UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION

JACLYN BJORKLUND,

Plaintiff,

v.

NOVO NORDISK A/S, NOVO NORDISK NORTH AMERICA OPERATIONS A/S, NOVO NORDISK US HOLDINGS INC., NOVO NORDISK US COMMERCIAL HOLDINGS INC., NOVO NORDISK INC., NOVO NORDISK RESEARCH CENTER SEATTLE, INC., NOVO NORDISK PHARMACEUTICAL INDUSTRIES LP, and ELI LILLY AND COMPANY,

Defendants.

CASE NO. 2:23-cv-01020

JUDGE JAMES D. CAIN, JR.

MAGISTRATE JUDGE KATHLEEN KAY

MEMORANDUM OF LAW IN SUPPORT OF NOVO NORDISK DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT PURSUANT TO RULE 12(b)(6)

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Novo Nordisk U.S. Holdings Inc., Novo Nordisk U.S. Commercial Holdings Inc., Novo Nordisk Inc., Novo Nordisk Research Center Seattle, Inc., and Novo Nordisk Pharmaceutical Industries LP (collectively the "Novo Nordisk Defendants")[1] respectfully move to dismiss Plaintiff's First Amended Complaint ("FAC") pursuant to Federal Rule of Civil Procedure 12(b)(6).

INTRODUCTION

This is a product liability case in which Plaintiff Jaclyn Bjorklund alleges that she experienced certain gastrointestinal side effects after taking two different medicines indicated for the treatment of type 2 diabetes: Ozempic®, which is marketed in the U.S. by Novo Nordisk Inc., and Mounjaro®, which is marketed in the U.S. by Eli Lilly and Company ("Lilly"). Plaintiff acknowledges in her complaint that "gastrointestinal events are well known side effects" which are extensively discussed in the U.S. Food and Drug Administration ("FDA") approved labeling for both products. Nonetheless, Plaintiff somehow claims her unidentified physician(s)[2] were not adequately warned of these risks and alleges that both the Novo Nordisk Defendants and Lilly

[1] As of the filing of this motion, Novo Nordisk A/S and Novo Nordisk North America Operations A/S have not been served.

[2] In this motion, the Novo Nordisk Defendants identify pleading deficiencies that concern the FAC's general allegations regarding unidentified "physician(s)", to whom Plaintiff refers to as "he/she/they." *See* FAC at ¶¶ 12, 120-21, 136. On October 31, 2023, Plaintiff served initial Rule 26 Disclosures and identified a prescribing physician for Ozempic® and Mounjaro® and that physician's medical practice. Even so, the Novo Nordisk Defendants maintain that the FAC is not plausibly pleaded, particularly as to warnings causation, for the reasons discussed further herein. Moreover, a court considering a motion to dismiss is limited to a consideration of the matters in the pleadings, except as noted below in footnote 5. *See PHI Group, Inc. v. Zurich Am. Ins. Co.*, 58 F.4th 838, 841 (5th Cir. 2023). As such, Plaintiff's Rule 26 Initial Disclosures are not properly considered at the motion to dismiss stage. *See Baxa v. Seterus, Inc.*, No. 17-cv-5434, 2019 WL 315096, at *1 (E.D. La. Jan. 24, 2019) (explaining "the Court need not strike" the "Plaintiffs' initial disclosures," which were attached to defendant's motion to dismiss because the "Court will not consider them at this stage of the proceedings."). Further, the violations of Rule 8 detailed in this motion still warrant the FAC's dismissal, in light of the joint Rule 26(f) Report filed on October 31, 2023, wherein Plaintiff stated that she had already amended the Complaint (ECF No. 5) and no additional amendments are expected. *See* ECF No. 52 at 3.

violated an ill-defined express warranty. Plaintiff's allegations as pleaded do not come close to "rais[ing] a right to relief above the speculative level" for either claim. *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 555 (2007).

As an initial matter, Plaintiff fails to plausibly allege the basic elements of her failure-to-warn and breach-of-express-warranty claims under the Louisiana Products Liability Act ("LPLA"). With respect to the first, Plaintiff does not adequately allege, as required under the LPLA, that her treating physician(s) would have changed their prescribing decision(s) had different or additional warnings been provided in the product labeling. *See Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098-99 (5th Cir. 1991). This is particularly problematic considering that the LPLA imposes no duty to warn a physician about known risks such as the well-known side effects of Ozempic® and Mounjaro® she claims to have experienced—nausea, abdominal pain, and heartburn. *See Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 268 (5th Cir. 2002). The express warranty claim fails for similar reasons: Plaintiff does not allege any specific warranty made by the Novo Nordisk Defendants and does not adequately plead the required element of inducement. *See Fuller v. Eisai Inc.,* 513 F. Supp. 3d 710, 723-24 (E.D. La. 2021).

