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
TIA HAIRSTON, *Plaintiff,* v. NOVO NORDISK A/S, NOVO NORDISK INC., ELI LILLY AND COMPANY *Defendant.*	COMPLAINT AND JURY DEMAND CIVIL ACTION NO.: _____

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

X Plaintiff currently resides in Ridgeway, Virginia (City/State).

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

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

X The Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, specifically (28 USC § 1391(b)(2)): Western District of Virginia – Danville, VA.

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

__ Other reason (please explain): _____.

NATURE OF THE CASE

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

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

3. Trulicity is also known as dulaglutide. Trulicity works by stimulating insulin production and reducing glucose production in the liver helping to lower blood sugar levels.

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

5. Defendants acknowledge that gastrointestinal events are well known side effects of the GLP-1RA class of drugs.[1] However, Defendants have downplayed the severity of the gastrointestinal events caused by their GLP-1RAs, never, for example, warning of the risk of ileus, intestinal obstruction, and their sequalae.

6. Ileus is "a temporary lack of the normal muscle contractions of the intestines."[2] 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, 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.[3]

7. Paralytic ileus, also known as a pseudo-obstruction, is the most severe form of ileus and

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

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

[3] 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).

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.[4]

8. 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.[5] 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."[6] 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.[7] 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.[8]

PARTY PLAINTIFF

9. Plaintiff, Tia Hairston, is a citizen of the United States, and is a resident of the State of Virginia.

10. Plaintiff is 45 years old.

11. Plaintiff used Ozempic from June 2021 to July 2022.

12. Plaintiff used Trulicity from approximately August 2022 to September 2023.

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[4] 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).

[5] 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); *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).

[7] Mayo Clinic, Intestinal Obstruction, available at https://www.mayoclinic.org/diseases-conditions/intestinal-obstruction/symptoms-causes/syc-20351460 (last visited on 10/16/23).

[8] 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).

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

14. As a result of using Ozempic and Trulicity, Plaintiff was caused to suffer from ileus and/or intestinal obstruction, and their sequelae and, as a result, sustained severe and permanent personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

15. As a result of using Ozempic and Trulicity, Plaintiff was caused to suffer from ileus and/or intestinal obstruction, and their sequelae, which resulted in, for example, extreme nausea, vomiting, severe abdominal pain, and requiring surgery to treat bowel obstruction.

PARTY DEFENDANTS

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

17. 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.

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

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

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

21. Eli Lilly designed, researched, manufactured, tested, labeled, advertised, promoted, marketed, sold, and/or distributed Trulicity and is identified on its label.[9]

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

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

FACTUAL BACKGROUND

A. FDA's Approval of Ozempic

23. 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."[10]

24. 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.[11]

25. On March 20, 2019, Defendant Novo Nordisk Inc. submitted supplemental new drug application (sNDA) 209637/S-003 for Ozempic (semaglutide) 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.[12] On January 16, 2020, the FDA approved sNDA 209637/S-003.[13]

26. 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

[10] 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).
[11] 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).
[12] *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).
[13] 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).

FDA approved sNDA 209637/S-009.[14]

B. FDA's Approval of Trulicity

27. On September 18, 2014, the FDA approved Eli Lilly's Biologics License Application ("BLA") for dulaglutide "as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus" to be marketed as Trulicity in "single dose pre-filled syringes and pre-filled pens." As initially approved, the recommended dose for Trulicity was 1.5 mg per week.[15]

28. On April 19, 2019, Eli Lilly submitted supplemental BLA 125469/S-033, requesting approval to expand its marketing of Trulicity by adding an indication for reduction of major cardiovascular events in adults with type 2 diabetes. On February 21, 2020, the FDA approved the request.[16]

29. On November 4, 2019, Eli Lilly submitted BLA 125469/S-036, seeking approval for higher doses (3 mg per week and 4.5 per week) of Trulicity. On September 3, 2020, the FDA approved that request.[17]

30. On May 17, 2022, Eli Lilly submitted BLA 125469/S-051, seeking to add an indication for a new patient population: "pediatric patients 10 years of age and older with type 2 diabetes mellitus." On November 17, 2022, the FDA approved the drug for pediatric use.[18]

31. At all times, Trulicity's label has indicated that Trulicity delays gastric emptying and that the delay in gastric emptying "diminishes with subsequent doses." However, Trulicity's label has never warned that Trulicity can cause ileus, intestinal obstruction, and their sequelae.

