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
RONALD W. FEEZOR, Plaintiff, v. Novo Nordisk Inc. and Novo Nordisk A/S, Defendants.	COMPLAINT AND JURY DEMAND CIVIL ACTION NO.: 2:24-cv-5153

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 Kentucky as Plaintiff's designated venue ("Original Venue"). Plaintiff makes this selection based upon one (or more) of the following factors:

__X__ Plaintiff currently resides in Clinton, Kentucky.

__X__ Plaintiff purchased and used Defendant(s)' products in Clinton, Kentucky.

____ 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 Tennessee.

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

Plaintiff, RONALD W. FEEZOR, by Plaintiff's attorneys, The Gori Law Firm, P.C., upon information and belief, at all times hereinafter mentioned, alleges as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiff, RONALD W. FEEZOR, who was severely injured as a result of Plaintiff's use of Ozempic and Rybelsus, injectable / oral prescription medications, respectively, that are used to control blood sugar in adults with type 2 diabetes.

2. Ozempic and Rybelsus are also known as semaglutide. Ozempic and Rybelsus work by stimulating insulin production and reducing glucose production in the liver helping to lower blood sugar levels.

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

4. Ileus is "a temporary lack of the normal muscle contractions of the intestines."[1] Muscles in the intestines normally contract and relax, causing a wave-like motion called peristalsis, which moves food through the intestines. When ileus occurs, this peristalsis is slowed or stopped, preventing food, gas, and liquids from passing through the digestive tract. This causes pain,

[1] Parswa Ansari, *Ileus*, Merck Manual (April 2023), available at https://www.merckmanuals.com/home/digestive-disorders/gastrointestinal-emergencies/ (last visited on 10/16/23).

cramps, abdominal bloating, nausea, vomiting, severe constipation, and loss of appetite. When a person suffering from ileus eats solid food, a backlog of food particles may cause a partial or total obstruction of the intestines.[2]

5. Paralytic ileus, also known as a pseudo-obstruction, is the most severe form of ileus and occurs when nerves in the intestinal walls do not work as they should, and peristalsis is temporarily paralyzed. Paralytic ileus is a functional problem in which the muscles and nerves mimic an intestinal obstruction, even when there is no actual obstruction in the intestines; this causes food to be trapped in the intestines.[3]

6. Intestinal obstruction, which may also arise from ileus, refers to a partial or total blockage of the intestine, preventing food, liquids or gas from passing through.[4] This may cause the intestine to rupture, leaking harmful contents into the abdominal cavity, or "the blocked parts of the intestine can die, leading to serious problems."[5] Similar to ileus, symptoms of intestinal obstruction include cramps, abdominal pain, loss of appetite, constipation, vomiting, inability to have a bowel movement or pass gas, and swelling of the abdomen.[6] But in contrast to ileus, which refers to the slowing or stopping of peristalsis, generally from muscle or nerve problems, intestinal obstruction refers to the physical blockage of the digestive tract.[7]

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[2] Jayne Leonard, Youssef (Joe) Soliman, *What is Ileus?*, Medical News Today (March 13, 2023), available at https://www.medicalnewstoday.com/articles/322149 (last visited on 10/16/23).
[3] Cleveland Clinic, *Paralytic Ileus* (Oct. 8, 2021), available at https://my.clevelandclinic.org/health/diseases/21853-paralytic-ileus (last visited on 10/16/23); *see also* Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/diagnosis-treatment/drc-20351465?p=1 (last visited on 10/16/23).
[4] Kristeen Moore, E. Mimi Arquilla, *Bowel Obstruction and Blockage*, Healthline (March 15, 2023), available at https://www.healthline.com/health/intestinal-obstruction (last visited on 10/16/23).
[5] Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/symptoms-causes/syc-20351460 (last visited on 10/16/23); *see also* Kristeen Moore, E. Mimi Arquilla, *Bowel Obstruction and Blockage*, Healthline (March 15, 2023), available at https://www.healthline.com/health/intestinal-obstruction (last visited on 10/16/23).
[6] Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/symptoms-causes/syc-20351460 (last visited on 10/16/23).
[7] Jayne Leonard, Youssef (Joe) Soliman, *What is Ileus?*, Medical News Today (March 13, 2023), available at https://www.medicalnewstoday.com/articles/322149 (last visited on 10/16/23).

