UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:	
FARXIGA (DAPAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	17 MD 2776 (LGS) 17 MC 2776 (LGS)
This Document Relates to: Aron v. Bristol-Myers Squibb Co., et al., 16 Civ. 10003 Perez v. Bristol-Myers Squibb Co., et al., 16 Civ. 8961 Ponce v. Bristol-Myers Squibb Co., et al., 16 Civ. 8959	**OPINION AND ORDER**

LORNA G. SCHOFIELD, District Judge:

Plaintiffs Chaim Aron, Cherie Perez and Arquimedes Ponce each sued Defendants Bristol-Myers Squibb Co., AstraZeneca LP, and AstraZeneca Pharmaceuticals LP under Texas law, alleging that they developed diabetic ketoacidosis as a result of taking Farxiga, an FDA-approved prescription medication for the treatment of type 2 diabetes. Defendants filed a consolidated motion to dismiss Plaintiffs' Amended Complaints (the "Complaints") under Federal Rule of Civil Procedure 12(b)(6). Defendants' motion is denied.

I. BACKGROUND

The following alleged facts are drawn from the Complaints[1] and are accepted as true for the purpose of this motion. The facts are construed, and all reasonable inferences are drawn, in favor of Plaintiff as the non-moving party. *See Trs. of Upstate N.Y. Eng'rs Pension Fund v. Ivy Asset Mgmt.*, 843 F.3d 561, 566 (2d Cir. 2016).

[1] As Plaintiffs could have moved to amend the Complaints to include the facts alleged in the Amended Master Long Form Complaint (the "Master Complaint" or together, with the individual Complaints, the "Complaints"), and the Court likely would have granted such a motion, the alleged facts also are drawn from the Amended Master Long Form Complaint.

A. Farxiga

On January 8, 2014, the Food and Drug Administration ("FDA") approved Farxiga (dapagliflozin) for the treatment of type 2 diabetes. Farxiga belongs to a class of drugs called "gliflozins" that are referred to as "Sodium Glucose Cotransporter 2 inhibitors" or "SGLT2 inhibitors." Farxiga is indicated for only one use -- lowering blood glucose in adults who have type 2 diabetes.

The Complaints allege that, although Farxiga is indicated only for lowering blood glucose in adults who have type 2 diabetes, "Defendants have marketed and continue to market Farxiga to both healthcare professionals and directly to consumers for off label purposes, including but not limited to weight loss and reduced blood pressure." For example, in a January 13, 2014, press release, Defendants stated that "[i]n clinical trials, Farxiga helped improve glycemic control, and offered additional benefits of weight and blood pressure reductions." Other advertisements stated "Farxiga may help you lose weight, and may even lower systolic blood pressure"; "lose weight -- on average 3%"; "significant weight reduction with 10mg dose"; and "THE ONLY SGLT2 inhibitor with efficacy and safety data over 4 years; lowers A1c; with secondary benefit of weight loss." The Complaints allege that Defendants conducted clinical trials of Farxiga's effectiveness for weight loss and cholesterol reduction so as to promote the drug for those off-label uses and asked prescribing physicians to recruit patients for those clinical trials, which made them aware of the drug's purported off-label uses. Each Complaint also alleges, upon information and belief, that Defendants informed each Plaintiff's physician (through marketing materials and direct communications) that Farxiga could be used for these off-label purposes.

