and Trulicity.

168. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Ozempic, Rybelsus and Trulicity due to the risks of gastroparesis and its sequelae, or the lack of adequate testing for safety risks, then Plaintiff's prescribing physician(s) would not have prescribed Ozempic, Rybelsus and Trulicity.

169. By reason of the foregoing, Defendant has become liable to Plaintiff for the designing, marketing, promoting, distribution and/or selling of an unreasonably dangerous product, Ozempic, Rybelsus and Trulicity.

170. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore liable for the injuries sustained by Plaintiff.

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

172. Said inadequate warnings for Defendants' drugs Ozempic, Rybelsus and Trulicity were a substantial factor in causing Plaintiff's injuries.

173. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including gastroparesis and its sequelae, which resulted in other

severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

174. As a result of the foregoing acts and omissions, Plaintiff did incur medical, health, incidental, and related expenses, and requires and/or will require more health care and services. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SECOND CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY –
AGAINST ALL DEFENDANTS)

175. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

177. At all relevant times, Defendants expressly warranted to Plaintiff and Plaintiff's prescribing physician(s) that Ozempic, Rybelsus and Trulicity were safe and effective as an adjunct to diet and exercise to improve glycemic control and to reduce cardiovascular risks in adults with type 2 diabetes mellitus.

178. The aforementioned express warranties were made to Plaintiff and Plaintiff's prescribing physician(s) by way of Ozempic's and Trulicity's labels, websites, advertisements, promotional materials, and through other statements.

179. As a result of Defendants' express warranties, Plaintiff's prescribing physician(s) was/were induced to prescribe Ozempic, Rybelsus and Trulicity to Plaintiff, and Plaintiff was induced to use Ozempic, Rybelsus and Trulicity.

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

181. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Ozempic, Rybelsus and Trulicity based upon their express warranties.

182. At all relevant times, Defendants knew or should have known that Ozempic, Rybelsus and Trulicity were unreasonably dangerous because of their increased risk of gastroparesis and its sequelae, especially when the drugs were used in the form and manner as provided by Defendants.

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

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

185. The unreasonably dangerous characteristics of Ozempic, Rybelsus and Trulicity were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drugs' characteristics.

186. At the time Ozempic, Rybelsus and Trulicity left Defendants' control, Ozempic, Rybelsus and Trulicity did not conform to Defendants' express warranties because Ozempic,

Rybelsus and Trulicity were not safe to use as an adjunct to diet and exercise to improve glycemic control or to reduce cardiovascular risks in adults with type 2 diabetes mellitus, in that they were causally associated with increased risks of gastroparesis and its sequelae.

187. The express warranties made by Defendants regarding the safety of Ozempic, Rybelsus and Trulicity were made with the intent to induce Plaintiff to use the products and/or Plaintiff's prescribing physician(s) to prescribe the products.

188. Defendants knew and/or should have known that by making the express warranties to Plaintiff and/or Plaintiff's prescribing physician(s), it would be the natural tendency of Plaintiff to use Ozempic, Rybelsus and Trulicity, and/or the natural tendency of Plaintiff's prescribing physician(s) to prescribe Ozempic, Rybelsus and Trulicity.

189. Plaintiff and Plaintiff's prescribing physician(s), as well as members of the medical community, relied on the express warranties of Defendants identified herein.

190. Had Defendants not made these express warranties, Plaintiff would not have used Ozempic, Rybelsus and Trulicity and/or, upon information and belief, Plaintiff's prescribing physician(s) would not have prescribed Ozempic, Rybelsus and Trulicity.

191. Plaintiff's injuries and damages were directly caused by Defendants' breach of the aforementioned express warranties.

192. Plaintiff's injuries and damages arose from a reasonably anticipated use of the products by Plaintiff.

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

194. Defendants' breach of express warranties for Ozempic, Rybelsus and Trulicity was a proximate cause of, and/or a substantial factor in causing, Plaintiff's injuries and damages.

195. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

196. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Ozempic, Rybelsus and Trulicity drugs.

197. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

THIRD CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY – AGAINST ALL DEFENDANTS)

198. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

200. Ozempic, Rybelsus and Trulicity were expected to and did reach the usual consumers, handlers, and persons encountering said product without substantial change in the

condition in which they were produced, manufactured, sold, distributed, and marketed by the Defendants.

201. At all relevant times, Defendants impliedly warranted to Plaintiff, Plaintiff's prescribing physician(s), and the medical community that Ozempic, Rybelsus and Trulicity were of merchantable quality and safe and fit for their ordinary purposes.

202. At all relevant times, Defendants knew or should have known that Ozempic, Rybelsus and Trulicity were unreasonably dangerous because of the increased risk of gastroparesis and its sequelae, especially when the drugs were used in the form and manner as provided by Defendants.