PARTY PLAINTIFF

7. Plaintiff, RONALD W. FEEZOR, is a citizen of the United States, and is a resident of the State of Kentucky.

8. Plaintiff is 61 years old.

9. Plaintiff used both Ozempic and then Rybelsus from 2022 to Fall, 2023.

10. Plaintiff purchased and used Defendants' products in Clinton, Kentucky.

11. Plaintiff's physician(s) ("prescribing physician(s)") prescribed the Ozempic and Rybelsus that was used by Plaintiff.

12. As a result of using Ozempic and Rybelsus, Plaintiff was caused to suffer an intestinal atony and, as a result, sustained severe and permanent personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

13. As a result of using Ozempic and Rybelsus, Plaintiff was caused to suffer from an intestinal atony, which resulted in, for example, severe nausea, vomiting, abdominal discomfort, and constipation, requiring additional medications to alleviate nausea, vomiting, abdominal discomfort, and constipation, numerous emergency room visits due to severe nausea, vomiting and abdominal discomfort to alleviate symptoms.

PARTY DEFENDANTS

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

15. 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.

16. Defendants Novo Nordisk Inc. and Novo Nordisk A/S are referred to collectively herein as "Novo Nordisk."

17. Novo Nordisk also designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic and Rybelsus.

FACTUAL BACKGROUND

A. FDA's Approval of Ozempic

18. 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 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."[8]

19. 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.[9]

20. 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

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

of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.[10] On January 16, 2020, the FDA approved sNDA 209637/S-003.[11]

21. 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.[12]

B. Novo Nordisk's Marketing and Promotion of Ozempic

22. 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."[13]

23. 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

[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 (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).

[11] 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).

[12] 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).

[13] *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).

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."[14]

24. 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.

25. 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.[15]

26. 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."[16]

27. 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.[17]

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

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

[16] *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).

[17] 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).

28. 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 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.[18]

29. 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."[19] 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.[20]

30. 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.[21]

31. 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

[18] 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).
[19] 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).
[20] 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).
[21] 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).

high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.[22] In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.[23]

32. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,[24] and currently has over 1.3 billion views.[25]

33. 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.[26]

34. 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."[27]

35. 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.

C. FDA's Approval of Rybelsus

36. On March 20, 2019, the Novo Nordisk Defendants announced the submission of a

[22] 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).
[23] 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).
[24] 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).
[25] https://www.tiktok.com/tag/ozempic (visited on 11/14/23).
[26] 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).
[27] 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).

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.[28]

37. 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.[29] On September 20, 2019, the FDA approved NDA 213051.[30]

38. 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.'"[31] On January 16, 2020, the FDA approved NDA 213051/S-001.[32]

39. 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.

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[28] *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).

[29] 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).

[30] 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).

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

[32] 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).

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.[33]

40. 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.[34]

41. 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 Rybelsus and provided links to its Medication Guide and Prescribing Information, but

[33] 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).
[34] *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).

gastroparesis was not identified as a side effect or risk.[35]

D. Novo Nordisk's Marketing and Promotion of Rybelsus

42. 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 … 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.[36]

43. 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

[35] 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).

[36] *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).

(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 allergic reactions as "serious side effects", they failed to list severe gastrointestinal events, including gastroparesis.[37]

44. 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.[38]

45. The Novo Nordisk Defendants promoted the safety and sale of Rybelsus in the

[37] *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).

[38] *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).

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.

46. 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.[39] Also, the Novo Nordisk Defendants identified only one "serious side effect" of taking Rybelsus in the ad, pancreatitis.