At the time that the FDA approved Farxiga, Farxiga's label did not include any warnings, precautions or adverse event reports related to diabetic ketoacidosis or acute kidney injury. The label stated only that Farxiga should not be used to treat people suffering from diabetic ketoacidosis and identified generic "kidney problems" as a possible side effect. The Complaints allege, however, that Defendants knew or should have known that taking Farxiga was associated with significant risks of developing those conditions. The Complaints allege that Defendants failed to warn Plaintiffs' physicians and the medical community of those risks. The Complaints refer to a number of studies, including one published in 2013 and two published in 2014, each of which suggested an association between SGLT2 inhibitors and diabetic ketoacidosis, but did not directly address Farxiga. The Complaints further allege that Defendants "conduct[ed] regular literature searches" as part of their pharmacovigilance programs and therefore knew or should have known of those and other studies published as early as 2012 showing that SGLT2 inhibitors like Farxiga are associated with diabetic ketoacidosis, acute kidney injury and renal failure. The Complaints also allege that Defendants knew or should have known that Farxiga, "by its very mechanism of action causes dehydration and osmotic diuresis," which can cause acute kidney injury, including renal failure. In support of this allegation, the Complaints refer to the 2012 medical review of Farxiga-competitor, Invokana, which "disclosed a nearly three-fold increase . . . in acute renal failure for patients taking the higher dose of Invokana compared to those taking placebo, even in patients whose kidney function was normal."

The Complaints allege, upon information and belief, that as early as 2009 Defendants received adverse event reports involving patients who developed diabetic ketoacidosis while taking Farxiga; Defendants failed to make accurate and/or timely reports to the FDA of adverse

events of diabetic ketoacidosis; and Defendants misrepresented the nature of adverse events when they did report them to the FDA.

On December 4, 2015, the FDA issued a safety alert stating that seventy-three adverse events related to SGLT2 inhibitors, including Farxiga, had been reported to the agency between March 2013 and May 2015. The FDA also mandated a label change for Farxiga and other FDA-approved SGLT2 inhibitors to include a warning "about the risks of too much acid in the blood." On June 14, 2016, the FDA issued another safety alert -- about dapagliflozin -- and required Defendants to change Farxiga's label to warn about the risk of acute kidney injury associated with taking Farxiga.

B. Plaintiffs Aron, Perez and Ponce

Chaim Aron is a resident of Harris County, Texas. In or around July 2015, Aron's physician prescribed, and Aron began taking, Farxiga to treat his type 2 diabetes and induce weight loss and/or lower his blood pressure. On February 3, 2016, Plaintiff was admitted to critical care for symptoms of dyspnea, coughing, nausea and dizziness, diagnosed with diabetic ketoacidosis and hospitalized for four days. The Aron Complaint alleges that Defendants failed to warn Aron's prescribing physician or Aron of the risk of diabetic ketoacidosis associated with taking Farxiga, and that Aron would not have taken it had Defendants disclosed that risk.

Cherie Perez is a resident of Bexar County, Texas. In or around June 2015, Perez's physician prescribed, and Perez began taking, Farxiga to treat her type 2 diabetes, to induce weight loss and/or lower her blood pressure. On July 7, 2015, Perez was admitted to the hospital for severe euglycemic diabetic ketoacidosis and sepsis and hospitalized for four days. The Perez Complaint alleges that Defendants failed to warn Perez's physician or Perez about the risk of taking Farxiga, and that Perez would not have taken it had Defendants disclosed that risk.

Arquimedes Ponce is a resident of Harris County, Texas. In or around March 2015, Ponce was diagnosed with type 2 diabetes and prescribed Farxiga. Ponce's physician prescribed Farxiga to treat Ponce's type 2 diabetes and induce weight loss. On March 7, 2015, Ponce was admitted to the hospital for severe euglycemic diabetic ketoacidosis and acute renal failure and hospitalized for nine days. The Ponce Complaint alleges that Defendants failed to warn Ponce's physician or Ponce of the risks associated with taking Farxiga, and that Ponce would not have taken it had Defendants disclosed those risks.

