IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

JEFFERY POPE AND CYNTHIA POPE, Plaintiffs, v. ASTRAZENECA AB, ASTRAZENECA PHARMACEUTICALS LP, and BRISTOL-MYERS SQUIBB CO. Defendants.	)	C.A. No.: N20C-06-116 FAR

MEMORANDUM OPINION

Upon Consideration of Defendants' Motion to Dismiss,

GRANTED

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Rennie, J.

I. INTRODUCTION

Plaintiffs, Jeffery Pope and Cynthia Pope ("Plaintiffs"), bring this suit against Defendants, AstraZeneca AB, AstraZeneca Pharmaceuticals LP, and Bristol-Myers Squibb Co. ("Defendants"), to recover for medical injuries that were allegedly caused by Defendants' medication, Farxiga. Defendants filed this Motion to Dismiss pursuant to Superior Court Rule 12(b)(6). For the reasons that follow, Defendants' Motion to Dismiss is **GRANTED**.

II. STATEMENT OF THE CASE

A. Factual Background

Plaintiff, Jeffery Pope ("Pope") began taking Farxiga in January 2016. Pope's healthcare provider prescribed Farxiga to treat his Type 2 diabetes as well as to aid in weight loss.[1] On June 11, 2018, Pope was diagnosed with Fournier's gangrene.[2] As a result, he underwent emergency surgery and additional life-saving procedures. Pope was hospitalized for approximately ten days.

Farxiga is a prescription drug approved by the Food and Drug Administration ("FDA") for the treatment of Type 2 diabetes. Farxiga does not have FDA approval for weight loss.

[1] *See* Plaintiffs' Answering Brief in Opposition to Defendants' Motion to Dismiss at 1 [hereinafter "Pl.s' Resp."]; *see also* Compl. ¶¶ 44–45.

[2] *See* Pl.s' Resp. at 1 ("Fournier's gangrene, also known as necrotizing fasciitis of the perineum, is a deadly flesh-eating infection of the genitals and area around the genitals.").

B. Procedural Background

On June 10, 2020, Plaintiffs filed a Complaint against Defendants for injuries allegedly caused by Pope's use of Farxiga.[3] On August 12, 2020, Defendants filed their Motion to Dismiss Pursuant to Superior Court Civil Rule 12(b)(6).[4] On October 8, 2020, Plaintiffs filed their Answering Brief in Opposition. On October 23, 2020, Defendants filed their Reply. This Court heard oral argument on December 3, 2020.

III. STANDARD OF REVIEW

In considering, a motion to dismiss for failure to state a claim under Superior Court Civil Rule 12(b)(6),[5] all well-pleaded allegations in the complaint must be accepted as true.[6] Even vague allegations are considered well-pleaded if they give the opposing party notice of a claim.[7] The Court must draw all reasonable inferences in favor of the non-moving party;[8] however, it will not "accept conclusory allegations unsupported by specific facts," nor will it "draw

[3] In their Complaint, Plaintiffs assert eight counts against Defendants: Negligence (Count One); Breach of Implied Warranty of Merchantability (Count Two); Breach of Implied Warranty of Fitness for a Particular Purpose (Count Three); Breach of Express Warranty (Count Four); Strict Product Liability – Failure to Warn (Count Five); Strict Product Liability – Defective Design (Count Six); Punitive Damages (Count Seven); and Loss of Consortium as to Cynthia Pope (Count Eight).
[4] *See* Defendants' Motion to Dismiss; *see also* Defendants' Opening Brief in Support of its Motion to Dismiss [hereinafter "Def.s' Mot."].
[5] Super. Ct. Civ. R. 12(b)(6).
[6] *Spence v. Funk*, 396 A.2d 967, 968 (Del. 1978).
[7] *In re Gen. Motors (Hughes) S'holder Litig.*, 897 A.2d 162, 168 (Del. 2006) (quoting *Savor, Inc. v. FMR Corp.*, 812 A.2d 894, 896–97 (Del. 2002)).
[8] *In re Gen. Motors (Hughes) S'holder Litig.*, 897 A.2d at 168.

unreasonable inferences in favor of the non-moving party."[9] Dismissal under Rule 12(b)(6) must be denied if the plaintiff could recover under "any reasonably conceivable set of circumstances susceptible of proof under the complaint."[10]

IV. CONTENTIONS OF PARTIES

Defendants assert that Plaintiffs' pleadings fail to state a claim upon which relief can be granted for the following reasons: (1) Farxiga's FDA-approved warnings were adequate as a matter of law under Section 82.007;[11] and (2) Farxiga is not unreasonably dangerous, and a safer-alternative requirement is preempted. On these bases, Defendants argue that Plaintiffs' derivative claims, which are inextricably intertwined with Plaintiffs' failure to warn and design defect claims, also fail. In response, Plaintiffs argue that each claim is adequately pled with sufficient facts for support.