Plaintiff attempts to obscure these fundamental deficiencies in her FAC through the use of shotgun pleadings "calculated to confuse" with redundancies and irrelevant allegations. *Weiland v. Palm Beach Cnty. Sheriff's Off.*, 792 F.3d 1313, 1320-23 (11th Cir. 2015). The FAC devotes numerous pages and paragraphs to allegations that are in no way connected to her claims—discussing pricing, promotion, off-label use, and physician meals and travel—while at the same time failing to provide basic information about her individual case, such as who prescribed her medications, where the medications were prescribed, filled, and purchased, what condition she was being treated for, or when she first experienced her alleged side effects.

Plaintiff compounds these problems by making her substantive allegations without distinguishing in any way between the eight defendants and the two different medicines at issue. As a result of this "group pleading," the Court and the parties have no way to "discern[] which defendants are allegedly responsible for which allegedly unlawful actions." *Cain v. City of New Orleans*, No. 15-cv-4479, 2016 WL 2849478, at *5 (E.D. La. May 13, 2016). The FAC does not even plausibly identify the product that purportedly caused her injuries, a necessary element for an LPLA claim.

For all these reasons, as discussed further below, this Court should dismiss the claims against the Novo Nordisk Defendants pursuant to Federal Rule of Civil Procedure 12(b)(6).[3] In addition, the Novo Nordisk Defendants request that the Court strike Plaintiff's request for punitive damages and attorney's fees, as neither are permitted under the LPLA.

BACKGROUND

I. Ozempic®

Ozempic® (semaglutide) is a once-weekly prescription medicine used to treat type 2 diabetes. Ozempic® is part of a class of medicines known as glucagon-like peptide-1 receptor agonists (or GLP-1RAs for short).[4] For nearly two decades, GLP-1RA medicines have been used

[3] Lilly separately moved to dismiss Plaintiff's FAC on October 26, 2023. In addition to raising similar arguments as the Novo Nordisk Defendants, Lilly also raised preemption as a basis for seeking dismissal. *See* Dkt. No. 49-1. The Novo Nordisk Defendants agree with Lilly that, to plead a non-preempted failure-to-warn claim, Plaintiff must point to "newly acquired information" that "reveal risks of a different type or greater severity or frequency than previously included in submissions to the FDA"—the threshold regulatory prerequisite for changing an FDA-approved label for a prescription drug. *Id.* at 10-13 (quoting 21 C.F.R. § 314.3(b)); *see also* 21 C.F.R. § 314.70(c)(6)(iii). The Novo Nordisk Defendants do not address that argument here given the threshold pleading deficiencies described in this Motion. If the Plaintiff were able to cure the plainly inadequate pleadings, the Novo Nordisk Defendants reserve the right to raise preemption as a defense and grounds for dismissal of this lawsuit, or in a subsequent motion for judgment on the pleadings.

[4] Mounjaro® (tirzepatide) is a different medication, which acts as both a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist. Mounjaro was first

to treat type 2 diabetes and, in that time, have revolutionized the treatment of this chronic disease. Today, millions of Americans rely on these medicines to help control their blood sugars and to minimize their risk of diabetic complications.

Ozempic® was first approved by the FDA in 2017 as "an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." *See* Ozempic® Label, dated Dec. 5, 2017, at 1 (attached as Ex. 1 to the Declaration of Diana Cole Surprenant ("Surprenant Decl.")).[5] Prior to approval, the safety and efficacy of the medicine was evaluated in seven (7) phase 3 clinical trials in which 3,150 patients were treated with Ozempic®. *See id*. at 6. As reported in the FDA-approved product labeling, the most commonly reported adverse events in those trials were nausea, vomiting, diarrhea, abdominal pain, and constipation—the very symptoms Plaintiff alleges. *See id*. at 7. In 2020, FDA approved an additional indication for cardiovascular risk reduction in patients with type 2 diabetes and established cardiovascular disease, based on clinical trial data showing that Ozempic® decreased the risk of major adverse cardiovascular events (including death, heart attacks, and strokes) by 26%. *See* Ozempic® Label, dated Jan. 16, 2020, at 3 (attached as Ex. 2 to the Surprenant Decl.).

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approved by FDA in May 2022. The clinical data and product labeling for Mounjaro® is different than that for Ozempic®.

[5] On a motion to dismiss, the Court may consider documents that are referred to in the Complaint or central to the claims in the Complaint without converting the motion to one for summary judgment. *See Coleman v. Sears Home Improvement Prod., Inc.*, No. 16-cv-2537, 2017 WL 1089580, at *6 (E.D. La. Mar. 21, 2017) (considering documents with sufficient indicia of reliability attached to a motion to dismiss without converting it to a motion for summary judgment because they were referenced in the complaint and central to plaintiff's claims). Further, the Court may take judicial notice of the Ozempic® label. *See Funk v. Stryker Corp*., 631 F.3d 777, 783 (5th Cir. 2011) (stating judicial notice was appropriate for "publicly-available documents and transcripts produced by the FDA, which were matters of public record directly relevant to the issue at hand"); *Pramann v. Janssen Pharm., Inc*., No. 16-cv-12413, 2017 WL 58469, at *2 n.3 (E.D. La. Jan. 5, 2017) (taking judicial notice of the "FDA approved Risperidone label" attached to defendant's motion to dismiss).