47. 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).[40]

48. In 2021, the Novo Nordisk Defendants spent $307.6 million on Rybelsus ads making it the No. 2 top spender that year.[41] In 2022, the Novo Nordisk Defendants spent $167.2 million on Rybelsus advertisements, making it the No. 7 top spender last year.[42] In 2022, the Novo Nordisk Defendants spent an estimated $123.9 million on Rybelsus television ads alone.[43] 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.[44] 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

[39] *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).
[40] 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).
[41] 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).
[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] *Down With RYBELSUS*, https://www.ispot.tv/ad/btuw/rybelsus-down-with-rybelsus (last visited on 9/20/23).

drug, Januvia.[45] The television ad identified only one "serious side effect" of taking Rybelsus, pancreatitis.[46] As a result of its GLP-1RA treatments, including Rybelsus, the Novo Nordisk Defendants forecast sales growth of 13% to 19% for 2023.[47]

49. 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 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.[48]

50. 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."[49]

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[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).
[47] 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).
[48] 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).
[49] 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).

51. 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.[50]

52. On TikTok, there are currently over 54.5M views on #rybelsus-review, 46 million views on #rybelsus, and 44.1M views on #rybelsus-experience.[51]

53. 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.[52]

54. 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."[53]

55. 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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[50] *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).

[51] 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).

[52] 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).

[53] 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).

E. The Medical Literature and Clinical Trials Gave Defendants Notice of Ileus and Intestinal Obstruction and Their Sequelae Being Causally Associated with GLP-1RAs.

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

2. 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.[54]

3. Because the risk of ileus, intestinal obstruction, and their sequelae are common to the entire class of drugs, any published literature regarding the association between ileus, intestinal obstruction, and their sequelae 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 ileus, intestinal obstruction, and their sequelae associated with these drugs.

4. In addition to pancreatic effects, the published medical literature shows that GLP-1 slows gastric emptying and intestinal motility. As explained above, slowing of gastrointestinal motility is what causes ileus and can lead to non-mechanical obstruction.

5. As early as 2010, a study published in The Journal of Clinical Endocrinology & Metabolism concluded that GLP-1 slows gastric emptying.[55]

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[54] 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).

[55] 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).

6. Defendants knew or should have known of the risks of ileus, intestinal obstruction, and their sequelae from the clinical trials, medical literature, and case reports.

7. In 2008, the New England Journal of Medicine noted that "serious complications" reported as adverse events for the GLP-1RA exenatide included "suspected ileus."[56]

8. In 2012, Japan's Pharmaceutical and Food Safety Bureau advised that "[i]ntestinal obstruction may occur" in patients taking the GLP-1RAs exenatide and liraglutide, and as a result "[p]atients should be carefully monitored, and if any abnormalities including severe constipation, abdominal distention, persistent abdominal pain, or vomiting are observed, administration of [the drugs] should be discontinued, and appropriate measures should be taken." The agency further reported that in the previous 1 year and 8 months, three cases of intestinal obstruction had been reported in liraglutide users "for which causality [associated with] the drug could not be ruled out." At least one of those patients was diagnosed with ileus.[57]

9. A 2013 article by a co-author who had participated on Novo Nordisk advisory boards, explained that "[a]cute, intravenous infusion of GLP-1 (in pharmacological doses) slows gastric emptying markedly in both healthy subjects and patients with type 2 diabetes in a dose-dependent manner by mechanisms that include relaxation of the proximal stomach, reduction of antral and duodenal motility, and an increase in pyloric tone, and which involve vagal pathways."[58]

10. In 2013, the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) received a "safety communication from the Japanese medicines agency …

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[56] Ahmad, et al., *Exenatide and Rare Adverse Events*, 358 New Eng. J. Med. 1969-1972 (May 2008), available at https://www.nejm.org/doi/full/10.1056/nejmc0707137#:~:text=In%20patients%20with%20gastroparesis%2C%20exenatide,in%20patients%20during%20exenatide%20treatment. (last visited Nov. 16, 2023).

[57] Pharmaceuticals and Medical Devices Safety Information No. 291, Pharmaceutical and Food Safety Bureau (June 2012), available at https://www.pmda.go.jp/files/000153459.pdf (last visited Nov. 16, 2023).

[58] Marathe C, *Relationships Between Gastric Emptying, Postprandial Glycemia, and Incretin Hormones*, 36(5) Diabetes Care, 1396-1405 (April 13, 2013), available at https://diabetesjournals.org/care/article/36/5/1396/29534/Relationships-Between-Gastric-Emptying (last visited October 26, 2023).

reporting intestinal obstruction in patients treated with" GLP-1RAs. As a result, PRAC searched EudraVigilance "for intestinal obstruction and related terms" and retrieved 59 cases for the GLP-1RAs exenatide and liraglutide, leading PRAC to recommend appropriate amendments to the product information.[59] Notably, Novo Nordisk manufactures and markets liraglutide under the brand names Saxenda and Victoza.