V. DISCUSSION

In assessing Defendants' Motion to Dismiss, the Court applies Texas law to the substantive issues. In doing so, the Court finds that: (1) Plaintiffs' Failure to Warn claims fail under Section 82.007; (2) Plaintiffs cannot satisfy the elements to establish a Design Defect claim; and (3) Plaintiffs' Negligence claims are derivative or are not properly pled.

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[9] *Price v. E.I. DuPont de Nemours & Co.*, 26 A.3d 162, 166 (Del. 2011) (internal citation omitted).
[10] *Spence*, 396 A.2d at 968 (citing *Klein v. Sunbeam Corp.*, 94 A.2d 385, 391 (Del. 1952)).
[11] *See* Tex. Civ. Prac. & Rem. Code § 82.007.

A. Plaintiffs' Failure to Warn Claims Fail Under Section 82.007

Texas Civil Practice and Remedies Code Section 82.007 ("Section 82.007") establishes a rebuttable presumption that pharmaceutical companies are not liable in failure-to-warn cases where the FDA approved the warnings accompanying the product.[12] Here, the warnings and information that accompanied Farxiga's distribution, were approved by the FDA "for a product approved under the Federal Food, Drug, and Cosmetic Act."[13] Plaintiffs do not dispute that Farxiga is FDA approved for the treatment of Type 2 diabetes. Hence, Farxiga's "FDA-approved warning label is presumed to be an adequate warning" as it pertains to such treatment, and there exists a presumption of non-liability under Section 82.007.[14]

A plaintiff may rebut that presumption by showing one of the following: (1) "fraud on the FDA[;]" (2) that the product was sold after the FDA ordered that it be removed from the market; (3) that the manufacturer promoted the product for a use not approved by the FDA; (4) that there existed an off-label prescription; or (5)

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[12] *See* Tex. Civ. Prac. & Rem. Code § 82.007(a)(1); *see also Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 374 (5th Cir. 2012) (citing Tex. Civ. Prac. & Rem. Code § 82.007(a)(1)).

[13] *See* FDA Approval Letter (Jan 8, 2014), http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/202293Orig1s000ltr.pdf.

[14] *Thurston v. Merck & Co. Inc.*, 415 F. App'x 585, 586 (5th Cir. 2011) (citing Tex. Civ. Prac. & Rem. Code § 82.007(a)(1)). *See Eckhardt v. Qualitest Pharm. Inc.*, 858 F. Supp. 2d 792, 799 (S.D. Tex. 2012) *aff'd*, 751 F.3d 674 (recognizing presumption where plaintiffs did not dispute FDA approval of warnings and drug information); *see also Acker v. Schering-Plough Corp*., 2011 WL 13196513, at *4 (E.D. Tex. July 15, 2011) (recognizing presumption with FDA-approved prescribing information).

the "bribery of a public official."[15] Plaintiffs argue that the exception set forth in Section 82.007(b)(3) applies.[16]

In *Johnson v. Novartis Pharm. Corp.* ("*Johnson*"),[17] the United States District Court, Western District of Texas, San Antonio Division (the "District Court"),[18] found that pleading an exception under Section 82.007(b)(3), required a plaintiff to allege that: (1) the defendant "marketed and promoted the unauthorized use of the drugs to the prescribing doctors[;]" (2) the plaintiff "relied on that specifically promoted use, and that[;]" (3) the injuries sustained by plaintiff "were caused by that off-label promotion."[19] Plaintiffs' pleadings have satisfied the first two prongs under this exception. However, the Court cannot find that Plaintiffs have properly pled facts to establish the causation prong under this exception, without accepting conclusory allegations unsupported by specific facts.

Plaintiffs contend that because Pope was prescribed Farxiga to "aid in weight loss, in addition to treating his Type 2 diabetes[,]" the exception under

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[15] *Johnson v. Novartis Pharm. Corp.*, 2020 WL 2300139, at *3 (W.D. Tex. May 7, 2020), *aff'd sub nom; Ramon D. Johnson, II, Plaintiff-Appellant, v. Novartis Pharm. Corporation; Taro Pharm. USA, Incorporated; Bausch Health US, L.L.C.; Sun Pharm. Indus., Incorporated; Torrent Pharma, Inc., Defendants-Appellees.*, No. 20-50462, 2021 WL 406098 (5th Cir. Feb. 5, 2021) (citing Tex. Civ. Prac. & Rem. Code § 82.007(b)(1)-(5)).