II. STANDARD

On a motion to dismiss, a court accepts as true all well-pleaded factual allegations and draws all reasonable inferences in favor of the non-moving party, *Trs. of Upstate N.Y. Eng'rs Pension Fund*, 843 F.3d at 566, but gives "no effect to legal conclusions couched as factual allegations," *Stadnick v. Vivint Solar, Inc.*, 861 F.3d 31, 35 (2d Cir. 2017). To withstand a motion to dismiss, a pleading "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* "The *Twombly* plausibility standard . . . does not prevent a plaintiff from pleading facts alleged upon information and belief where the facts are peculiarly within the possession and control of the defendant, or where the belief is based on factual information that makes the inference of culpability plausible." *Arista Records, LLC v. Doe 3*, 604 F.3d 110, 120 (2d Cir. 2010) (internal citations and quotation marks omitted); *accord Kelly Compton v. Sessions*, No. 17 Civ. 5581, 2017 WL 5903360, at *3 (S.D.N.Y. Nov. 28, 2017). The complaint must include "something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable

right of action." *Twombly*, 550 U.S. at 555 (quoting 5 Wright & Miller, Fed. Prac. & Proc. § 1216 (3d ed. 2004) (alterations in original and internal quotation marks omitted)).

The parties' memoranda of law assume that Texas law governs the Complaints' claims, which are asserted exclusively under common law. "[S]uch implied consent is . . . sufficient to establish the applicable choice of law." *Trikona Advisers Ltd. v. Chugh*, 846 F.3d 22, 31 (2d Cir. 2017) (quoting *Arch Ins. Co. v. Precision Stone, Inc.*, 584 F.3d 33, 39 (2d Cir. 2009)). Second Circuit law -- not Texas or Fifth Circuit law -- governs procedural questions, including pleading requirements and federal preemption. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 91 (2d Cir. 2006) ("[E]ven in the transfer context, a court of appeals must develop its own circuit law on federal questions . . . ."), *aff'd sub nom. Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008)).

III. DISCUSSION

The Complaints assert causes of action under Texas law based on Defendants' failure to warn of the risks of diabetic ketoacidosis and acute kidney injury, negligent testing and gross negligence.[2] The Perez Complaint also alleges a cause of action under Texas law of loss of consortium.

A. Failure to Warn Claims

The Complaints allege that Defendants are liable in strict liability and negligence for failing to warn Plaintiffs about the dangers associated with taking Farxiga -- specifically, the risk of developing diabetic ketoacidosis. Defendants argue that these claims fail because Farxiga's warnings were adequate as a matter of law under the Texas statutory safe harbor for warnings approved by the FDA, Texas Civil Practice and Remedies Code ("CPRC") § 82.007, and that the Complaints do not allege facts sufficient to establish that an exception to the statute applies.

[2] In letters dated December 19, 2017, and December 20, 2017, Plaintiffs withdrew their negligent design claim.

Defendants' motion to dismiss the failure to warn claims is denied because the Complaints plead sufficient facts to support an exception to the statutory safe harbor.

CPRC § 82.007 creates a rebuttable presumption that a manufacturer or distributor, among others, is not liable for failure to warn if the warnings provided were those approved by the FDA.[3] A plaintiff can rebut the presumption by proving that one of five statutory exceptions applies. Two exceptions are relevant here:

> (1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;
>
> . . .
>
> (3)(A) the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration;
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> (B) the product was used as recommended, promoted, or advertised; and
>
> (C) the claimant's injury was causally related to the recommended, promoted, or advertised use of the product . . . . CPRC §§ 82.007(1), (3).

State law governs whether the exceptions in CPRC § 82.007 are to be treated as an element of a failure to warn claim, which must be pleaded and proved, or as an affirmative defense, which is germane only after a defendant invokes it. *See Desiano*, 467 F.3d at 96 (looking to Michigan law to conclude that the fraud exception in a Michigan statute similar to CPRC § 82.007 is not an element, but a defense, and therefore is not preempted by federal law). Under Texas law, "[a] plaintiff must sufficiently plead at least one of the statutory exceptions to

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[3] Section 82.007(a)(1) states, in relevant part:

> In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants . . . are not liable with respect to the allegations involving failure to provide adequate warnings or information if: (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration . . . .

Section 82.007(a) to state a claim and avoid dismissal." *Murthy v. Abbott Labs*., No. 4:11 Civ. 105, 2012 WL 6020157, at *3 (S.D. Tex. Dec. 3, 2012); *accord Lucas v. Abbott Labs*., No. 3:12 Civ. 3654, 2013 WL 2905488, at *3, *5 (N.D. Tex. June 13, 2013) (holding that plaintiffs adequately pleaded an exception to the presumption of non-liability in § 82.007); *Gonzalez v. Bayer Healthcare Pharm., Inc*., 930 F. Supp. 2d 808, 821 (S.D. Tex. 2013) (granting leave to replead to enable plaintiff to meet the requirements of § 82.007).

The Complaints do not plead adequately the "fraud-on-the-FDA" exception under § 82.007(b)(1). Where, as here, the Complaints plead allegations sounding in fraud, they must meet the heightened pleading standard of Federal Rule of Civil Procedure 9(b). *See, e.g.*, *MLSMK Inv. Co. v. J.P. Morgan Chase & Co.* 431 F. App'x 17, 18 (2d Cir. 2011) (summary order) (noting that allegations that sound in fraud must be pleaded with particularity); 5 Wright & Miller, *supra* § 1297 ("Even when a plaintiff is not making a fraud claim, courts will require particularity in the pleading if the cause of action is premised on fraudulent conduct."). To satisfy Rule 9(b), a complaint "must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *United States ex rel. Ladas v. Exelis, Inc*., 824 F.3d 16, 25 (2d Cir. 2016) (internal quotation marks omitted).

Although the Complaints describe in some detail the false and misleading adverse event reports that Defendants allegedly submitted to the FDA, the Complaints do not identify which statements were allegedly false or in what reports they were included. Plaintiffs seek to have these omissions excused by disclosing in their memorandum of law that the allegations are based on actual adverse event reports, which are subject to the Protective Order in this case. Plaintiffs do not cite any law to support the proposition that Rule 9(b)'s requirements are relaxed in these

circumstances. The parties could have agreed, or the Court could have allowed, an exception to the Protective Order, and the Complaints could have been filed with redactions if the legal requirements for sealing were satisfied. The Complaints do not plead adequately the fraud exception in § 82.007(b)(1).[4]

The Complaints do, however, plead adequately the "off-label" marketing exception in § 82.007(b)(3). "Section 82.007(b)(3) requires plaintiff to plead facts establishing that: (A) [Defendants] promoted [Farxiga] to plaintiff's prescribing physician for an indication not approved by the FDA (an 'off-label' use); (B) plaintiff used [Farxiga] for that off-label use; and (C) the off-label promotion caused the prescribing physician to prescribe the drug to plaintiff for that off-label use." *Murthy*, 2012 WL 6020157, at *3. Here, the Complaints allege that Defendants promoted Farxiga for off-label uses, including promoting weight loss and reducing blood pressure and that Plaintiffs were prescribed and used Farxiga to treat type 2 diabetes, induce weight loss and/or lower blood pressure. In substance, the Complaints allege that although Plaintiffs suffered from and were prescribed Farxiga to treat type 2 diabetes, they were prescribed Farxiga specifically because Defendants promoted the product to treat Plaintiffs' other conditions (i.e., off-label uses), including hypertension and obesity.

Defendants argue that as long as Farxiga was prescribed and used for an FDA-approved purpose -- to treat type 2 diabetes -- the exception in CPRC § 82.007(b)(3) is unavailable, even if it also was marketed, prescribed and used for an off-label purpose. That argument is unpersuasive. First, § 82.007(b)(3) requires only that the "claimant's injury was causally

[4] Defendants argue that the fraud exception is preempted by federal law. That issue requires consideration of conflicting decisions of the Fifth Circuit concerning § 82.007 and the Second Circuit concerning a similar Michigan statute. *Compare Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 380 (5th Cir. 2012) *with Desiano*, 467 F.3d at 95. Because, as explained, Plaintiffs have not pleaded the fraud exception with sufficient particularity, this Opinion does not address the preemption issue.