C. Novo Nordisk's Marketing and Promotion of Ozempic

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[14] 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).

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

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

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

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

32. 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."[19]

33. On February 5, 2018, Novo Nordisk announced that it had started selling Ozempic in the United States and touted the medication as a "new treatment option[]" that "addresses the concerns and needs of people with diabetes[.]" Novo Nordisk offered an "Instant Savings Card to reduce co-pays to as low as $25 per prescription fill for up to two years."[20]

34. 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.

35. 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.[21]

36. 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

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[19] *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).

[20] *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).

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

represented Ozempic as having "proven safety" and advertised that "plus it can help many patients lose some weight."[22]

37. 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.[23]

38. 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.[24]

39. 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."[25] 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.[26]

40. 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

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[22] *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).

[23] 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).

[24] 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).

[25] 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).

[26] 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).

GLP-1RA drugs.[27]

41. As a result of Novo Nordisk's advertising and promotion efforts, Ozempic has been widely used throughout the United States. The number of prescriptions filled reached an all-time high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.[28] In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.[29]

42. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,[30] and currently has over 1.3 billion views.[31]

43. 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.[32]

44. 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."[33]

45. At all relevant times, Novo Nordisk was in the business of and did design, research,

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[27] 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).

[28] 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).

[29] 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).

[30] 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).

[31] https://www.tiktok.com/tag/ozempic (visited on 11/14/23).

[32] 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).

[33] 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).

manufacture, test, advertise, promote, market, sell, and/or distribute Ozempic.

D. Eli Lilly's Marketing and Promotion of Trulicity

46. Trulicity has been the top earning product for Eli Lilly for the past several years, with the drug bringing in more than $5.6 billion in revenue in 2022 in the United States alone. The demand for Trulicity is largely driven by Eli Lilly's advertising, which costs the company more than $1 billion annually. Indeed, Eli Lilly advertises Trulicity through its websites, press releases, in-person presentations, the drug's label, print materials, social media, and other public outlets. Eli Lilly's advertisements tout the health benefits of Trulicity, without warning of the risk of ileus, intestinal obstruction, or their sequelae.[34]

47. Upon the approval of Trulicity on September 18, 2014, an Eli Lilly spokesperson indicated that Trulicity "has demonstrated proven glycemic control, only has to be taken once weekly, and comes in an easy-to-use pen."[35] Although a press release accompanying Trulicity's approval acknowledged that "nausea," "vomiting" abdominal pain" were among the most common adverse reactions reported with use of Trulicity, the press release did not indicate that those common adverse reactions were symptoms of ileus or intestinal obstruction or warn of the risk of ileus, intestinal obstruction, or their sequelae.[36]

48. Following the FDA's approval of Trulicity in September 2014, Eli Lilly launched its direct-to-consumer ad campaign in 2015, with print and digital ads first appearing in September 2015 and the first Trulicity television ad launching on October 19, 2015.[37]

49. On November 5, 2018, in a press release announcing Trulicity's "superiority in reduction

[34] Eli Lilly and Company 2022 Annual Report, available at https://investor.lilly.com/static-files/2f9b7bb1-f955-448d-baa2-c4343d39ee62 (last visited Nov. 15, 2023).
[35] *Lilly's Trulicity (dulaglutide) Now Available in U.S. Pharmacies,* PR Newswire (Nov. 10, 2014), available at https://www.prnewswire.com/news-releases/lillys-trulicity-dulaglutide-now-available-in-us-pharmacies-282138401.html (last visited Nov. 15, 2023).
[36] *News Release: FDA Approves Trulicity (dulaglutide), Lilly's Once-Weekly Therapy for Adults with Type 2 Diabetes,* Eli Lilly (Sept. 18, 2014), available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-trulicitytm-dulaglutide-lillys-once-weekly-therapy (last visited Nov. 15, 2023).
[37] Beth Snyder Bulik, *One year after FDA nod, Eli Lilly's Trulicity launches first consumer campaign,* Fierce Pharma (Oct. 19, 2015) https://www.fiercepharma.com/dtc-advertising/one-year-after-fda-nod-eli-lilly-s-trulicity-launches-first-consumer-campaign (last visited Nov. 15, 2023).

of cardiovascular events," as shown by an internal clinical trial, Eli Lilly acknowledged that "[t]he safety profile of Trulicity ... was generally consistent with the GLP-1 receptor agonist class." Although the press release included a section titled "Important Safety Information for Trulicity," the press release did not warn that Trulicity can cause ileus, intestinal obstruction, or their sequelae.[38]

50. In a February 21, 2020, press release announcing Trulicity's new indication for reduction of cardiovascular risk, Eli Lilly touted Trulicity's ability to reduce the risk of major adverse cardiovascular events, including heart attack and stroke, even in adults without established cardiovascular disease.[39] In the press release, Eli Lilly again indicated that "Trulicity's safety profile [is] consistent with the GLP-1 receptor agonist (RA) class," but despite warning of certain risks, the press release did not warn of the risk of ileus, intestinal obstruction, or their sequelae, associated with GLP-1RAs.

51. When announcing the approval of higher weekly doses of Trulicity in September 2020, Eli Lilly's press release indicated that "with the 3.0 and 4.5 [mg] doses available, people with type 2 diabetes who use Trulicity can benefit from additional A1C and weight loss as their condition progresses."[40] Despite touting the off-label use of Trulicity for "weight loss," Eli Lilly did not warn of the associated risk of ileus, intestinal obstruction, or their sequelae.

52. Around this same time, Robert H. Schmerling, MD, Senior Faculty Editor and Editorial Advisory Board Member at Harvard Health Publishing commented that the actors in the tv ads for

[38] *News Release: Trulicity (dulaglutide) demonstrates superiority in reduction of cardiovascular events for broad range of people with type 2 diabetes,* Eli Lilly (Nov. 5, 2018), available at https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-demonstrates-superiority-reduction (last visited Nov. 15, 2023).
[39] *News Release: Trulicity (dulaglutide) is the first and only type 2 diabetes medicine approved to reduce cardiovascular events in adults with and without established cardiovascular disease,* Eli Lilly (Feb. 21, 2020), available at https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-first-and-only-type-2-diabetes-medicine (last visited Nov. 15, 2023).
[40] *News Release: FDA approves additional doses of Trulicity (dulaglutide) for the treatment of type 2 diabetes,* Eli Lilly (Sept. 3, 2020) available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-additional-doses-trulicityr-dulaglutide-treatment (last visited Nov.15, 2023).

Trulicity appeared notably thinner than the typical person with type 2 diabetes.[41]

53. In Summer 2021, in conjunction with Eli Lilly's sponsorship of the rescheduled Summer Olympics, Eli Lilly ran extensive television advertisements for Trulicity featuring Olympic gymnast Laurie Hernandez and her father, who has type 2 diabetes. The advertisement indicates that treatment with Trulicity is the "right choice" for people with type 2 diabetes but does not mention or warn about ileus, intestinal obstruction, or their sequelae.[42]

54. In a similar January 2022 tv ad featuring Olympic figure skater Madison Chock and her mother, Eli Lilly again indicated that Trulicity was the "right choice" for people with type 2 diabetes. However, the ad did not warn that Trulicity can cause ileus, intestinal obstruction, or their sequelae.[43]

55. In January 2022, the FDA determined that Eli Lilly's "10,800 Minutes" Instagram advertisement for Trulicity "ma[de] false or misleading claims and representations about the benefits and risks of Trulicity" and that the advertisement elicits "a misleading impression regarding the safety and effectiveness of Trulicity" that "minimizes the risks associated with the use of Trulicity." In response to a letter from the FDA, Eli Lilly temporarily removed the Trulicity Instagram account.[44] The FDA citation is emblematic of Eli Lilly's willingness to mislead and omit important information, focusing on profit over safety, specifically with respect to Trulicity.