[16] Pl.s' Resp. at 11 ("Plaintiffs argue that the exception set forth in Section 82.007(b)(3) applies and is sufficiently pleaded to defeat Defendants' motion to dismiss Plaintiffs' failure to warn claims.").

[17] 2020 WL 2300139 (W.D. Tex. May 7, 2020).

[18] The Court will utilize the term "District Court" to reference all United States District Courts of the State of Texas.

[19] *Johnson*, 2020 WL 2300139, at *4.

Section 82.007(b)(3) applies.[20] Plaintiffs state that Farxiga is not FDA approved for weight loss, and on this basis argue that the Court should find that Pope's use was for an off-label purpose as set forth in Section 82.007(b)(3). The Court is unable to reach that conclusion, where Plaintiffs themselves admit that Pope was prescribed Farxiga for an approved and indicated purpose in addition to an off-label purpose.[21]

Texas courts have found that the exception under Section 82.007(b)(3) is not available to plaintiffs who take a drug for its approved indication, even where plaintiffs and their doctors are also interested in a drug's other observed benefits.[22] In analyzing Texas law, this Court arrives at the same determination. The Court turns to the following cases, in reaching this conclusion: (1) *Cooper v. Pfizer*,[23] and (2) *Jackson v. Wyeth LLC*.[24]

In *Cooper*, the District Court granted the defendant's motion for judgment on the pleadings, as it pertained to Section 82.007(b)(3), where the plaintiff was

[20] Pl.s' Resp. at 1.
[21] *See id.*; *see also* Compl. ¶¶ 44–45.
[22] *See Jackson v. Wyeth LLC*, 2015 WL 363513, at *2 (S.D. Tex. Jan. 27, 2015); s*ee also Cooper v. Pfizer, Inc.*, 2015 WL 2341888, at *2 (S.D. Tex. May 13, 2015).
[23] 2015 WL 2341888 (S.D. Tex. May 13, 2015).
[24] 2015 WL 363513 (S.D. Tex. Jan. 27, 2015). Plaintiffs attempt to distinguish this case from the *Cooper* and *Jackson* cases. This Court is not persuaded by such attempts and rules in alignment with the well-reasoned, on-point Texas case law. In addition to attempting to distinguish those cases, Plaintiffs also rely on *In re Farxiga (dapagliflozin) Prod. Liab. Litig.*, 2018 WL 1274929 (S.D.N.Y. Mar. 9, 2018), for the proposition that Section 82.007(b)(3) remains applicable even in light of Pope being prescribed Farxiga for both an approved and non-approved indication. This Court reviewed and considered the application of this case, but declines to apply it here, where the Texas case law established by Federal District Courts in Texas remain consistent and persuasive.

prescribed the drug at issue "for its intended and approved purpose[.]"[25] The plaintiff argued that the exception under Section 82.007(b)(3) was applicable to his case because he was prescribed the drug for a non-indicated "off-label" purpose. He pled that he "'was prescribed Lipitor for Off–Label usage, just as [the defendant] had marketed[.]'"[26] However, the record in that case did not support these allegations. Rather, the plaintiff's medical records demonstrated that in addition to alleged use of the drug for the unapproved indication of treating hypertension, he was also prescribed the drug "for the treatment of his hypercholesterolemia," which was "a labeled indication for Lipitor at the time it was prescribed."[27] The District Court found that because the plaintiff was prescribed and used Lipitor "for its intended and approved purpose," he could not rely upon "§ 82.007(b)(3) to overcome the presumption of non-liability."[28]

The Complaint here alleges that Pope was prescribed Farxiga for an indicated use – treatment of his Type 2 diabetes – even though he simultaneously used the drug for a non-approved purpose.[29] Thus, because Pope ingested Farxiga for its intended and approved purpose, like the plaintiff in *Cooper*, Plaintiffs

[25] *Cooper*, 2015 WL 2341888, at *2.
[26] *Id.* (citing to the plaintiff's complaint).
[27] *Id.*
[28] *Id.*
[29] S*ee* Compl. ¶¶ 44–45.

cannot establish causation and are unable to overcome the presumption of non-liability under Section 82.007(a).[30]

Next, the Court turns to *Jackson v. Wyeth LLC*,[31] which Plaintiffs reference for the purpose of distinguishing this case. However, *Jackson* serves to highlight the consistency in the Texas case law on this issue. In *Jackson*, the District Court found that the plaintiff could not invoke Section 82.007(b)(3), where the plaintiff's ingestion of the medication was for an approved indication, even though off-label uses were touted by the defendant.[32] The *Jackson* plaintiff alleged that she was prescribed a drug both for its approved indication of treating gastroesophageal reflux and for an unapproved indication of long-term use.[33] The Court found that the defendants' promotion of the drug "for an unapproved indication [did] not matter[,] [because] [s]uch conduct would have no causal relationship with [the plaintiff's] claim."[34]