II. Gastroparesis

Plaintiff Bjorklund alleges that she developed "gastroparesis and its sequelae" (vomiting, abdominal pain, and heartburn) at some point while taking Ozempic® and Mounjaro®. FAC ¶¶ 13-14. Gastroparesis—which Plaintiff notes also is known as delayed gastric emptying—is a disorder that slows or stops the movement of food from the stomach to the small intestine.[6] FAC ¶ 80. Symptoms of gastroparesis or delayed gastric emptying include nausea, vomiting, bloating, and heartburn.[7] Patients with uncontrolled diabetes are at increased risk for developing gastroparesis / delayed gastric emptying.[8]

It is widely recognized that delayed gastric emptying is an effect, and part of the mechanism of action, of all GLP-1RA medicines. FDA acknowledged this fact at the time it approved Ozempic®: "Non-pancreatic effects of GLP-1 include slowing of gastric emptying, reduction of food intake, and an increase in satiety, all of which contribute to improved glycemic control and decreased body weight." FDA Nov. 22, 2017 Clinical Review, at 33 (attached as Ex. 3 to the Surprenant Decl.). As reflected in Plaintiff's FAC, the effects of GLP-1RA medicines on gastric emptying and the potential for gastroparesis have long been known in the medical community and in the published literature. For example, Plaintiff states in her FAC:

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[6] *See also* Camilleri M, *Gastroparesis,* NIH National Institute of Diabetes and Digestive and Kidney Diseases, https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis (last visited Nov. 3, 2023).

[7] *See* Zheng T, Camilleri M, *Management of Gastroparesis,* 17 Gastroenterology & Hepatology 515 (Nov. 2021), https://www.gastroenterologyandhepatology.net/files/2021/11/1121-Zheng-Camilleri.pdf; *see also* FAC ¶ 81.

[8] *See* Young CF, Moussa M, Shubrook JH, *Diabetic Gastroparesis: A Review*, 33 Diabetes Spectrum 290, 290 (Nov. 2021), ("This complication is associated with uncontrolled diabetes, contributing to approximately one-third of all gastroparesis cases."), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/pdf/diaspectds190062.pdf; *see also* FAC¶ 68 n. 37.

- "As early as 2010"—12 years before Plaintiff allegedly was prescribed Ozempic®—"a study published in The Journal of Clinical Endocrinology & Metabolism indicated that GLP-1 slows gastric emptying." FAC ¶ 61;

- "[A] study published in October 2017"—more than four years before Plaintiff was allegedly prescribed Ozempic®—"explained that 'GLP-1 suppresses gastric emptying by inhibiting peristalsis of the stomach while increasing tonic contraction of the pyloric region.'" *Id.* at ¶ 60;

- "In August 2020"—nearly two years before Plaintiff was allegedly prescribed Ozempic®—"medical literature advised that . . .this [GLP-1] class of drugs can exacerbate the symptoms of diabetic gastroparesis[,]" and thus "GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis." *Id*. at ¶ 68;

- "An October 2021 article in the Journal of Investigative Medicine ('JIM')"—nearly a year before Plaintiff was allegedly prescribed Ozempic®—stated that "both diabetes and GLP-1 RAs can cause delayed gastric emptying," and "reviewed two case reports," finding gastroparesis was induced by GLP-1 Ras. *Id.* at ¶¶ 71-73).

As Plaintiff herself acknowledged, it also is well recognized that gastrointestinal side effects, including nausea, vomiting, diarrhea, and abdominal pain (the "sequelae of gastroparesis") are the most common side effects of Ozempic® and other GLP-1RAs. *See id*. at ¶¶ 69-87. This is consistent with FDA's analysis of the evidence completed prior to approving Ozempic® in 2017. FDA Nov. 22, 2017 Clinical Review, at 260.

III. Ozempic® Product Labeling

The FDA-approved labeling for Ozempic® always has prominently stated that the medicine may cause delayed gastric emptying (also known as gastroparesis) and has included extensive information and warnings about potential gastrointestinal side effects, including the very symptoms Plaintiff alleges she experienced. The effects of Ozempic® on gastric emptying are discussed in many parts of the product labeling, including on the first page, which states directly: "OZEMPIC delays gastric emptying." *See* Ozempic® Label, dated Oct. 6, 2022, at 1 (attached as Ex. 4 to the Surprenant Decl.). Additional information for prescribers is included in Section 7

(Drug Interactions), *id.* at 9; Section 12.1 (Mechanism of Action), *id.* at 12; Section 12.2 (Pharmacodynamics), *id.* at 14; and Section 12.3 (Pharmacokinetics), *id.* at 15.