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

204. At the time Ozempic, Rybelsus and Trulicity left Defendants' control, they did not conform to Defendants' implied warranties because they were unfit for their ordinary purpose, in that they are causally associated with gastroparesis and its sequelae.

205. At the time Ozempic, Rybelsus and Trulicity left Defendants' control, Ozempic, Rybelsus and Trulicity did not confirm to Defendants' implied warranty and were unfit for their ordinary purposes because Defendants failed to provide adequate warnings of the drugs' causal association with increased risk of gastroparesis and its sequelae.

206. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense Ozempic, Rybelsus and Trulicity for use by their patients to improve glycemic control in adults with type 2 diabetes, to reduce cardiovascular risk, and/or to promote weight loss.

207. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Ozempic, Rybelsus and Trulicity for their ordinary purposes.

208. Despite the fact that Defendants knew or should have known that Ozempic, Rybelsus and Trulicity cause unreasonably dangerous injuries, such as gastroparesis and its sequelae, Defendants continued to market, distribute, and/or sell Ozempic, Rybelsus and Trulicity to consumers, including Plaintiff, without adequate warnings.

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

210. The unreasonably dangerous characteristics of Ozempic, Rybelsus and Trulicity were beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drugs' characteristics.

211. Plaintiff reasonably relied on Defendants' implied warranty of merchantability relating to Ozempic's, Rybelsus's and Trulicity's safety and efficacy.

212. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Ozempic, Rybelsus and Trulicity were of merchantable quality and safe and fit for their intended use.

213. Upon information and belief, Plaintiff's prescribing physician(s) relied on Defendants' implied warranty of merchantability and fitness for the ordinary use and purpose relating to Ozempic, Rybelsus and Trulicity.

214. Upon information and belief, Plaintiff's prescribing physician(s) reasonably relied upon the skill and judgment of Defendants as to whether Ozempic, Rybelsus and Trulicity were of merchantable quality and safe and fit for their intended use.

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

216. Defendants herein breached the aforesaid implied warranty of merchantability because the drugs Ozempic, Rybelsus and Trulicity were not fit for their intended purposes.

217. Defendants' breaches of implied warranty of merchantability were a proximate cause of, and/or substantial factor in causing Plaintiff's injuries.

218. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

219. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

FOURTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT –
AGAINST ALL DEFENDANTS)

220. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

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

223. At all relevant times, Defendants knew or should have known that Ozempic, Rybelsus and Trulicity were unreasonably dangerous because of the increased risk of gastroparesis and its sequelae, especially when the drugs were used in the form and manner as provided by Defendants.

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

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

226. Although the Ozempic labels lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Ozempic patients, it does not mention gastroparesis as a risk of taking Ozempic, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Ozempic.

227. Although the Trulicity label lists nausea, vomiting, diarrhea, abdominal pain, and decreased appetite as common adverse reactions reported in Trulicity patients, it does not mention gastroparesis as a risk of taking Trulicity, nor does it disclose gastroparesis as a chronic condition that can result as a consequence of taking Trulicity.

228. Although the Rybelsus labels lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Rybelsus patients, it does not mention gastroparesis as a risk of taking Rybelsus, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Rybelsus.

229. Defendants' promotional websites for Ozempic, Rybelsus and Trulicity similarly do not disclose that Ozempic, Rybelsus and Trulicity are causally associated with increased risk of gastroparesis.

230. Defendants' omissions and concealment of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and adult type 2 diabetes patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Ozempic, Rybelsus and Trulicity for treatment of adults with type 2 diabetes.

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

232. Defendants knew that Plaintiff and Plaintiff's prescribing physicians (s) had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding Ozempic, Rybelsus and Trulicity, as set forth herein.

233. Upon information and belief, Plaintiffs prescribing physician(s) justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to dispense, provide, and prescribe Ozempic, Rybelsus and Trulicity.

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

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

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

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

238. Defendants' fraudulent concealment was a proximate cause of, and/or a substantial factor in causing Plaintiff's injuries.

239. As a direct and proximate result of the above stated omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries, including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

240. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

FIFTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION – AGAINST ALL DEFENDANTS)

241. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

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

244. At all relevant times, Defendants knew or should have known of the serious side effects of Ozempic, Rybelsus and Trulicity, including gastroparesis and its sequelae.

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

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

247. Defendants represented affirmatively and by omission on advertisements and on the labels of Ozempic, Rybelsus and Trulicity that Ozempic, Rybelsus and Trulicity were safe and effective drugs for treatment of adults with type 2 diabetes, despite being aware of increased risks of gastroparesis and its sequelae causally associated with using Ozempic, Rybelsus and Trulicity.

248. Defendants were aware or should have been aware that their representations were false or misleading, and they knew that they were concealing and/or omitting material information from Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community, and the general public.