Like the plaintiffs in *Jackson*, Plaintiffs here are unable to satisfy the causation element under Section 82.007(b)(3). Pope was using Farxiga for both an indicated and non-indicated use. And Plaintiffs cannot establish, nor have they even pled, that Pope's injuries were caused by his off-label use of Farxiga for weight loss, as opposed to his FDA approved use of Farxiga to treat his Type 2

[30] *See* Tex. Civ. Prac. & Rem. Code § 82.007(a).
[31] 2015 WL 363513 (S.D. Tex. Jan. 27, 2015).
[32] *Id.* at *2.
[33] *Id.*
[34] *Id.*

diabetes. In other words, based on the allegations in the Complaint, Plaintiffs are unable to establish that Pope's injuries were caused by his use of Farxiga for weight loss. Thus, Plaintiffs cannot use Section 82.007(b)(3) to overcome the presumption of non-liability. Accordingly, Defendants' Motion to Dismiss Plaintiffs' Failure to Warn claims is **GRANTED**.

B. Plaintiffs Cannot Satisfy the Elements of a Design Defect Claim

The Court next addresses Plaintiffs' Design Defect claim. In Texas, "the duty to design a safe product is 'an obligation imposed by law.'"[35] To succeed on their design defect claim, Plaintiffs must prove (1) that Farxiga was defectively designed so as to render it unreasonably dangerous, (2) a safer alternative design exists, and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery.[36]

Because these factors are laid out in the conjunctive, in order to succeed, Plaintiffs must prove each of the three above elements. As to the first element, this Court recently ruled under similar facts that a drug that is "properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous."[37] This Court found that because the plaintiffs were unable to rebut the presumption afforded under Section 82.007(a), that the label

[35] *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 432 (Tex. 1997) (quoting *McKisson v. Sales Affiliates, Inc.*, 416 S.W.2d 787, 789 (Tex. 1967)).
[36] *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009).
[37] *Kumaritakis v. Astrazeneca Pharm., LP*, 2020 WL 1024933, at *2 (Del. Super. Mar. 2, 2020) (quoting Restatement (Second) of Torts § 402A cmt. k (Am. Law Inst. 1965)).

contained adequate warnings, the defendants satisfied their duty to not furnish an "unreasonably dangerous" product.[38] Plaintiffs' inability to establish that Farxiga was defectively designed so as to render it unreasonably dangerous is fatal to their design defect claim. Notwithstanding, the Court will address Plaintiffs' attempt to parse the safer alternative design requirement between post-approval and pre-approval obligations.

Under FDA regulations, "once a drug . . . is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application.'"[39] Plaintiffs argue that Defendants bear the burden of showing "that Farxiga's risk is unavoidable by demonstrating that, given the current state of knowledge, no feasible alternative design exists that would accomplish the same purpose with less risk."[40] However, as set forth in *Kumaritakis* this argument is preempted under the doctrine of conflict preemption which is implicated when it is impossible for a defendant to comply with both state and federal law.[41] To establish that a safer alternative design exists would invoke a state law duty to change the design of the drug.

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[38] *Kumaritakis*, 2020 WL 1024933, at *3.
[39] *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 808 F.3d 281, 298 (6th Cir. 2015).
[40] Pl.s' Resp. at 19 (citing *Romero v. Wyeth Pharms., Inc.*, 2012 WL 12547449, at *6 (E.D. Tex., Aug. 31, 2012)).
[41] *See Kumaritakis*, 2020 WL 1024933, at *3; *see also Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 299–300 (1988).

Plaintiffs concede that Defendants do not have the ability to change the design of a drug without FDA intervention, and acknowledge that attempting to assert a claim that a safer alternative is available post-approval would be federally preempted. They instead argue that their design defect claim is valid as it pertains to Defendants' pre-approval design. However, Plaintiffs' attempt to plead a valid design defect claim based on Defendants' alleged defective pre-approval design is also preempted. In order to find for Plaintiffs on such a claim, the Court would be required to engage in multiple levels of supposition. For instance, the Court would have to speculate about whether a pre-approval design change would have fixed the problem; whether the FDA would have approved such changes; whether Pope's physician would have recommended and prescribed the differently designed drug, if it was FDA approved; and whether Pope would have taken the drug after such changes and processes were executed. The Court would be required to make unfounded inferences as to each of these questions to find for Plaintiffs, and thus is unable to countenance Plaintiffs' pre-approval design defect argument.[42]

For these reasons, Plaintiffs' safer alternative argument fails. Federal law prohibits Defendants from changing the design of Farxiga, post-approval, without prior FDA approval.[43] Hence, Texas law is preempted to the extent it requires Defendants to unilaterally redesign Farxiga in a way that federal law forbids.