Gastrointestinal side effects are also discussed throughout the label, including in the Warnings & Precautions in Section 5, *id.* at 4-6, Adverse Reactions in Section 6, *id.* at 6-9, and the Clinical Trials Experience in Section 6.1, *id.* at 6-9, as well as in the Medication Guide for patients, *id.* at 27-end. Again, on the first page, the product labeling warns: "The most common adverse reactions, reported in ≥5% of patients treated with OZEMPIC are: **nausea**, **vomiting**, **diarrhea**, **abdominal pain** and **constipation**." *Id.* at 1 (emphasis added). More detailed information on these reactions is included in Section 6.1 of the label, which discusses **nausea**, **vomiting**, **diarrhea**, **dyspepsia**, **eructation** (or burping), **flatulence**, **gastroesophageal reflux disease** (or heartburn), and **gastritis**, and notes that, in clinical trials, approximately 3% of patients had to stop taking Ozempic® due to the severity of their GI side effects. *Id.* at 7 (emphasis added). Similarly, the Medication Guide for patients states: "The most common side effects of OZEMPIC may include **nausea**, **vomiting**, **diarrhea**, **stomach (abdominal) pain**, and **constipation**." *Id.* at 28 (emphasis added).

IV. Plaintiff and Her Allegations

Plaintiff's FAC includes very limited information regarding her history and alleged injuries. Plaintiff is a forty-five (45) year old woman who allegedly took Ozempic® "for more than one year" until "stopping use in or around July 2023, at which point she began using Mounjaro." FAC ¶ 10-11. Plaintiff claims that she was prescribed Ozempic® and Mounjaro® by one or more unidentified physicians, to whom she refers generally as "he/she/they." *Id.* at ¶¶ 12, 120-21, 136. She does not allege where she was prescribed the medicines, what condition the medicines were prescribed to treat, where she purchased the medicines, or where she took the medicines. *Id.*; *see also id.* ¶¶ 9-15. At some point while taking these medicines, she allegedly

experienced "gastroparesis and its sequalae," including symptoms of "severe vomiting, stomach pain, [and] gastrointestinal burning." *Id.* at ¶¶ 13-14. Plaintiff does not specify which medicine caused her alleged symptoms or state when her symptoms first began. *See id.* ¶¶ 9-15. She also does not state where these alleged complications occurred, or where she received treatment for her condition. *See id.*

Plaintiff brings two causes of action against all Defendants: (1) inadequate warning under LA. REV. STAT. § 9:2800.57 and (2) breach of express warranty under LA. REV. STAT. § 9:2800.58. With respect to the first, Plaintiff alleges that, if her "prescribing physician(s)" had been (1) "warned of the increased risk of gastroparesis causally associated with Ozempic® and Mounjaro" or (2) had known that Ozempic® and Mounjaro® "had not been sufficiently and/or adequately tested for safety risks, including gastroparesis," "he/she/they would not have prescribed Ozempic® and Mounjaro® and/or would have provided Plaintiff with adequate warnings." *Id.* at ¶¶ 120-21. As to the second, Plaintiff claims that the "Defendants expressly warranted to [her] and her prescribing physician(s) that Ozempic® and Mounjaro® were safe as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." *Id.* at ¶ 134.

LEGAL STANDARD

Rule 8(a)(2) of the Federal Rules of Civil Procedure governs the requirements for pleadings that state a claim for relief. Such a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." F.R.C.P. 8(a)(2). Under this standard, "factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly,* 550 U.S. at 555. If a pleading only contains "labels and conclusions" or "a formulaic recitation of the elements of a cause of action," the pleading does not meet the standards of Rule 8(a)(2). *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009) (citation omitted). In deciding a Rule12(b)(6) motion

to dismiss, courts must accept all allegations in a complaint as true, but courts do not have to accept legal conclusions as facts. *Id.* Only those complaints that are facially plausible under the *Iqbal* and *Twombly* standards survive a Rule 12(b)(6) motion to dismiss.

ARGUMENT

I. Plaintiff's "Shotgun Pleading" Does Not Satisfy Rule 8 And Warrants Dismissal of the FAC in its Entirety.

Plaintiff's FAC is a classic example of an impermissible "shotgun pleading"—a complaint that substitutes generalities, broad allegations, and group pleading in place of substantive pleadings that establish plausible allegations as to the particular plaintiff and her specific claims. The "unifying characteristic" of shotgun pleadings "is that they fail to one degree or another, and in one way or another, to give defendants adequate notice of the claims against them and the grounds upon which each claim rests." *Weiland v. Beach Cnty. Sheriff's Off.*, 792 F.3d 1313, 1323 (11th Cir. 2015). Courts therefore routinely dismiss complaints utilizing this "vexing" strategy because it "patently violates Rule 8's command [for] 'a short and plain statement,' in favor of a shotgun approach that packs so many redundancies and irrelevant allegations into what *might* be a meritorious claim that it is impossible to accurately understand the scope of the dispute." *Scott v. City of Baton Rouge/Par. of E. Baton Rouge*, No. 22-cv-00488, 2023 WL 3746477, at *2 (M.D. La. May 31, 2023) (emphasis in original); *see also Weiland*, 792 F.3d at 1323.