related" to an off-label advertised use, not that the drug was prescribed exclusively for an off-label use. Second, the cases on which Defendants rely are inapposite. In *Cooper v. Pfizer, Inc.*, although the complaint alleged that plaintiff was prescribed the drug in question for an off-label use, the medical records attached to the complaint contradicted that allegation. No. H-14 Civ. 3705, 2015 WL 2341888, at *2 (S.D. Tex. May 13, 2015). In *Jackson v. Wyeth, LLC*, the complaint alleged that plaintiff's ingestion of the drug at issue was for an approved purpose, such that any marketing for off-label purposes "would have no causal relationship with her claim." No. 2:12 Civ. 196, 2015 WL 363513, at *2 (S.D. Tex. Jan. 27, 2015). The motion to dismiss the failure to warn claims based on CPRC § 82.007 is denied.

B. Negligent Testing

The Complaints allege that Defendants negligently failed to test Farxiga before and after Farxiga was released onto the prescription drug market. Defendants move to dismiss this claim, arguing that it is "inextricably intertwined" with Plaintiffs' failure to warn claim and is insufficiently pleaded. Defendants' motion is denied.

Under Texas law, "[a] manufacturer has a duty to test . . . [its] product. The extent of research . . . must be commensurate with the dangers involved." *Romero v. Wyeth Pharm., Inc.*, No. 03 Civ. 1367, 2012 WL 12547449, at *4 (E.D. Tex. Aug. 31, 2012) (quoting *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1090 (5th Cir. 1973) (alterations in original)). Courts in Texas have recognized an independent cause of action based on negligent failure to test. *See, e.g.*, *Romero*, 2012 WL 12547449, at *4 (holding that the plaintiff sufficiently alleged "an independent negligence cause of action based upon [the defendant's] failure to test, a claim that does not pertain to any purportedly inadequate warnings issued by [the defendant]"; collecting cases); *Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 977 (S.D. Tex. Mar. 6, 2012)

(recognizing the plaintiff's failure to test claim as distinct from its failure to warn claim, but dismissing it for failure to plead sufficient facts); *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997) (recognizing plaintiff's negligent failure to test claim as distinct from its failure to warn claim).

Contrary to Defendants' assertion, the Complaints sufficiently allege an independent cause of action based on Defendants' alleged failure to test Farxiga. The Complaints allege that Defendants owed and breached a duty to Plaintiffs "to conduct proper safety studies" and "to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users." The Complaints further allege that Defendants "fail[ed] to properly and thoroughly test Farxiga before releasing the drugs to market"; "fail[ed] to properly and thoroughly analyze the data resulting from the pre-marketing tests of Farxiga"; and "fail[ed] to conduct sufficient post-market testing and surveillance of Farxiga." To support these allegations, the Complaints refer, for example, to the previously mentioned 2013 post-marketing observational study that Defendants initiated and terminated without posting any results. The Master Complaint elaborates that, although the study was terminated, Defendants collected data but allegedly failed to analyze it.

The Master Complaint further alleges that as early as 2009, Defendants received adverse event reports of patients treated with dapagliflozin who developed diabetic ketoacidosis. Although some of these adverse event reports characterized the adverse event as "related" to the patient's use of Farxiga, Defendants "almost always" characterized these events as "unrelated." The Complaints likewise refer to pre-market studies of SGLT2 inhibitors that suggested "the potential for Farxiga . . . to cause kidney failure and/or acute kidney injury." Drawing all reasonable inferences in Plaintiffs' favor, the Complaints suggest that Defendants failed to test

Farxiga adequately in light of these adverse event reports and other early signs -- described above -- of an association between Farxiga and diabetic ketoacidosis and/or acute kidney injury. This is sufficient to defeat a motion to dismiss. *See Romero*, 2012 WL 12547449, at *4.