[42] *See Yates*, 808 F.3d at 299–300.
[43] *Kumaritakis*, 2020 WL 1024933, at *3.

Further, any argument based on pre-approval design necessarily requires rank speculation and is also preempted by federal law. Because the requirement to establish a safer alternative design is federally preempted, it is impossible for Plaintiffs to satisfy the necessary elements of a defective design claim.

Thus, Defendants' Motion to Dismiss Plaintiffs' Design Defect claim is **GRANTED**.

C. Plaintiffs' Negligence Claims are Derivative and Must Be Dismissed

Finally, the Court addresses Plaintiffs' Negligence claims. Under Texas law, to prevail on a negligence cause of action a plaintiff "must establish the existence of a legal duty, a breach of that duty, and damages proximately caused by the breach."[44] Most of Plaintiffs' Negligence claims are derivative of their now dismissed Failure to Warn and Design Defect claims, and thus they also fail.[45] The remaining allegations in the Complaint purport to establish a claim for negligent failure to test.

Courts in Texas have recognized an independent cause of action based on negligent failure to test, but such a claim requires more than conclusory assertions

[44] *Bustamante v. Ponte*, 529 S.W.3d 447, 456 (Tex. 2017) (quoting *IHS Cedars Treatment Ctr. of DeSoto, Tex., Inc. v. Mason*, 143 S.W.3d 794, 798 (Tex. 2004)) ("The two elements of proximate cause are cause in fact (or substantial factor) and foreseeability . . . . Cause in fact is established when the act or omission was a substantial factor in bringing about the injuries, and without it, the harm would not have occurred.").

[45] *See Murthy v. Abbott Lab'ys*, 847 F. Supp. 2d 958, 977 (S.D. Tex. 2012) (recognizing the feasibility of an independent failure to test claim but dismissing it for failure to plead sufficient facts). Because Plaintiffs' negligence claims are premised on failure to warn and design defect which have already been disposed of here, they must be dismissed.

of failure to test.[46] There must be some factual support for the assertions that Defendants failed to test. Here, Plaintiffs' Complaint alleges in conclusory fashion that Defendants were negligent in their testing of Farxiga by: (1) "Failing to properly and thoroughly test Farxiga before releasing the drug to market;" (2) "Failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of Farxiga;" and (3) "Failing to conduct sufficient post-market testing and surveillance of Farxiga[.]"[47] Plaintiffs argue that these allegations are sufficient to establish an independent "failure to test" claim. This Court disagrees. Plaintiffs' failure to test assertions are merely conclusory, and inadequately pled. While such a claim is cognizable under Texas law, it must be accompanied by facts to support the theory of liability.[48] For these reasons, Defendants' Motion to Dismiss Plaintiffs' Negligence claims is **GRANTED**.

[46] *See Murthy*, 847 F. Supp. 2d at 977.
[47] Compl. ¶¶ 64 (a)–(c).
[48] *See Murthy*, 847 F. Supp. 2d at 977 (recognizing a failure to test claim as a distinct standalone claim but dismissing the claim for failure to adequately plead sufficient facts); *see also Atkinson v. Luitpold Pharm., Inc.*, 448 F. Supp. 3d 441, 453 (E.D. Pa. 2020) (applying Texas law and acknowledging a separate claim for failure to test but dismissing the claim for failure to plead adequate facts in support of the claim).

VI. CONCLUSION

For the foregoing reasons, Plaintiffs' Failure to Warn, Design Defect, and Negligence claims must be dismissed. Plaintiffs' derivative claims stemming therefrom, including claims for breach of warranty, loss of consortium, and punitive damages, must also be dismissed.[49] Plaintiffs' claims premised on a theory of failure to properly test shall be dismissed with leave to amend the Complaint to set forth allegations in support of an independent failure to test claim. Therefore, Defendants' Motion to Dismiss is **GRANTED**.

IT SO ORDERED THIS 5th day of April, 2021.

Sheldon K. Rennie, Judge

[49] *Cooper v. Pfizer, Inc.*, 2015 WL 2341888, at *3 (S.D. Tex. May 13, 2015) (citing Tex. Civ. Prac. Rem. Code § 82.001(2)).