Plaintiff's FAC is 30 pages long and includes more than 150 paragraphs. But the length of the FAC should not be confused with its adequacy. To the contrary, a closer look at the FAC shows in numerous ways that this is exactly the type of shotgun pleading that "[t]he Fifth Circuit specifically discourages" and which "are subject to dismissal pursuant to Federal Rule of Civil Procedure 12(b)(6)." *Copeland v. Axion Mortg. Grp. LLC*, No. 16-cv-159, 2016 WL 4250431, at *4 (S.D. Miss. Aug. 11, 2016).

First, each of Plaintiff's substantive allegations lump together the two manufacturer defendants (the Novo Nordisk Defendants and Lilly) and the two medicines at issue (Ozempic® and Mounjaro®), ignoring the differences in their conduct, data, and labeling. *See* FAC ¶¶ 100-108, 116-117, 127-128, 133-145 (allegations about "Defendants'" conduct); *id*. at ¶¶110-115; *id.* at ¶ 134 ("Defendants expressly warranted to Plaintiff and her prescribing physician(s) that Ozempic and Mounjaro were safe[.]"). As numerous courts have concluded, such a "theory of collective responsibility cannot withstand a motion to dismiss." *Cain v. City of New Orleans*, No. 15-cv-4479, 2016 WL 2849478, at *5 (E.D. La. May 13, 2016) (citation omitted); *see also Sistrunk v. Haddox*, No. 18-cv-516, 2020 WL 2549699, at *11 (W.D. La. May 19, 2020) (dismissing a complaint because it asserted "multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions, or which of the defendants the claim is brought against."); *Ware v. U.S. Bank Nat. Ass'n*, No. 13-cv-387, 2013 WL 6805153, at *4 (S.D. Miss. Dec. 20, 2013) (plaintiff "should avoid lumping the defendants together and should instead separately allege the scope of any duties owed and conduct alleged to have breached those duties as to each defendant."); *Rogers v. Raycom Media, Inc.*, No. 14-cv-425, 2014 WL 4471456, at *3 (W.D. La. Sept. 5, 2014), aff'd in part, vacated in part, remanded on other grounds, 628 F. App'x 324 (5th Cir. 2016) (dismissing a 42-page complaint naming nine defendants that was "replete with conclusory allegations that the Defendants engaged in certain conduct, making no distinction among the nine Defendants[.]"). The FAC's use of group pleading for essential elements of the failure-to-warn and express warranty claims is grounds for dismissal.

Second, large swaths of the FAC have no relevance to the Plaintiff or the specific claims in this case. For example, the FAC includes allegations about Ozempic® pricing (FAC ¶ 39), savings cards (*id*. at ¶ 40), promotion for weight loss (*id*. at ¶¶ 42, 47), television advertising (*id*.

at ¶ 43), and "food and travel" for physicians (*id*. at ¶ 44); tellingly, however, Plaintiff does not allege how any of these claims related to her treatment and alleged injuries. Further, within each of her causes of action, the FAC then "repeats, reiterates, and realleges each and every allegation," thereby incorporating scores of irrelevant assertions into each claim, "making it impossible for Defendants to accurately understand the scope and nature of Plaintiff's claims." FAC ¶¶ 98, 132. *See O'Neal v. Universal Prot. Serv., LLC*, No. 21-cv-00737, 2022 WL 1631970, at *1, 5-6 (M.D. La. May 23, 2022).

Finally, as outlined further below, the FAC is bereft of allegations with actual connection to Plaintiff's failure-to-warn or express warranty claims. The barebones pleading fails to allege when or where Plaintiff was first prescribed Ozempic®, who prescribed Ozempic® to her, whether the prescribing physician(s) had knowledge of Ozempic®'s label and whether they were aware of its disclosed gastrointestinal side effects, when her gastrointestinal side effects allegedly began and when they resolved, what medication she was taking when the side effects started, or where or when she received treatment (if any) for those side effects. *See generally* FAC; *see also id*. ¶¶ 9-15, 120-21, 136.

For all these reasons, the FAC should be dismissed as a shotgun pleading that fails basic Rule 8 pleading requirements.