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

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

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

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

253. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic, Rybelsus and Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, they would not have prescribed Ozempic, Rybelsus or

Trulicity, and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic, Rybelsus and Trulicity, so that Plaintiff can make an informed decision regarding Plaintiff's use of Ozempic, Rybelsus and Trulicity.

254. Plaintiff had no way to determine the truth behind Defendants' false and/or misleading statements, concealments and omissions surrounding Ozempic, Rybelsus and Trulicity, and Plaintiff reasonably relied on false and/or misleading facts and information disseminated by Defendants, including Defendants' omissions of material facts which Plaintiff had no way to know were omitted.

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

256. Had Plaintiff been told of the increased risk of gastroparesis and its sequelae causally associated with Ozempic, Rybelsus and Trulicity, Plaintiff would not have used Ozempic, Rybelsus or Trulicity and/or suffered gastroparesis and its sequelae.

257. Had Plaintiff been told of the lack of sufficient and/or appropriate testing of Ozempic, Rybelsus and Trulicity for safety risks, including gastroparesis and its sequelae, Plaintiff would not have used Ozempic, Rybelsus or Trulicity and/or suffered gastroparesis and its sequelae.

258. As a direct and proximate result of these false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries, including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

259. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SIXTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION –
AGAINST ALL DEFENDANTS)

260. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

261. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Ozempic, Rybelsus and Trulicity that were used by Plaintiff as hereinabove described.

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

263. At all relevant times, Defendants knew or should have known that Ozempic, Rybelsus and Trulicity were unreasonably dangerous because of the increased risk of gastroparesis and its sequelae, especially when the drugs were used in the form and manner as provided by Defendants.

264. Defendants, as manufacturers of pharmaceutical drugs, had a duty to disclose material information about Ozempic, Rybelsus and Trulicity to Plaintiff and Plaintiff's prescribing physician(s), namely that Ozempic, Rybelsus and Trulicity are causally associated with increased risk of gastroparesis and its sequelae,

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

266. Although the Ozempic labels lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Ozempic patients, it does not mention gastroparesis as a risk of taking Ozempic, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Ozempic.

267. Although the Trulicity label lists nausea, vomiting, diarrhea, abdominal pain, and decreased appetite as common adverse reactions reported in Trulicity patients, it does not mention gastroparesis as a risk of taking Trulicity, nor does it disclose gastroparesis as a chronic condition that can result as a consequence of taking Trulicity.

268. Although the Rybelsus labels lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Rybelsus patients, it does not mention gastroparesis as a risk of taking Rybelsus, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Rybelsus.

269. Defendants' promotional websites for Ozempic, Rybelsus and Trulicity similarly do not disclose that Ozempic, Rybelsus and Trulicity are causally associated with increased risk of gastroparesis.

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

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

272. Defendants knew that Plaintiff and Plaintiff's prescribing physician(s) had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding Ozempic, Rybelsus and Trulicity, as set forth herein.

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

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

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

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

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

278. Defendants' fraudulent concealment was a proximate cause of, and/or substantial factor in causing, Plaintiff's injuries.

279. As a result of the above stated omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

280. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SEVENTH CAUSE OF ACTION
(UNFAIR TRADE/CONSUMER PROTECTION VIOLATIONS UNDER NORTH CAROLINA'S UNFAIR AND DECEPTIVE TRADE PRACTICES ACT § 75-1.1 et seq.)

281. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

282. Defendants deliberately and/or negligently misrepresented the safety of Ozempic, Rybelsus and Trulicity and concealed the risks attendant to the use of Ozempic, Rybelsus and Trulicity. Through their misrepresentations, Defendants' conduct had the tendency or capacity to deceive, and affected the decisions of consumers, particularly Plaintiff and Plaintiff's prescribing physician(s), to purchase, prescribe and use Ozempic, Rybelsus and Trulicity, and to exclude the option of not using Ozempic, Rybelsus and Trulicity for treatment.

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

a. Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of Ozempic, Rybelsus and Trulicity;

b. Representing that Ozempic, Rybelsus and Trulicity have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have;

c. Representing that Defendants' authors, key opinion leaders, consultants, and speakers do not have a sponsorship, approval, status, affiliation, or connection that they do have;

d. Representing that Ozempic, Rybelsus and Trulicity are of a particular standard, quality, or grade;

e. Concealing information that gastroparesis is a risk of taking Ozempic, Rybelsus and Trulicity and a chronic condition that can result as a consequence of taking Ozempic, Rybelsus and Trulicity;

f. Concealing information that Ozempic, Rybelsus and Trulicity had not been adequately and/or sufficiently tested for safety;

g. Engaging in other fraudulent or deceptive conduct which creates the likelihood of confusion or of misunderstanding, as alleged in this Complaint.

284. As a result of the above stated false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

285. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and Causes of Action and 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 hereby demands trial by jury as to all issues.

Dated: February 25, 2025 RESPECTFULLY SUBMITTED,

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