11. By 2014, animal studies with the GLP-1RA albiglutide demonstrated increased rates of morbidity and mortality in lactating mice, consistent with lactational ileus syndrome.

12. 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 as abdominal pain (upper and lower), intestinal obstruction, change of bowel habits, vomiting, and diarrhea.[60]

13. 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.

14. 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

[59] European Medicine Agency, Pharmacovigilance Risk Assessment Committee, minutes of meeting (January 7-10, 2013) available at https://www.ema.europa.eu/en/documents/minutes/minutes-prac-meeting-7-10-january-2013_.pdf (last visited 10/20/23).
[60] 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).

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."[61]

15. 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%)."[62] As explained above, these are symptoms of ileus and intestinal obstruction.

16. A 2019 study of the GLP-1RA drug dulaglutide identified adverse events for impaired gastric emptying.

17. In May 2020, the Journal of the Endocrine Society reported a case of a 52-year-old male, with no history of abdominal surgeries, who presented with a partial bowel obstruction that progressed to a full obstruction requiring life-threatening surgical intervention. The patient had begun taking Rybelsus (dulaglutide) three weeks prior to hospital admission. The authors noted that "[d]ulaglutide (Rybelsus) is associated with small bowel obstruction" but that "the actual mechanism [of] Rybelsus causing the small bowel obstruction is unknown." The authors further reported that "[a] total of 8 cases" of bowel obstruction in Rybelsus users "were reported in 2017 with a majority of them requiring surgical intervention." In the subject patient, the authors concluded that because "[a]ll the other cause[s] of small bowel obstructions had been ruled out[,] ... Rybelsus was the culprit of this unfortunate case."[63]

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[61] 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).

[62] 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/

[63] Gandhi, et al., *Dulaglutide Commonly Known as Rybelsus; An Anti-Diabetic Medication Causing Small Bowel Obstruction*, 4 J. Endocrine Soc. A309 (May 2020), available at https://academic.oup.com/jes/article/4/Supplement_1/MON-681/5832661 (last visited Nov. 16, 2023).

18. 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 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."[64]

19. 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

[64] 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).

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[.]"[65]

20. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[66]

21. 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.[67]

22. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[68]

23. 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.[69]

24. 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

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[65] 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).
[66] Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).
[67] 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).
[68] Mirsha, *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).
[69] 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).

the drug."[70]

25. In a May 2023 letter to the editor published in Acta Pharmaceutica Sinica B, the authors commented on GLP-1RAs, including Ozempic, Wegovy and Rybelsus, and noted "adverse events such as increased risk of intestinal obstruction have been reported in diabetic patients, which is 4.5 times higher than those receiving other glucose control medications" based on a study published in 2020. The authors further noted a study published in 2022 "of 25,617 subjects demonstrated a 3.5-fold increase in the intestinal obstruction rate associated with GLP-1RA treatment."[71]

26. In May 2023, the risk of intestinal obstruction was specifically cited in the Lu study, concluding that the use of GLP-1RAs may result in continuous increases in intestinal length, causing the intestines to "become as inelastic and fibrotic as a loose spring." The study indicated that intestinal blockage peaked after using GLP-1RAs for a year and a half, which the authors noted was longer than the duration of most clinical studies involving GLP-1RAs.[72]

27. 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

[70] 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).
[71] Lu J et al., *A Potentially Serious Adverse Effect of GLP-1 Receptor Agonists*, 13(5) Acta Pharmaceutica Sinica B, 2291-2293 (May 2023), available at https://www.sciencedirect.com/science/article/pii/S2211383523000679 (last visited on 10/19/23); *see also* Faillie JL, et al., *Incretin-Based Drugs and Risk of Intestinal Obstruction Among Patients with Type 2 Diabetes*, Clinical Pharmacology Therapeutics vol. 11, Issue 1 (Jan. 2022), available at https://doi.org/10.1002/cpt.2430 (last visited on 10/19/23) and Gudin B, et al. *Incretin-based drugs and intestinal obstruction: a pharmacovigilance study*, 75(6) Therapies 641-47 (November-December 2020).
[72] Lu, J, et al., *A Potentially Serious Adverse Effect of GLP-1 Receptor Agonists*, 13(5) Acta Pharmaceutica Sinica B, 2291-2293 (May 2023), available at https://www.sciencedirect.com/science/article/pii/S2211383523000679 (last visited on 10/19/23).

warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[73]

28. News sources have identified the potential for serious side effects in users of Ozempic leading to hospitalization.[74] 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."[75]

29. A July 25, 2023, article in Rolling Stone magazine—"*Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell*'"—discussed the severe gastrointestinal effects of GLP-1RAs. 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 ileus, intestinal obstruction, and their sequelae, or other severe gastrointestinal issues.[76]

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[73] 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).

[74] 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).

[75] 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).

[76] 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).

30. On July 25, 2023, CNN Health reported that patients taking GLP-1Ras are experiencing severe gastrointestinal reactions. One patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.[77]

31. On July 26, 2023, a New York hospital published an article to its online health blog section noting that GLP-1RAs 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 doctors often misdiagnose the patients' symptoms, meaning it may take a long time for someone to be diagnosed correctly.[78]

32. In an article published on September 29, 2023, Dr. Caroline Apovian, a Professor of Medicine at Harvard Medical School, indicated that "her team had observed ileus in patients who had been prescribed semaglutide well before the FDA's label change [on September 22, 2023]." In the same article, Dr. Dan Azagury, a Medical Director at Stanford University, explained that "ileus is a rare but potentially severe complication. So, we have to inform patients and we have to let them know that if they have these symptoms they need to check in with their physician."[79]

33. 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

[77] 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).
[78] *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).
[79] Mammoser G, *Ozempic Label Updated to Include Blocked Intestines as Potential Side Effect*, healthline (September 29, 2023), https://www.healthline.com/health-news/fda-updates-ozempic-label-to-include-blocked-intestines-as-potential-side-effect (last visited 10/20/23).

compared with use of bupropion-naltrexone was associated with increased risk of pancreatitis, gastroparesis, and bowel obstruction.[80] The study found that patients prescribed GLP-1RAs were at 4.22 times higher risk of intestinal obstruction.

34. Also on October 5, 2023, a medical journal reported a case of Mounjaro (tirzepatide) induced ileus. The authors concluded that the case "highlights the dangers of lack of ... monitoring of Mounjaro," especially in "patients who may be more susceptible to the gastrointestinal side effects of Mounjaro," and noted the need to "rais[e] awareness of potential side effects" of the drug "and their severity."[81]

35. 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.[82]

36. Defendants knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing ileus, intestinal obstruction, and their 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.

37. On information and belief, Defendants not only knew or should have known that

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[80] 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).

[81] Kamini Rao et al., *Mounjaro: A Side Effect,* 7 J. Endocrine Soc. A69-70 (Oct.-Nov. 2023), available at https://academic.oup.com/jes/article/7/Supplement_1/bvad114.128/7290694 (last visited Nov. 16, 2023).

[82] 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).

their GLP-1RAs cause delayed gastric emptying, resulting in risks of ileus, intestinal obstruction, and their sequelae, 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."[83]

F. Defendants Failed to Warn of the Risks of Ileus, Intestinal Obstruction, and Their Sequelae from Ozempic and Rybelsus

1. The Prescribing Information for Ozempic (the "Ozempic label") discloses "Warnings and Precautions" and "Adverse Reactions" but does not adequately warn of the risk of ileus or intestinal obstruction.[84]

2. 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 ileus, intestinal obstruction, and their sequelae. Intestinal obstruction is not mentioned at all in the label.

3. On September 22, 2023, Novo Nordisk changed the Ozempic label by adding "Gastrointestinal Disorders: Ileus" to the "Adverse Reactions" section of the label under a subheading of "Postmarketing Experience".[85] The label notes that ileus has "been reported during post-approval use of semaglutide, the active ingredient of OZEMPIC." Still, however, Novo

[83] 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).
[84] https://www.novo-pi.com/ozempic.pdf
[85] https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=2183

Nordisk downplays the severity of the risk, does not warn that Ozempic can cause ileus, and does not include ileus as a risk in the "Warnings and Precautions" section of the label, even though Novo Nordisk had knowledge of the risk.