C. Gross Negligence

Defendants seek to dismiss the Complaints' gross negligence claim, arguing that "[i]t is merely a restatement of Plaintiffs' deficient negligence count." Defendants' motion to dismiss this claim is denied.

Under Texas law, a plaintiff alleging gross negligence must establish:

> (1) viewed objectively from the actor's standpoint, the act or omission complained of must involve an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and (2) the actor must have actual, subjective awareness of the risk involved, but nevertheless proceed[s] in conscious indifference to the rights, safety, or welfare of others.

Boerjan v. Rodriguez, 436 S.W.3d 307, 311 (Tex. 2014) (quoting *Lee Lewis Constr., Inc. v. Harrison*, 70 S.W.3d 778, 785 (Tex. 2001) (alterations in original). "Under the first, objective element, an extreme risk is not a remote possibility of injury or even a high probability of minor harm, but rather the likelihood of serious injury to the plaintiff." *Id*. (internal quotation marks omitted). "Under the subjective element, actual awareness means the defendant knew about the peril, but its acts or omissions demonstrated that it did not care." *Id.* (internal quotation marks omitted).

Here, the Complaints sufficiently allege a claim of gross negligence. With respect to the objective element, the Complaints plead sufficient facts to support an inference that Defendants' conduct posed an extreme degree of risk of developing diabetic ketoacidosis and/or acute kidney injury. The 2012 medical review of Farxiga-competitor Invokana, for example, "disclosed a nearly three-fold increase . . . in acute renal failure for patients taking the higher dose of

Invokana compared to those taking placebo, even in patients whose kidney function was normal." The Complaints further allege that as early as 2009, adverse event reports from clinical trials suggested an association between Farxiga and diabetic ketoacidosis and/or acute kidney injury. With respect to the subjective element, the Complaints allege that Defendants had a subjective awareness of these risks and either intentionally or recklessly disregarded them. The bases for this allegation, as above, include Defendants' post-market study in September 2013, for which they collected more than two years of data, as well as the above-described post-market studies for which Defendants collected data (but did not post the results) and early adverse event reports, some of which were reported to Defendants as "related" to the patient's use of Farxiga. Construing these alleged facts and drawing all reasonable inferences in Plaintiffs' favor, the Complaints plead sufficient facts to support an inference that Farxiga posed an extreme risk to consumers of which Defendants were subjectively aware, and that Defendants either intentionally or recklessly disregarded that risk. Defendants' motion to dismiss this claim is denied.

D. Loss of Consortium

The Perez Complaint alleges a claim of loss of consortium on behalf of Perez's spouse, Plaintiff Rodney Perez, which Defendants seek to dismiss. Defendants' motion to dismiss this claim is denied.

Under Texas law, loss of consortium is defined as "the mutual right of the husband and wife to that affection, solace, comfort, companionship, society, assistance, and sexual relations necessary to a successful marriage." *Wal-Mart Stores, Inc.*, 868 S.W.2d 322, 328 (Tex. 1993) (quoting *Whittlesey v. Miller*, 572 S.W.2d 665, 666 (Tex. 1978)). Defendants' motion is denied because the Perez Complaint and Master Complaint, together, sufficiently allege that, as a result

of Defendants' alleged tortious conduct, Plaintiffs' "marital relationship has been impaired and depreciated"; Plaintiff Rodney Perez has "suffered great emotional pain and mental anguish"; and Plaintiff Rodney Perez has experienced severe emotional distress and economic loss resulting from Plaintiff Cherie Perez's medical expenses. This is sufficient at this early stage of the litigation to sustain Plaintiff Rodney Perez's derivative claim of loss of consortium.

IV. CONCLUSION

Defendants' motion to dismiss the Complaints is **DENIED**. The Clerk of Court is directed to close the motions at No. 17 MD 2776, Dkt. Nos. 53 and 74.

Dated: March 9, 2018
New York, New York

LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE