UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF IOWA
CEDAR RAPIDS DIVISION

ALLEE SMITH,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. _____

Judge _____

JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, Allee Smith, by Plaintiff's attorneys, Mark DiCello, Diandra Debrosse Zimmermann, Mark Abramowitz and Christopher Stombaugh, of DiCello Levitt, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which Plaintiff resides, which is Iowa.

2. This Court has personal jurisdiction over Defendants, consistent with the United States Constitution and Iowa Code § 617.3 (Iowa's "long arm" statute), as Plaintiff's claims arise out of Defendants' transaction of business and the tortious acts within the State of Iowa, and by virtue of Defendants' substantial, continuous, and systematic contacts with the State of Iowa unrelated to Plaintiff's claims.

NATURE OF THE CASE

3. This is an action for damages suffered by Plaintiff, Allee Smith, who was severely injured as a result of Plaintiff's use of Trulicity, an injectable prescription medication that is used to control blood sugar in adults with type 2 diabetes.

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

5. Trulicity belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

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

7. Gastroparesis is a condition that affects normal muscle movement in the stomach. Ordinarily, strong muscular contractions propel food through the digestive tract. However, in a person suffering from gastroparesis, the stomach's motility is slowed down or does not work at all, preventing the stomach from emptying properly. Gastroparesis can interfere with normal digestion and cause nausea, vomiting (including vomiting of undigested food), abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, undigested food hardening and remaining in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, malnutrition, and a decreased quality of life. There is no cure for gastroparesis.[2]

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

PARTY PLAINTIFF

8. Plaintiff, Allee Smith, is a citizen of the United States, and is a resident of the State of Iowa.

9. Plaintiff is 35 years old.

10. Plaintiff used Trulicity from May 2021 to January 2022.

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

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

13. As a result of using Trulicity, Plaintiff was caused to suffer from gastroparesis and its sequelae, which resulted in, for example, persistent vomiting, persistent diarrhea, extreme abdominal pain, requiring additional medications to treat diarrhea and vomiting, and multiple emergency room visits.

PARTY DEFENDANT

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

15. Eli Lilly designed, researched, manufactured, tested, labeled, advertised, promoted, marketed, sold, and/or distributed Trulicity and is identified on its label.[3]

[3] *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 Trulicity

16. 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.[4]

17. 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.[5]

18. 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.[6]

19. 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.[7]

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[4] 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).

[5] 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).

[6] *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).

[7] 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).

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

B. Eli Lilly's Marketing and Promotion of Trulicity

21. Trulicity has been the top earning product for Eli Lilly for the past several years, with the drug bringing in more than $5.6 billion in revenue in 2022 in the United States alone. The demand for Trulicity is largely driven by Eli Lilly's advertising, which costs the company more than $1 billion annually. Indeed, Eli Lilly advertises Trulicity through its websites, press releases, in-person presentations, the drug's label, print materials, social media, and other public outlets. Eli Lilly's advertisements tout the health benefits of Trulicity, without warning of the risk of gastroparesis or its sequelae.[8]

22. 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."[9] Although a press release accompanying Trulicity's approval acknowledged that "nausea," "vomiting" abdominal pain" were among the most common adverse reactions reported with use of Trulicity, the press release did not indicate that those common adverse reactions were symptoms of gastroparesis or warn of the risk of gastroparesis or its sequelae. Instead, the press release merely indicated that "Trulicity has not been studied in patients with ... [pre-existing] gastroparesis."[10]

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[8] 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).

[9] *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).

[10] *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).

23. 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.[11]

24. On November 5, 2018, in a press release announcing Trulicity's "superiority in reduction of cardiovascular events," as shown by an internal clinical trial, Eli Lilly acknowledged that "[t]he safety profile of Trulicity ... was generally consistent with the GLP-1 receptor agonist class." Although the press release included a section titled "Important Safety Information for Trulicity," the press release did not warn that Trulicity can cause gastroparesis or its sequelae.[12]

25. 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.[13] In the press release, Eli Lilly again indicated that "Trulicity's safety profile [is] consistent with the GLP-1 receptor agonist (RA) class," but despite warning of certain risks, the press release did not warn of the risk of gastroparesis, or its sequelae, associated with GLP-1RAs.

26. 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

[11] 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).
[12] *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).
[13] *News Release: Trulicity (dulaglutide) is the first and only type 2 diabetes medicine approved to reduce cardiovascular events in adults with and without established cardiovascular disease,* Eli Lilly (Feb. 21, 2020), available at https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-first-and-only-type-2-diabetes-medicine (last visited Nov. 15, 2023).

condition progresses."[14] Despite touting the off-label use of Trulicity for "weight loss," Eli Lilly did not warn of the associated risk of gastroparesis or its sequelae.

27. Around this same time, Robert H. Schmerling, MD, Senior Faculty Editor and Editorial Advisory Board Member at Harvard Health Publishing commented that the actors in the tv ads for Trulicity appeared notably thinner than the typical person with type 2 diabetes.[15]

28. In Summer 2021, in conjunction with Eli Lilly's sponsorship of the rescheduled Summer Olympics, Eli Lilly ran extensive television advertisements for Trulicity featuring Olympic gymnast Laurie Hernandez and her father, who has type 2 diabetes. The advertisement indicates that treatment with Trulicity is the "right choice" for people with type 2 diabetes but does not mention or warn about gastroparesis or its sequelae.[16]

29. In a similar January 2022 tv ad featuring Olympic figure skater Madison Chock and her mother, Eli Lilly again indicated that Trulicity was the "right choice" for people with type 2 diabetes. However, the ad did not warn that Trulicity can cause gastroparesis or its sequelae.[17]

30. 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

[14] *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).
[15] 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).
[16] *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).
[17] *See* Trulicity TV advertisement (Madison Chock), available at https://www.ispot.tv/ad/q3ii/trulicity-shes-got-this-featuring-madison-chock (last visited Nov. 15, 2023).

use of Trulicity." In response to a letter from the FDA, Eli Lilly temporarily removed the Trulicity Instagram account.[18] 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.

31. That same month, it was reported that Trulicity was the most advertised drug on United States television, with Eli Lilly spending an estimated $36.2 million on national television advertisements in January 2022 alone.[19]

32. In another Trulicity tv ad that premiered in February 2022, Eli Lilly boasted that Trulicity "can help you lose up to ten pounds," a use for which Trulicity is not indicated, but did not mention the risk of gastroparesis or its sequelae.[20]

33. Similarly, Eli Lilly's website used to promote Trulicity (Trulicity.com) states that people taking Trulicity "lost up to 10 lbs," without disclosing the risk of gastroparesis.[21]

34. By the end of 2022, the market was experiencing shortages of Trulicity due to "high demand" driven by Eli Lilly's advertising.[22]

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

35. As previously noted, Trulicity (dulaglutide) belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

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[18] 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).
[19] 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).
[20] Trulicity TV advertisement ("Father-Son"), available at https://www.ispot.tv/ad/q4Kl/trulicity-father-son (last visited Nov. 15, 2023).
[21] *See* https://www.trulicity.com/what-is-trulicity#what-is-trulicity.
[22] https://www.fiercepharma.com/manufacturing/after-novos-wegovy-supply-woes-lillys-would-be-obesity-rival-tirzepatide-runs-scarce

36. 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.[23]

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

38. In addition to pancreatic effects, the published medical literature shows that GLP-1 slows gastric emptying. As early as 2010, a study published in The Journal of Clinical Endocrinology & Metabolism indicated this effect.[24]

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

40. 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

[23] 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).
[24] Deane AM et al., *Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia*, 95(1) J Clinical Endo Metabolism, 225-221 (January 1, 2010), available at https://academic.oup.com/jcem/article/95/1/215/2835243 (visited on 9/26/23); American Society of Anesthesiologists, *Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests* (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery (visited on 9/26/23).

as abdominal pain (upper and lower), intestinal obstruction, change of bowel habits, vomiting, and diarrhea.[25]

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

42. 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."[26]

43. 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%)."[27] As explained above, these are symptoms of gastroparesis.

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[25] 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).

[26] 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).

[27] 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/

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

45. In August of 2020, medical literature advised that some "patients do not know they have diabetic gastroparesis until they are put on a glucagon-like peptide 1 (GLP-1) receptor agonist such as ... semaglutide ... to manage their blood glucose." The article went on to explain that "[t]his class of drugs can exacerbate the symptoms of diabetic gastroparesis. ... Thus, GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis."[28]

46. 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

[28] Young CF, Moussa M, Shubrook JH, *Diabetic Gastroparesis: A Review*, Diabetes Spectr. (2020), Aug; 33(3): 290–297, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/ (visited on 9/26/23).

with GLP-1RAs." The study further identified as one "key clinical take-home point" that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs."[29]

47. A July 2021 article funded and reviewed by Novo Nordisk considered 23 randomized control trials conducted across the United States, Japan, and China and concluded that "gastrointestinal disturbances" were "well-known" side effects associated with semaglutide use. When compared with placebos, the subcutaneous (injection) form of the drug induced nausea in up to 20% of patients (versus up to 8% on the placebo group), vomiting in up to 11.5% of patients (versus up to 3% in the placebo group) and diarrhea in up to 11.3% of patients (versus up to 6% in the placebo group). Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for gastrointestinal related adverse events, with some trials experiencing 100% discontinuation due to gastrointestinal related adverse events. The mean value of gastrointestinal related adverse events that led to discontinuation averaged 57.75%. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"[30]

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

[29] 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).
[30] Smits MM & Van Raalte DH (2021), *Safety of Semaglutide*, Front. Endocrinol., 07 July 2021, doi: 10.3389/fendo.2021.645563, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8294388/ (visited on 9/26/23).

below) and concluded that history taking and making an accurate diagnosis of diabetic gastroparesis versus medication-induced gastroparesis is critical.[31]

49. Case Report #1 in JIM involved a 52-year-old female with long-standing (10 years) well-controlled, type 2 diabetes who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis symptoms. The patient was referred with a 7-month history of post-prandial epigastric pain, accompanied by fullness, bloating, and nausea. A gastric emptying study showed a 24% retention of isotope in the patient's stomach at four hours, indicative of delayed gastric emptying. The patient discontinued semaglutide and her symptoms resolved after six weeks. The case report authors concluded that "thorough history taking revealed the cause [of gastroparesis] to be medication induced."[32]

50. Case Report #2 in JIM involved a 57-year-old female with a long-standing (16 years) type 2 diabetes who had been taking weekly dulaglutide injections (another GLP-1RA) for 15 months and suffering from abdominal bloating, nausea, and vomiting for 12 of those months. A gastric emptying study showed 35% retention of isotope in the patient's stomach at four hours, indicating delayed gastric emptying. After discontinuing dulaglutide, the patient experienced a gradual resolution of symptoms over a four-week period.[33]

51. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[34]

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[31] Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (visited on 9/26/23).
[32] Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (visited on 9/26/23).
[33] Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (visited on 9/26/23).
[34] Jastreboff, *Tirzepatide Once Weekly for the Treatment of Obesity*, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).

52. 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.[35]

53. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[36]

54. 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.[37]

55. 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."[38]

56. 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

[35] 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).
[36] Mirsha, *Adverse Events Related to Tirzepatide*, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).
[37] 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).
[38] Klein, Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report, Can J. Anesth (Mar. 28, 2023) (https://doi.org/10.1007/s12630-023-02440-3).

warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[39]

57. News sources have identified the potential for serious side effects in users of Ozempic, including gastroparesis, leading to hospitalization.[40] For example, NBC News reported in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable, and one user said that five weeks into taking the medication she found herself unable to move off the bathroom floor because she had "vomited so much that [she] didn't have the energy to get up."[41] CNN reported in July that one Ozempic user diagnosed with gastroparesis vomits so frequently that she had to take a leave of absence from her teaching job.[42]

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

[39] 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).
[40] Penny Min, *Ozempic May Cause Potential Hospitalizations*, healthnews (June 26, 2023), available at https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/ (visited on 9/26/23); Elizabeth Laura Nelson, *These Are the 5 Most Common Ozempic Side Effects, According to Doctors*, Best Life (April 3, 2023), available at https://bestlifeonline.com/ozempic-side-effects-news/ (visited on 9/26/23); Cara Shultz, *Ozempic and Wegovy May Cause Stomach Paralysis in Some Patients*, People (July 26, 2023), available at https://people.com/ozempic-wegovy-weight-loss-stomach-paralysis-7565833 (visited on 9/26/23); CBS News Philadelphia, *Popular weight loss drugs Ozempic and Wegovy may cause stomach paralysis, doctors warn* (July 23, 2023), available at https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomach-paralysis/ (visited on 9/26/23).
[41] 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).
[42] Brenda Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed*, CNN (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis/index.html (visited on 9/26/23).

(female) used Ozempic for one year and reported incidents of vomiting, including multiple times per day. The patient's physician diagnosed her with severe gastroparesis related to her Ozempic use. Patient 3 (female, age 42) experienced severe nausea both during and after she discontinued use of a GLP-1RA. In a statement to Rolling Stone, Novo Nordisk acknowledged that "[t]he most common adverse reactions, as with all GLP-1 RAs, are gastrointestinal related." Novo Nordisk further stated that while "GLP-1 RAs are known to cause a delay in gastric emptying, … [s]ymptoms of delayed gastric emptying, nausea and vomiting are listed as side effects." Novo Nordisk did not claim to have warned consumers about gastroparesis, or other severe gastrointestinal issues.[43]

59. On July 25, 2023, CNN Health reported that patients taking Ozempic have been diagnosed "with severe gastroparesis, or stomach paralysis, which their doctors think may have resulted from or been exacerbated by the medication they were taking, Ozempic." Another patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.[44]

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

[43] 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).
[44] Brenca Goodman, *They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed,* CNN Health (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis (last visited on 9/26/23).

doctors often assume the symptoms of gastroparesis are reflux or other gastrointestinal conditions, meaning it may take a long time for someone to be diagnosed correctly.[45]

61. 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.[46] The study found that patients prescribed GLP-1RAs were at 4.22 times higher risk of intestinal obstruction and at 3.67 times higher risk of gastroparesis.

62. 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.[47]

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

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[45] *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).

[46] 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).

[47] 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).

64. On information and belief, Defendant not only knew or should have known that their GLP-1RAs cause delayed gastric emptying, resulting in risks of gastroparesis, but they may have sought out the delayed gastric emptying effect due to its association with weight loss. For example, a recent study published in 2023 notes that "it has been previously proposed that long-acting GLP-1RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying,]" and the study authors suggested "further exploration of peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake."[48]

D. Defendant Failed to Warn of the Risk of Gastroparesis from Trulicity

65. The Prescribing Information for Trulicity (the "label") discloses "Warnings and Precautions" and "Adverse Reactions" but does not adequately warn of the risk of gastroparesis and its sequalae.[49]

66. The Trulicity label lists nausea, vomiting, diarrhea, abdominal pain, and decreased appetite as the most common adverse reactions reported in Trulicity patients, but it does not include these adverse reactions in its "Warnings and Precautions" section, nor does it warn that these adverse reactions are symptoms of more severe conditions, including gastroparesis. While the Warnings and Precautions section indicates that "Use of TRULICITY may be associated with gastrointestinal adverse reactions, sometime severe," the warning is lacking in urgency and specificity.[50]

[48] 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).
[49] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).
[50] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).

67. Instead of properly disclosing gastrointestinal risks, the label for Trulicity encourages prescribing physicians and patients to ignore the signs of gastroparesis and continue therapy with Trulicity because the Drug Interactions and Clinical Pharmacology sections of the label state that the delayed gastric emptying caused by Trulicity "is largest after the first dose and diminishes with subsequent doses."[51]

68. Similarly, Eli Lilly's main promotional website for Trulicity (trulicity.com) includes a variety of information about the benefits of Trulicity relating to blood sugar, cardiovascular health, and weight loss, and includes a section about "Side Effects" and a sidebar containing a "SAFETY SUMMARY WITH WARNINGS." However, Eli Lilly does not disclose the risk of gastroparesis within either the "Side Effects" or "SAFETY SUMMARY WITH WARNINGS" sections of the website.[52]

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

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

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

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

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

73. None of Defendant's additional advertising or promotional materials warned prescription providers or the general public of the risks of gastroparesis and its sequalae.

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

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

76. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from gastroparesis and its sequelae, which resulted in severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

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

77. 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.

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

79. At all times mentioned herein, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Trulicity that was used by Plaintiff.

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

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

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

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

84. Defendant 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.

85. At all relevant times, given their increased safety risks, Trulicity was not fit for the ordinary purpose for which it was intended.

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

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

88. At all relevant times, Plaintiff was using Trulicity for the purposes and in a manner normally intended—namely, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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

90. The Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendant knew or should have known of the risks of serious side effects, including gastroparesis and its sequalae, as well as other severe and permanent health consequences from 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 product, Trulicity.

91. The label for Trulicity was inadequate because it did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Trulicity, including the increased risk of gastroparesis and its sequelae.

92. The label for Trulicity was inadequate because it did not warn and/or adequately warn that Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae.

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

94. The label for Trulicity was inadequate because it did not warn and/or adequately warn of the severity and duration of adverse effects, as the warnings given did not accurately or unambiguously reflect the scope and nature of symptoms or severity of the side effects.

95. The label for Trulicity was inadequate because it did not state with sufficient specificity the increased risk of gastroparesis and its sequela causally associated with Trulicity.

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

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

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

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

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

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

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

103. If Plaintiff had been warned that Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequalae, then Plaintiff would not have used Trulicity and/or suffered gastroparesis and its sequelae.

104. If Plaintiff had been warned of the increased risks of gastroparesis and its sequelae, which is causally associated with Trulicity, then Plaintiff would have informed Plaintiff's prescribers that Plaintiff did not want to take Trulicity.

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

106. By reason of the foregoing, Defendant has become liable to Plaintiff for the designing, marketing, promoting, distribution and/or selling of unreasonably dangerous products, Trulicity.

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

108. Defendant's inadequate warnings for Trulicity was acts that amount to willful, wanton, and/or reckless conduct by Defendant.

109. Said inadequate warnings for Defendant's drugs Trulicity was a substantial factor in causing Plaintiff's injuries.

110. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment,

monitoring and/or medications, and fear of developing any of the above-named health consequences.

111. 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 UNDER I.C.A. § 554.2313 – AGAINST ALL DEFENDANTS)

112. 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.

113. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have acquired the Defendant who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Trulicity, which was used by Plaintiff as hereinabove described.

114. At all relevant times, Defendant expressly warranted to Plaintiff and Plaintiff's prescribing physician(s) that Trulicity was safe as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

115. The aforementioned express warranties were made to Plaintiff and Plaintiff's prescribing physician(s) by way of Trulicity's label, website, advertisements, promotional materials, and through other statements.

116. As a result of Defendant's express warranties, Plaintiff's prescribing physician(s) were induced to prescribe Trulicity to Plaintiff, and Plaintiff was induced to use Trulicity.

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

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

119. At all relevant times, Defendant knew or should have known that Trulicity was unreasonably dangerous because of the increased risk of gastroparesis and its sequelae, especially when the drug was used in the form and manner as provided by Defendant.

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

121. The unreasonably dangerous characteristics of Trulicity was beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drug's characteristics.

122. The unreasonably dangerous characteristics of Trulicity was beyond that which would be contemplated by Plaintiff's prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drug's characteristics.

123. At the time Trulicity left Defendant's control, Trulicity did not conform to Defendant's express warranties because Trulicity was not safe to use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, in that the drug was causally associated with increased risks of gastroparesis and its sequelae.

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

125. Defendant 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 Trulicity and/or the natural tendency of Plaintiff's prescribing physician(s) to prescribe Trulicity.

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

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

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

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

130. Accordingly, Defendant is liable as a result of their breach of express warranties to Plaintiff.

131. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment,

monitoring and/or medications, and fear of developing any of the above-named health consequences.

132. 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 Defendant's drug, Trulicity.

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

THIRD CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY UNDER I.C.A. § 554.2314 - AGAINST ALL DEFENDANTS)

134. 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.

135. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Trulicity drugs used by Plaintiff.

136. Trulicity was expected to and did reach the usual consumers, handlers, and persons encountering said products without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendant.

137. At all relevant times, Defendant impliedly warranted to Plaintiff, Plaintiff's prescribing physician(s), and the medical community that Trulicity was of merchantable quality and safe and fit for their ordinary purposes.

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

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

140. At the time Trulicity left Defendant's control, Trulicity did not confirm to Defendant's implied warranty and were unfit for its ordinary purposes because Defendant failed to provide adequate warnings of the drug's causal association with increased risk of gastroparesis and its sequelae.

141. At all relevant times, Defendant reasonably anticipated and expected that prescribing physician(s), such as Plaintiff's prescribing physician(s), would recommend, prescribe and/or dispense 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.

142. At all relevant times, Defendant reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Trulicity for its ordinary purposes.

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

144. The unreasonably dangerous characteristics of Trulicity was 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.

145. The unreasonably dangerous characteristics of Trulicity was 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.

146. Plaintiff reasonably relied on Defendant's implied warranty of merchantability relating to Trulicity's safety and efficacy.

147. Plaintiff reasonably relied upon the skill and judgment of Defendant as to whether Trulicity was of merchantable quality and safe and fit for their intended use.

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

149. Upon information and belief Plaintiff's prescribing physician(s), reasonably relied upon the skill and judgment of Defendant as to whether Trulicity was of merchantable quality and safe and fit for the drug's intended use.

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

151. Defendant herein breached the aforesaid implied warranty of merchantability because the drugs Trulicity was not fit for the drug's intended purposes.

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

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

154. 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)

155. 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.

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

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

158. At all relevant times, Defendant knew or should have known that Trulicity was unreasonably dangerous because of the increased risk of gastroparesis and its sequelae, especially when the drug was used in the form and manner as provided by Defendant.

159. Defendant had a duty to disclose material information about Trulicity to Plaintiff and Plaintiff's prescribing physician(s), namely that Trulicity is causally associated with increased risk of gastroparesis and its sequelae, because Defendant has 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 Defendant knew or should have known that Plaintiff and Plaintiff's prescribing physician(s) would act on the basis of mistaken knowledge.

160. Nonetheless, Defendant 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.

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

162. Defendant's promotional website for Trulicity similarly does not disclose that Trulicity is causally associated with increased risk of gastroparesis.

163. Defendant's 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 Trulicity for treatment of Type 2 Diabetes.

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

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

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

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

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

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

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

171. Defendant's fraudulent concealments were a substantial factor in causing Plaintiff's injuries.

172. As a direct and proximate result of the above stated omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, 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. 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-AGAINST ALL DEFENDANTS)

174. 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.

175. At all relevant times, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Trulicity, which was used by Plaintiff as hereinabove described.

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

177. At all relevant times, Defendant knew or should have known of the serious side effects of Trulicity, including gastroparesis and its sequelae.

178. At all relevant times, Defendant knew or should have known that Trulicity was not safe to improve glycemic control in adults with type 2 diabetes, reduce cardiovascular risk in patients with type 2 diabetes, or promote weight loss, given their increased risk of gastroparesis.

179. Nonetheless, Defendant 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 Trulicity

180. Defendant represented affirmatively and by omission on television advertisements and on the labels of Trulicity that Trulicity was safe and effective drugs for treatment of adults with Type 2 diabetes, despite being aware of increased risks of gastroparesis and its sequelae causally associated with using Trulicity.

181. Defendant was aware or should have been aware that Defendant's 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.

182. Defendant's 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 Trulicity for treatment of Type 2 Diabetes.

183. Upon information and belief that Plaintiff's prescribing physician(s) had no way to determine the truth behind Defendant's false and/or misleading statements, concealments and omissions surrounding Trulicity, and reasonably relied on false and/or misleading facts and

information disseminated by Defendant, which included Defendant's omissions of material facts in which Plaintiff's prescribing physician(s) had no way to know were omitted.

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

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

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

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

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

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

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

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

192. 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 Defendant 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 Defendant, 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 Defendant 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: April 5, 2024

By: */s/ Christopher D. Stombaugh*

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**Application for admission pro hac vice to be filed*