4. Instead of properly disclosing gastrointestinal risks, the Ozempic 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" 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 do not warn that ileus, intestinal obstruction, and their sequelae are risks of taking Ozempic.

5. 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 ileus or intestinal obstruction within the "Important Safety Information" section of their promotional website.[86]

6. None of Defendants' additional advertising or promotional materials warned prescription providers or the general public of the risks of ileus, intestinal obstruction, and/or their sequelae associated with GLP-1RAs.

7. 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.

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

8. 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 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 ileus, intestinal obstruction, and their sequelae.

9. 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 ileus and intestinal obstruction.

10. The Rybelsus label lists nausea, abdominal pain, diarrhea, decreased appetite, vomiting 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 ileus, intestinal obstruction, and their sequelae. Intestinal obstruction is not mentioned at all in the label.

11. Nothing in the label for Rybelsus has ever disclosed ileus or intestinal obstruction as a ***risk*** of taking Rybelsus.

12. None of Defendants' additional advertising or promotional materials warned prescription providers or the general public of the risks of ileus, intestinal obstruction, and their sequalae.

13. Upon information and belief, Defendants knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing ileus, intestinal obstruction, and their sequelae. Defendants' actual and constructive knowledge derived from their clinical

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

14. Upon information and belief, Defendants ignored the causal association between the use of GLP-1RAs and the risk of developing ileus, intestinal obstruction, and their sequelae.

15. Defendants' failure to disclose information that they possessed regarding the causal association between the use of GLP-1RAs and the risk of developing ileus, intestinal obstruction, and their sequelae, rendered the warnings for Ozempic and Rybelsus inadequate.

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

17. On information and belief, had Defendants adequately warned Plaintiff's prescribing physician(s) that Ozempic and Rybelsus are causally associated with ileus, intestinal obstruction, and their sequelae, then the physicians' prescribing decision would have changed by not prescribing Ozempic or Rybelsus, or by monitoring Plaintiff's health for symptoms of ileus, intestinal obstruction, and their sequelae and discontinuing Ozempic and Rybelsus when the symptoms first started.

18. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer ileus, intestinal obstruction, and/or their 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
(INADEQUATE WARNING—AGAINST ALL DEFENDANTS)

1. 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.

2. Kentucky 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.

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

4. Ozempic and Rybelsus 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 they were produced, manufactured, sold, distributed, and marketed by Defendants.

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

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

7. Despite the fact that Defendants knew or should have known that Ozempic and

Rybelsus caused unreasonably dangerous injuries, Defendants continued to market Ozempic and Rybelsus to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

8. 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.

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

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

11. 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 and Rybelsus into the stream of commerce, including a duty to assure that the products would not cause users to suffer unreasonable, dangerous injuries, such as ileus, intestinal obstruction, and their sequelae.

12. At all relevant times, Plaintiff were using Ozempic and Rybelsus in a reasonably foreseeable manner, for the purposes normally intended.

13. The Ozempic and Rybelsus 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 risks of serious and dangerous injuries, including ileus, intestinal obstruction, and their sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendants failed to adequately warn of said risks.

14. The Ozempic and Rybelsus 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 ileus, intestinal obstruction, and their sequalae, as well as other severe and permanent health consequences from Ozempic and Rybelsus, they failed to provide adequate warnings to users and/or prescribers of the products, and continued to improperly advertise, market and/or promote their products, Ozempic and Rybelsus.

15. The labels for Ozempic and Rybelsus were inadequate because they did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic and Rybelsus, including the increased risk of ileus, intestinal obstruction, and their sequelae.

16. The labels for Ozempic and Rybelsus were inadequate because they did not warn and/or adequately warn that Ozempic and Rybelsus had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae.

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

18. The labels for Ozempic and Rybelsus 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.

19. 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 and Rybelsus, including

the increased risk of ileus, intestinal obstruction, and their sequelae.

20. 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 and Rybelsus had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae.

21. 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.

22. 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 Defendants' warnings was reasonable.

23. Defendants knew or should have known that neither Plaintiff nor Plaintiff's prescribing physicians would realize the danger of ileus, intestinal obstruction, and their sequelae caused by Ozempic and Rybelsus.

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

25. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Ozempic and Rybelsus had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, the prescribing physician would not have prescribed Ozempic and Rybelsus and/or would have provided Plaintiff with adequate warnings

regarding the lack of sufficient and/or adequate testing of Ozempic and Rybelsus so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Rybelsus.

26. If Plaintiff had been warned of the increased risks ileus, intestinal obstruction, and their sequelae, which are causally associated with Ozempic and Rybelsus, then Plaintiff would not have used Ozempic and Rybelsus and/or suffered from ileus, intestinal obstruction, and their sequelae.

27. If Plaintiff had been warned that Ozempic and Rybelsus had not been sufficiently and/or adequately tested for safety risks, including for ileus, intestinal obstruction, and their sequalae, then Plaintiff would not have used Ozempic and Rybelsus and/or suffered ileus, intestinal obstruction, and their sequelae.

28. If Plaintiff had been warned of the increased risks of ileus, intestinal obstruction, and their sequelae, which are causally associated with Ozempic and Rybelsus, then Plaintiff would have informed Plaintiff's prescribers that Plaintiff did not want to take Ozempic and Rybelsus.

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

30. By reason of the foregoing, Defendants have become liable to Plaintiff for designing, marketing, promoting, distribution and/or selling of unreasonably dangerous products, Ozempic and Rybelsus.

31. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which created unreasonable risks to the health of consumers and to Plaintiff in particular, and Defendants are therefore liable for the injuries

sustained by Plaintiff.

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

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

34. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including ileus, intestinal obstruction, and their 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.

35. 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
(NEGLIGENT MISREPRESENTATION-AGAINST ALL DEFENDANTS)

36. 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.

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

38. At all relevant times, Defendants knew or should have known that Ozempic and

Rybelsus had not been adequately and/or sufficiently tested for safety.

39. At all relevant times, Defendants knew or should have known of the serious side effects of Ozempic and Rybelsus, including ileus, intestinal obstruction, and their sequelae.

40. Defendants had a duty to disclose material information about Ozempic and Rybelsus to Plaintiff and Plaintiff's prescribing physician(s) that Ozempic and Rybelsus are causally associated with increased risk of ileus, intestinal obstruction, and their sequelae, because Defendants held a special expertise with respect to Ozempic and Rybelsus, Plaintiff, as a user of Ozempic and Rybelsus, had a special relationship of trust with Defendants, and Defendants knew that their statements regarding the risks causally associated with Ozempic and Rybelsus would be relied on by Ozempic and Rybelsus users.

41. 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 and Rybelsus.

42. Defendants represented affirmatively and by omission on television advertisements and on the labels of Ozempic and Rybelsus that Ozempic and Rybelsus were safe and effective drugs for treatment of adults with type 2 diabetes, despite being aware of increased risks of ileus, intestinal obstruction, and their sequelae causally associated with using Ozempic and Rybelsus.

43. Defendants were aware or should have been aware that their representations were false or misleading and 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.

44. Defendants knew that Plaintiff and Plaintiff's prescribing physicians (s) had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding

Ozempic and Rybelsus, as set forth herein.

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

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

47. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic and Rybelsus had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, they would not have prescribed Ozempic and Rybelsus and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic and Rybelsus so that Plaintiff can make an informed decision regarding Plaintiff's use of Ozempic and Rybelsus.

48. Plaintiff reasonably relied on the false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiff had no way to know were omitted.

49. Had Plaintiff been told of the increased risk of ileus, intestinal obstruction, and their sequelae causally associated with Ozempic and Rybelsus, Plaintiff would not have used Ozempic and Rybelsus and/or suffered ileus, intestinal obstruction, and their sequelae.

50. Defendants' misrepresentations and omissions of material facts amount to willful,

wanton, and/or reckless conduct.

51. As a direct and proximate result of the above stated false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including ileus, intestinal obstruction, and their 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.

52. As a result of the foregoing acts and omissions the 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
(FRAUDULENT MISREPRESENTATION —AGAINST ALL DEFENDANTS)

53. 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.

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

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

56. At all relevant times, Defendants knew or should have known of the serious side

effects of Ozempic and Rybelsus, including ileus, intestinal obstruction, and their sequelae.

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

58. 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 and Rybelsus.

59. Defendants represented affirmatively and by omission on television advertisements and on the labels of Ozempic and Rybelsus that Ozempic and Rybelsus were safe and effective drugs for treatment of adults with type 2 diabetes, despite being aware of increased risks of ileus, intestinal obstruction, and their sequelae causally associated with using Ozempic and Rybelsus.

60. Defendants were aware or should have been aware that their representations were false or misleading and 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.

61. 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 and Rybelsus for treatment of type 2 diabetes.

62. Upon information and belief that Plaintiff's prescribing physician(s) had no way to determine the truth behind Defendants' false and/or misleading statements, concealments and

omissions surrounding Ozempic and Rybelsus, and reasonably relied on false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiff's prescribing physician(s) had no way to know were omitted.

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

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

65. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic and Rybelsus had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, they would not have prescribed Ozempic and Rybelsus and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic and Rybelsus so that Plaintiff can make an informed decision regarding Plaintiff's use of Ozempic and Rybelsus.

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

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

68. Had Plaintiff been told of the increased risk of ileus, intestinal obstruction, and their sequelae causally associated with Ozempic and Rybelsus, Plaintiff would not have used Ozempic and Rybelsus and/or suffered ileus, intestinal obstruction, and their sequelae.

69. Had Plaintiff been told of the lack of sufficient and/or appropriate testing of Ozempic and Rybelsus for safety risks, including ileus, intestinal obstruction, and their sequelae, Plaintiff would not have used Ozempic and Rybelsus and/or suffered ileus, intestinal obstruction, and their sequelae.

70. As a direct and proximate result of the above stated false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including ileus, intestinal obstruction, and their 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.

71. As a result of the foregoing acts and omissions the 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)

72. 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.

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

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

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

76. Defendants had a duty to disclose material information about Ozempic and Rybelsus to Plaintiff and Plaintiff's prescribing physician(s), namely that Ozempic and Rybelsus are causally associated with increased risks of ileus, intestinal obstruction, and their 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.

77. Nonetheless, Defendants failed to execute their duty to disclose these material facts. 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.

78. Although the Ozempic and the Rybelsus labels list nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Ozempic and Rybelsus patients, they do not mention ileus and intestinal obstruction as risks of taking Ozempic and Rybelsus, nor do they identify ileus and intestinal obstruction as chronic conditions that can result as a consequence of taking Ozempic and Rybelsus.

79. Defendants' promotional websites for Ozempic and Rybelsus similarly do not disclose that Ozempic and Rybelsus are causally associated with increased risk of ileus, intestinal obstruction, and their sequelae.

80. 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 and Rybelsus for treatment of type 2 diabetes.

81. Defendants knew or should have known that Plaintiff's prescribing physician(s) would prescribe, and Plaintiff would use Ozempic and Rybelsus without the awareness of the risks of serious side effects, including ileus, intestinal obstruction, and their sequelae.

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

83. 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 and Rybelsus.

84. Upon information and belief, had Plaintiff's prescribing physician(s) been warned

of the increased risks of ileus and intestinal obstruction causally associated with Ozempic and Rybelsus, they would not have prescribed Ozempic and Rybelsus and/or would have provided Plaintiff with adequate information regarding the increased risk of including ileus and intestinal obstruction causally associated with Ozempic and Rybelsus to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Rybelsus.

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

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

87. Had Plaintiff been informed of the increased risks causally associated with Ozempic and Rybelsus, Plaintiff would not have used Ozempic and Rybelsus and/or suffered ileus, intestinal obstruction, and their sequelae.

88. Defendants' fraudulent concealments were a substantial factor in causing Plaintiff's injuries.

89. As a direct and proximate result of the above stated omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries, including ileus, intestinal obstruction, and their 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.

90. As a result of the foregoing acts and omissions the 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: September 26, 2024

By:

THE GORI LAW FIRM, P.C.

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