II. Plaintiff Failed to Adequately Plead a Cause of Action for Inadequate Warning.

The FAC also fails to state a plausible failure-to-warn claim under the LPLA. The LPLA provides "the exclusive theories of liability for manufacturers for damage caused by their products." LA. REV. STAT. § 9:2800.52. "Louisiana applies the learned intermediary doctrine to product liability claims involving prescription drugs." *Stahl v. Novartis Pharmacy Corp.*, 283 F.3d 254, 265 (5th Cir. 2002). Applying the learned intermediary doctrine, the LPLA requires a plaintiff claiming failure-to-warn to plausibly plead (1) the defendant failed to warn her prescribing

physician about a risk that was otherwise unknown to the physician, and (2) the failure to warn was both a cause in fact and the proximate cause of her claimed injury. *Id.* at 265-66*; see also Willett*, 929 F.2d at 1098 ("[T]he manufacturer has no duty to warn the patient, but need only warn the patient's physician."). Plaintiff's FAC fails to satisfy both requirements.

A. Plaintiff failed to plead warnings causation.

Under the learned intermediary doctrine, "a patient's physician acts as an informed intermediary between the drug company and the patient . . . Thus, a drug manufacturer has a duty to warn the prescribing physician, rather than the patient, of potential risks associated with the use of the drug." *In re Taxotere (Docetaxel) Prod. Liab. Litig. (Philips)*, 994 F.3d 704, 708 (5th Cir. 2021) (citations omitted). "To prove causation in this context, a 'plaintiff must show that a proper warning *would have changed the decision of the [prescribing] physician*, *i.e.* that but for the inadequate warning, *the [prescribing] physician would not have used or prescribed the product*.'" *Id.* (quoting *Willet*, 929 F.2d at 1099) (emphases added). Plaintiff's scant allegations fall far short of pleading warnings causation.

Plaintiff's only allegation addressing warnings causation is a conclusory statement "[u]pon information and belief," that "had Plaintiff's prescribing physician(s) been warned of the increased risk of gastroparesis causally associated with Ozempic and Mounjaro, he/she/they [the unidentified physicians] would not have prescribed Ozempic and Mounjaro ***and/or*** would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic and Mounjaro so as to allow Plaintiff to make an informed decision regarding her use of Ozempic and Mounjaro." FAC ¶¶ 120 (emphasis added). Under Louisiana law, this fails for several reasons.

As a threshold matter, allegations made "[u]pon information and belief," are not sufficient to "nudge[] [plaintiff's] claims across the line from conceivable to plausible." *Bell Atl. Corp. v. Iqbal*, 550 U.S. 554, 551, 570 (2007). This disfavored information-and-belief allegation is further

undermined by improper group pleading—lumping together "Ozempic and Mounjaro"—and by pleading in multiple alternatives—"he/she/they" combined with "and/or." This pleading is so limited by these caveats and alternatives that no plausible pleading may be discerned.

Moreover, Plaintiff's failure to plead even minimal facts about her own prescribing physician(s) or any circumstance of the prescription decision demonstrates the inadequacy of the pleadings. Plaintiff's bare pleadings leave the FAC with no plausible claim that any prescribing physician or physicians would decide not to prescribe Ozempic® if a different or additional warning had been provided about the risk of gastrointestinal side effects. *See e.g.*, *Kennedy v. Pfizer, Inc.*, No. 12-cv-01858, 2013 WL 4590331, at *5 (W.D. La. Aug. 28, 2013) (dismissing inadequate warning claim where plaintiff failed to even identify "who administered the drug"). The net result is a complete failure to plausibly assert the key element of warnings causation.

It is further irrelevant to warnings causation whether Plaintiff's unidentified physician may have warned Plaintiff directly about the risk of gastrointestinal side effects. Under the learned intermediary rule, the duty to warn runs only to the physician, not the patient. *See In re Taxotere (Docetaxel) Prod. Liab. Litig.* (*Phillips*), 994 F.3d 704, 708 (5th Cir. 2021) ("[A] drug manufacturer has a duty to warn the prescribing physician, rather than the patient, of potential risks associated with the use of the drug."). Thus "a causation analysis in a failure-to-warn claim asserted against a drug's manufacturer (the only claim at issue here) is focused on the prescribing physician's decision to prescribe the drug." *Id.* at 709.

Likewise, no duty exists to warn a prescribing physician about the adequacy of *testing* for safety risks, which is also not information that would appear on an FDA-approved label for a prescription drug. *See* FAC at ¶¶ 121, 123; *Bell v. Danek Med., Inc.*, No. 96-cv-1393, 1999 WL 335612, at *4 (E.D. La. May 24, 1999) ("Because this case involves a medical product, the learned

intermediary doctrine applies. … Any argument that the warnings were inadequate because of a failure to test has been rejected by the Fifth Circuit[.]") (citing *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 256 (5th Cir. 1999)).[9]

B. Plaintiff failed to plead the breach of a duty where the asserted risks were disclosed on the label and well-known in the medical literature.

The LPLA imposes no duty to warn a physician of risks that are "within the knowledge of or obvious to the average learned intermediate." *Stahl*, 283 F.3d at 268 (citing *Willett*, 929 F.2d at 1098 n.16). Stated differently, a manufacturer has a duty to warn a learned intermediary of *unknown* risks. *See* LA. REV. STAT. § 9:2800.57(B)(2); *see In re Taxotere (Docetaxel) Prod. Liab. Litig.* (*Gahan*), 859 Fed. App'x 692, 694 (5th Cir. 2021) (per curiam) (declining to find duty to warn where prescribing physician and patient were aware of the claimed increased side-effect risk). No duty to provide additional warnings was required here where the gastrointestinal side effects of Ozempic® were publicized, were prominently disclosed in multiple locations on the Ozempic® label and were well-known to the medical community.

Indeed, the FAC is replete with published studies and other reference materials indicating that the gastrointestinal risks associated with the use of Ozempic®—including delayed gastric emptying, nausea, vomiting, and abdominal pain—have been known and understood in the medical community for years prior to Plaintiff's use of the medicines. *See e.g.*, FAC ¶¶ 59-61 ("It

[9] For these reasons, the FAC is distinguishable and inadequate in comparison to the complaint that was "barely sufficient" in *Harris v. Merck & Co. Inc.*, No. 12-cv-1446, 2012 WL 5384720, at *5 (W.D. La. Nov. 1, 2012). *Harris* involved neither group pleading, shotgun pleading, "upon information and belief" allegations nor the alternative pleading as to the elements of warnings causation, all of which highlight that the FAC here is merely a boilerplate recitation of the elements of this claim that does not survive a motion to dismiss. Moreover, plaintiff's failure-to-warn claim in *Harris* was at least predicated on an actual alleged *unknown* risk. *See* Plaintiff's Original Complaint at 4, *Harris v. Merck & Co. Inc.*, No. 12-cv-1446 (W.D. La. June 1, 2012) ECF No. 1 (identifying an FDA press release from nine years after Plaintiff began taking the medication at issue as the basis for her inadequate warning claim). Here, the risk and symptoms identified as the basis of Plaintiff's claim were widely known, as evidenced by the scientific journals and news reports cited in the FAC from 2010 through a month before Plaintiff filed her original complaint.

is well documented in the literature that GLP-1 RAs cause delayed gastric emptying. . . . As early as 2010, a study published in The Journal of Clinical Endocrinology & Metabolism indicated that that GLP-1 slows gastric emptying."); *see also id.* at ¶¶ 68-71; *id.* at n.37; *id.* at ¶ 80. Plaintiff's conclusory allegations to the contrary—that the gastrointestinal injuries she experienced were unknown to the medical community and her prescribing physician(s)—are implausible given the labeling for Ozempic® and the numerous published articles and news reports she cites that identify the very same risks. Because her injuries were "widely recognized to be possible outcomes" of taking Ozempic®, the FAC fails to plead the breach of a duty to warn under the LPLA. *See Stahl*, 283 F.3d at 268, *see also Thomas v. Bracco Diagnostics Inc.*, No. 3:19-cv-00493, 2020 WL 1016273, at *4 (W.D. La. Feb. 27, 2020), report and recommendation adopted, No. 3:19-cv-0493, 2020 WL 1243389 (W.D. La. Mar. 13, 2020) ("Plaintiff cannot show that his physician was not warned of a risk . . . that was not otherwise known" when "the amended complaint [also] asserts that an entire medical community was well aware of the alleged risk of which Plaintiff complains . . . and that the FDA label at the time . . . warned [of the risk].").

For all these reasons, Plaintiff's inadequate warnings claim should be dismissed.

III. Plaintiff Failed to Adequately Plead a Cause of Action for Breach of Express Warranty.

To plead a breach of express warranty under the LPLA, a plaintiff must establish: (1) a manufacturer made an express warranty, (2) the warranty induced the patient to use the product, (3) the product failed to conform to the warranty, and (4) her injury was proximately caused because the express warranty was untrue. LA. REV. STAT. § 9:2800.58. Here, Plaintiff alleges in only the most conclusory fashion that "Defendants expressly warranted to Plaintiff and her prescribing physician(s) that Ozempic and Mounjaro were safe," that Defendants made these representations on "Ozempic's and Mounjaro's labels, websites, advertisements, promotional

materials, and through other statements," and that these representations "induced" Plaintiff and her unnamed physicians to prescribe and use Ozempic® and Mounjaro®. FAC ¶¶ 134-36. These allegations are not sufficient to maintain a claim for breach of express warranty against the Novo Nordisk Defendants.

As a threshold matter, Plaintiff does not identify an express warranty under Louisiana law. As several courts have held, statements that a product is "safe" and "effective" do not constitute express warranties under the LPLA. *See Corley v. Stryker Corp.*, No. 13-cv-2571, 2014 WL 3375596, at *5 (W.D. La. May 27, 2014), report and recommendation adopted sub nom. *Corley v. Stryker Orthopaedics*, No. 13-cv-2571, 2014 WL 3125990 (W.D. La. July 3, 2014) ("The alleged representations that the product is 'safe' or 'effective' fail to rise to the level of an express warranty."); *see also Fuller,* 513 F. Supp. 3d at 723 (explaining "safe to use" and "effective to use" do not constitute express warranties under the LPLA and dismissing the claim); *Doe v. AstraZeneca Pharm., LP,* No. 15-cv-438, 2015 WL 4661814, at *4 (E.D. La. Aug. 5, 2015) (same). Under Louisiana law, such statements amount to nothing more than "general opinion or general praise of a product," which does not constitute an express warranty. *Fuller*, 513 F. Supp. 3d, at 722; *see also* LA. REV. STAT. § 9:2800.53(6). Further, if such statements are made on a website or in marketing materials they are not warranties, because they are generally considered to be mere "puffery, general praise, or general opinion." *Robertson v. AstraZeneca Pharms., LP,* No. 15-cv-438, 2015 WL 5823326, at *5 (E.D. La. Oct. 6, 2015) (citation omitted).[10]

[10] Again, *Harris* is distinguishable because there the defendant argued that Plaintiff failed to identify specific language of an express warranty. 2012 WL 5384720, at *5. Here, the Novo Nordisk Defendants argue that Plaintiff has failed to identify an express warranty *at all* under Louisiana law and that the FAC's allegations of inducement are conclusory and boilerplate. Subsequent precedent, cited above, moreover, has made clear that marketing of an FDA-approved product as "safe" and "effective" does not give rise to an express warranty.

Furthermore, Plaintiff's "conclusory allegation[s]" that she and her physician(s) were "induced" to use and prescribe Ozempic® and Mounjaro® "do[] no more than recite a required element of an LPLA express warranty claim." *Thomas,* 2020 WL 1016273, at *6 (citation omitted). In the FAC, Plaintiff does not include any facts that actually "show" how any alleged express warranty induced her or her physician(s) to prescribe or use Ozempic® and Mounjaro®, as required under Louisiana law. *Id*. (dismissing an express warranty claim where plaintiff "fail[ed] to plead any facts to show how an express warranty induced him to use the product" and his allegations simply "recite[d] a required element of … [the] claim."). As the *Fuller* court explained, the plaintiff's failure to "allege facts that the warranty was made to a specific audience . . . [and] identify the audience to whom the alleged warranties were made . . . underscores just how vague their warranty allegation is." 513 F. Supp. 3d at 723 (citation omitted).

Accordingly, Plaintiffs second cause of action for breach of express warranty should be dismissed.

IV. Punitive Damages and Attorneys' Fees are Not Available Under the LPLA as a Matter of Law.

Finally, Plaintiff seeks punitive and exemplary damages as well as attorneys' fees. *See* FAC at Prayer for Relief ¶¶ 2-3. Under Louisiana law, exemplary and punitive damages are only recoverable where expressly provided by statute. *See Albert v. Farm Bureau Ins., Co*., 940 So. 2d 620, 622 (La. 2006). "The Louisiana Products Liability Act provides the statutory framework for a products liability claim and does not authorize punitive damages." *Brookshire Bros. Holding Inc. v. Total Containment, Inc.,* 455 F. Supp. 2d 541, 543 (W.D. La. 2006). As none of the punitive and exemplary damages or attorneys' fees are available under the LPLA, they must be dismissed

as a matter of law.[11] *See Bladen v. C.B. Fleet Holding Co.*, 487 F. Supp. 2d 759, 770-71 (W.D. La. 2007); *see also Wilson v. Takata Corp.*, No. 16-cv-1356, 2019 WL 2546929, at *2 (E.D. La. June 20, 2019) ("The LPLA does not allow recovery of punitive damages, as courts in Louisiana have repeatedly recognized.") (collecting cases); *Watson v. Bayer Healthcare Pharm., Inc.*, No. 13-cv-212, 2013 WL 1558328, at *5 (E.D. La. April 11, 2013) (granting dismissal of punitive damages after plaintiff conceded they are not available under the LPLA).

CONCLUSION

For the foregoing reasons, the Novo Nordisk Defendants respectfully request that their motion to dismiss the FAC be granted in its entirety and with prejudice.

Dated: November 3, 2023

Respectfully submitted,

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[11] Any exceptions to this rule for are not present here. *See* La. Civ. Code Ann Arts. 2315.4, 2315.7; 3545.

Center Seattle, Inc., and Novo Nordisk Pharmaceutical Industries, LP

CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2023, I presented the foregoing to the Clerk of Court for filing and uploading to the CM/ECF system which will send notification of such filing to all attorneys of record using the CM/ECF system.

/s/ Diana Cole Surprenant
Diana Cole Surprenant