56. That same month, it was reported that Trulicity was the most advertised drug on United States television, with Eli Lilly spending an estimated $36.2 million on national television

[41] Robert H. Schmerling, MD, *Harvard Health Ad Watch: A feel-good message about a diabetes drug,* Harvard Health Publishing (Sept. 18, 2020), available at https://www.health.harvard.edu/blog/harvard-health-ad-watch-a-feel-good-message-about-a-diabetes-drug-2020091620961 (last visited Nov. 15, 2023).
[42] *See* Trulicity TV advertisement, available at https://www.youtube.com/watch?v=eVA1vYV980w (last visited Nov. 15, 2023); Beth Snyder Bulik, *Lilly warms up for Olympics with Team USA athletes in ads for Trulicity, Emgality and Verzenio,* Fierce Pharma (July 7, 2021), available at https://www.fiercepharma.com/marketing/lilly-warms-up-for-olympics-team-usa-athletes-ads-for-trulicity-emgality-and-verzenio (last visited Nov. 15, 2023).
[43] *See* Trulicity TV advertisement (Madison Chock), available at https://www.ispot.tv/ad/q3ii/trulicity-shes-got-this-featuring-madison-chock (last visited Nov. 15, 2023).
[44] Fraiser Kansteiner, *FDA chides Eli Lilly for 2nd misleading ad in 2 months, this time for diabetes blockbuster Trulicity,* Fierce Pharma (Jan. 25, 2022), available at https://www.fiercepharma.com/marketing/fda-chides-lilly-for-second-misleading-ad-2-months-time-for-diabetes-med-trulicity (last visited Nov. 15, 2023).

advertisements in January 2022 alone.[45]

57. In another Trulicity tv ad that premiered in February 2022, Eli Lilly boasted that Trulicity "can help you lose up to ten pounds," a use for which Trulicity is not indicated, but did not mention the risk of ileus, intestinal obstruction, or their sequelae.[46]

58. Similarly, Eli Lilly's website used to promote Trulicity (Trulicity.com) states that people taking Trulicity "lost up to 10 lbs," without disclosing the risk of ileus, intestinal obstruction, or their sequelae.[47]

59. By the end of 2022, the market was experiencing shortages of Trulicity due to "high demand" driven by Eli Lilly's advertising.[48]

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

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

61. 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.[49]

62. 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

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[45] Ben Adams, *Eli Lilly's Trulicity dethrones Dupixent, taking January's TV ad spending crown,* Fierce Pharma (Feb. 4, 2022), available at https://www.fiercepharma.com/marketing/sanofi-regeneron-s-dupixent-de-throned-as-lilly-s-trulicity-takes-crown-january-s-biggest (last visited Nov. 15, 2023).

[46] Trulicity TV advertisement ("Father-Son"), available at https://www.ispot.tv/ad/q4Kl/trulicity-father-son (last visited Nov. 15, 2023).

[47] *See* https://www.trulicity.com/what-is-trulicity#what-is-trulicity.

[48] https://www.fiercepharma.com/manufacturing/after-novos-wegovy-supply-woes-lillys-would-be-obesity-rival-tirzepatide-runs-scarce

[49] 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).

prescribing physicians of the risk of ileus, intestinal obstruction, and their sequelae associated with these drugs.

63. 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.

64. As early as 2010, a study published in The Journal of Clinical Endocrinology & Metabolism concluded that GLP-1 slows gastric emptying.[50]

65. 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.

66. In 2008, the New England Journal of Medicine noted that "serious complications" reported as adverse events for the GLP-1RA exenatide included "suspected ileus."[51]

67. 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.[52]

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[50] 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).

[51] 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).

[52] 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).

68. 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."[53]

69. In 2013, the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) received a "safety communication from the Japanese medicines agency … 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.[54] Notably, Novo Nordisk manufactures and markets liraglutide under the brand names Saxenda and Victoza.

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

71. 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.[55]

72. 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

[53] 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).

[54] 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).

[55] 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).

adverse events. Three subjects also reported mild adverse events of impaired gastric emptying in the semaglutide run-in period of trial 4376.

73. A study published in 2017 evaluated the effect of GLP-1RAs on gastrointestinal tract motility and residue rates and explained that "GLP-1 suppresses gastric emptying by inhibiting peristalsis of the stomach while increasing tonic contraction of the pyloric region." The study authors concluded that the GLP-1RA drug liraglutide "exhibited gastric-emptying delaying effects" and "the drug also inhibited duodenal and small bowel movements at the same time."[56]

74. 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%)."[57] As explained above, these are symptoms of ileus and intestinal obstruction.

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

76. 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 Trulicity (dulaglutide) three weeks prior to hospital admission. The authors noted that "[d]ulaglutide (Trulicity) is associated with small bowel obstruction" but that "the actual mechanism [of] Trulicity causing the small bowel obstruction is unknown." The authors further reported that "[a] total of 8 cases" of bowel obstruction in Trulicity users "were reported in 2017 with a majority of them requiring surgical

[56] 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).
[57] 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/

intervention." In the subject patient, the authors concluded that because "[a]ll the other cause[s] of small bowel obstructions had been ruled out[,] ... Trulicity was the culprit of this unfortunate case."[58]

77. 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."[59]

78. 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

[58] Gandhi, et al., *Dulaglutide Commonly Known as Trulicity; 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).

[59] 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).

percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for gastrointestinal related adverse events, with some trials experiencing 100% discontinuation due to gastrointestinal related adverse events. The mean value of gastrointestinal related adverse events that led to discontinuation averaged 57.75%. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"[60]

79. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[61]

80. 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.[62]

81. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[63]

82. 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.[64]

83. On March 28, 2023, a case study concluded that impaired gastric emptying is "a significant safety concern, especially since it is consistent with the known mechanism of action of the drug."[65]

84. 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

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[60] 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).
[61] Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).
[62] 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).
[63] Mirsha, *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).
[64] 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).
[65] 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).

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."[66]

85. 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.[67]

86. 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 warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[68]

87. News sources have identified the potential for serious side effects in users of Ozempic leading to hospitalization.[69] For example, NBC News reported in January 2023 that some Ozempic users

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[66] 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).

[67] 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).

[68] 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).

[69] 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,

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."[70]

88. 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.[71]

89. 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.[72]

90. 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

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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).

[70] 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).

[71] 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).

[72] 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).

misdiagnose the patients' symptoms, meaning it may take a long time for someone to be diagnosed correctly.[73]

91. 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."[74]

92. In an October 5, 2023, Research Letter published in the Journal of the American Medical Association ("JAMA"), the authors examined gastrointestinal adverse events associated with GLP-1RAs used for weight loss in clinical setting and reported that use of GLP-1RAs compared with use of bupropion-naltrexone was associated with increased risk of pancreatitis, gastroparesis, and bowel obstruction.[75] The study found that patients prescribed GLP-1RAs were at 4.22 times higher risk of intestinal obstruction.

93. 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."[76]

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[73] *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).

[74] 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).

[75] 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).

[76] 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).

94. 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.[77]

95. 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.

96. On information and belief, Defendants not only knew or should have known that 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."[78]

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

97. 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

[77] 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).

[78] 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).

obstruction.[79]

98. 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.

99. 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".[80] The label notes that ileus has "been reported during post-approval use of semaglutide, the active ingredient of OZEMPIC." Still, however, Novo 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.

100. 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.

101. 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

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

website.[81]

102. 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.

103. 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.

104. 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.

105. 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.

106. The Prescribing Information for Trulicity (the "label") discloses "Warnings and Precautions" and "Adverse Reactions" but does not warn that Trulicity can cause ileus or intestinal obstruction.[82]

107. The Trulicity label lists nausea, vomiting, diarrhea, abdominal pain, and decreased appetite as the most common adverse reactions reported in Trulicity patients, but it does not include these adverse

[81] *See* Ozempic.com (visited on 10/16/23).
[82] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).

reactions in its "Warnings and Precautions" section, nor does it warn that these adverse reactions may be symptoms of ileus and intestinal obstruction. While the Warnings and Precautions section indicates that "Use of TRULICITY may be associated with gastrointestinal adverse reactions, sometime severe," the warning is lacking in urgency and specificity.[83]

108. Instead of properly disclosing gastrointestinal risks, the label for Trulicity encourages prescribing physicians and patients to ignore the signs of ileus and intestinal obstruction and continue therapy with Trulicity because the Drug Interactions and Clinical Pharmacology sections of the label state that the delayed gastric emptying caused by Trulicity "is largest after the first dose and diminishes with subsequent doses."[84]

109. Similarly, Eli Lilly's main promotional website for Trulicity (trulicity.com) includes a variety of information about the benefits of Trulicity relating to blood sugar, cardiovascular health, and weight loss, and includes a section about "Side Effects" and a sidebar containing a "SAFETY SUMMARY WITH WARNINGS." However, Eli Lilly does not disclose the risks of ileus, intestinal obstruction, or their sequelae within either the "Side Effects" or "SAFETY SUMMARY WITH WARNINGS" sections of the website.[85]

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

111. 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.

112. 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

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

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.

113. 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.

114. 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 Trulicity inadequate.

115. 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 Trulicity 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.

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

117. 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
(NEGLIGENT FAILURE TO WARN—AGAINST ALL DEFENDANTS)

118. 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.

119. Under Virginia law, 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 Trulicity into the stream of commerce, including duty to ensure that the product would not cause users to suffer unreasonable, dangerous injuries, such as ileus, intestinal obstruction, and their sequelae.

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

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

122. At all relevant times, and at the times Ozempic and Trulicity left Defendants' control, Defendants knew or should have known that Ozempic and Trulicity 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.

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

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

125. 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.

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

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

128. At all relevant times, Plaintiff was using Ozempic, and Trulicity for the purposes and in a manner normally intended.

129. The Ozempic, and Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings or instructions, as Defendants knew or should have known that the products created a risk of serious and dangerous injuries, including 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 risk

130. The Ozempic and Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including ileus, intestinal obstruction, and their sequalae, as well as other severe and permanent health consequences from Ozempic and Trulicity, 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 Trulicity.

131. The labels for Ozempic and Trulicity were inadequate because they failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic and Trulicity, including the increased risk of ileus, intestinal obstruction, and their sequelae.

132. The labels for Ozempic and Trulicity were inadequate because they failed to warn and/or adequately warn that Ozempic and Trulicity had not been sufficiently and/or adequately tested for safety

risks, including ileus, intestinal obstruction, and their sequelae.

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

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

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

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

137. 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.

138. 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.

139. 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 Trulicity, then the prescribing physician would not have prescribed Ozempic and Trulicity and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic and

Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Trulicity.

140. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Ozempic and Trulicity 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 Trulicity and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic and Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Trulicity.

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

142. If Plaintiff had been warned that Ozempic and Trulicity 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 Trulicity and/or suffered ileus, intestinal obstruction, and their sequelae.

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

144. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Ozempic and Trulicity 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 Trulicity.

145. 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

Trulicity.

146. 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.

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

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

149. 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.

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

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

151. 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.

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

153. At all relevant times, Defendants expressly warranted to Plaintiff and Plaintiff's prescribing physician(s) that Ozempic, and Trulicity were safe to treat 2 diabetes, reduce cardiovascular risk, and promote weight loss and assure them it did not carry an increased risk of gastrointestinal complications, including, but not limited to, ileus, intestinal obstruction, and their sequelae.

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

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

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

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

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

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

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

161. The unreasonably dangerous characteristics of Ozempic, and Trulicity were beyond that

which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drugs' characteristics.

162. At the time, Ozempic, and Trulicity left Defendants' control, Ozempic, and Trulicity did not conform to Defendants' express warranties because Ozempic, and Trulicity were not safe to improve glycemic control in adults with type 2 diabetes, reduce cardiovascular risk in patients with type 2 diabetes, or to promote weight loss, in that is was casually associated with increased risks of ileus, intestinal obstruction, and their sequelae.

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

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

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

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

167. Had Plaintiff been warned of the increased risk of ileus, intestinal obstruction, and their sequelae causally associated with Ozempic, and Trulicity, Plaintiff would not have used Ozempic, and Trulicity and/or suffered from of ileus, intestinal obstruction, and their sequelae.

168. Had Plaintiff been warned that Ozempic, and Trulicity had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, Plaintiff would not have used Ozempic, and Trulicity and/or suffered ileus, intestinal obstruction, and their sequelae

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

170. Defendants' breach of express warranty was a substantial factor in causing Plaintiff's injuries.

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

172. As a result of the foregoing breaches, 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.

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

174. 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
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY —AGAINST ALL DEFENDANTS)

175. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint

contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

177. Ozempic and Trulicity were expected to and did reach the usual consumers, handlers, and persons encountering said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

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

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

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

181. At the time Ozempic, and Trulicity left Defendants' control, Ozempic, and Trulicity did not conform to Defendants' implied warranty and was unfit for its ordinary purpose because Defendants failed to provide adequate warnings of the drugs' causal association with increased risk of ileus, intestinal obstruction, and their sequelae.

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

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

184. Despite the fact that Defendants knew or should have known that Ozempic, and Trulicity causes unreasonably dangerous injuries, such as ileus, intestinal obstruction, and their sequelae, Defendants continued to market, distribute, and/or sell Ozempic, and Trulicity to consumers, including Plaintiff, without adequate warnings.

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

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

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

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

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

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

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

have prescribed Ozempic, and Trulicity, and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic, and Trulicity to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic, and Trulicity.

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

193. Defendants' breaches of implied warranty of merchantability were a substantial factor in causing Plaintiff's injuries.

194. As a result of the foregoing breaches, 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.

195. 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)

196. 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.

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

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

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

200. Defendants had a duty to disclose material information about Ozempic and Trulicity to Plaintiff and Plaintiff's prescribing physician(s), namely that Ozempic and Trulicity 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.

201. 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.

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

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

204. 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 Trulicity for treatment of type 2 diabetes.

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

206. 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 Trulicity, as set forth herein.

207. 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 Trulicity.

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

209. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic and Trulicity 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 Trulicity and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate

testing of Ozempic and Trulicity to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic and Trulicity.

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

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

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

213. 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.

214. 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.

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

215. 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.

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

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

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

219. At all relevant times, Defendants knew or should have known that Ozempic and Trulicity 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 its increased risk of ileus, intestinal obstruction, and their sequelae.

220. 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 Trulicity.

221. Defendants represented affirmatively and by omission on television advertisements and on the labels of Ozempic and Trulicity that Ozempic, and Trulicity were a safe and effective drug 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 Trulicity.

222. Defendants were aware or should have been aware that its 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.

223. 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 Trulicity for treatment of type 2 Diabetes.

224. 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 Trulicity, 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.

225. 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 Trulicity to Plaintiff.

226. 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 Trulicity, Plaintiff's prescribing physician(s) would not have prescribed Ozempic, and Trulicity and/or would have provided Plaintiff with adequate information regarding safety of Ozempic, and Trulicity to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic, and Trulicity.

227. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic, and Trulicity 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 Trulicity and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic, and Trulicity so that Plaintiff can make an informed decision regarding Plaintiff's use of Ozempic, and Trulicity.

228. Plaintiff had no way to determine the truth behind Defendants' false and/or misleading statements, concealments and omissions surrounding Ozempic, and Trulicity, 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.

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

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

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

232. 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.

233. 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.

SIXTH CAUSE OF ACTION
(NEGLIGENT MISREPRENTATION/CONSTRICTIVE FRAUD CONCEALMENT — AGAINST ALL DEFENDANTS)

234. 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.

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

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

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

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

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

240. Nonetheless, Defendants made material misrepresentations and omissions and/or concealments 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 Trulicity.

241. Defendants represented affirmatively and by omission on television advertisements and on the labels of Ozempic, and Trulicity that Ozempic, and Trulicity were safe and effective drugs for

treatment of adults with type 2 diabetes, despite being aware of the increased risks of ileus, intestinal obstruction, and their sequelae causally associated with using Ozempic, and Trulicity.

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

243. 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 Trulicity, as set forth herein.

244. 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 Trulicity to Plaintiff.

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

246. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic, and Trulicity 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 Trulicity and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic, and Trulicity so that Plaintiff can make an informed decision regarding Plaintiff's use of Ozempic, and Trulicity.

247. 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.

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

249. Defendants' misrepresentations and omissions of material facts amount to willful, wanton, and/or reckless conduct.

250. 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.

251. 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: August 29, 2025

RESPECTFULLY SUBMITTED,

By: */s/ Sara Schramm*
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