UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

ELISANDRO RODRIGUEZ,	§	
	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. 2:14-CV-324
	§	
GILEAD SCIENCES, INC., *et al*,	§	
	§	
Defendants.	§	

ORDER

Before the Court are: (1) Defendant Gilead Sciences, Inc.'s (Gilead's) Motion to Dismiss (D.E. 5); and (2) Texas Liver Institute, Inc. f/k/a Alamo Medical Research, Ltd. (TLI) and Eric Lawitz's (Lawitz's) 12(b)(6) Motion to Dismiss (D.E. 6). In connection with Plaintiff's Motion to Remand (D.E. 14), the Court found that Plaintiff had not stated a cognizable claim against either TLI or Lawitz and that those Defendants were improperly joined. D.E. 25. Plaintiff has taken the position that TLI and Lawitz are already dismissed from this case and declined to respond to the TLI/Lawitz motion. D.E. 32, p. 5. For the reasons expressed in this Court's prior Order (D.E. 25), the TLI/Lawitz motion is **GRANTED**. For the reasons set out below, the Gilead motion is **GRANTED IN PART** with respect to the design defect claims and **DENIED IN PART** with respect to the learned intermediary doctrine and the statutory presumption of non-liability.

THE COMPETING ISSUES

Plaintiff Elisandro Rodriguez (Rodriguez) seeks compensation for permanent heart damage he allegedly suffered as a result of participating in a clinical trial for the

treatment of hepatitis C (HCV) with the pharmaceutical, Sofosbuvir/Ledipasvir (S/L). D.E. 1-2. Gilead conducted the clinical trial in which Rodriguez participated, as required for obtaining the approval of the United States Food and Drug Administration (FDA) for the marketing of S/L. Gilead also designed and manufactured the S/L that was administered to Rodriguez.

Rodriguez alleges that Gilead, "[i]n its quest to be first and to grab a portion of the $20 billion a year market," turned Rodriguez's treating physician into nothing more than a conduit for gaining Rodriguez's participation in the clinical trial. D.E. 1-2, p. 4. According to Rodriguez, with speed and greed overriding medical judgment, and with full knowledge, Gilead's S/L was foisted upon him despite it being a defective product, ultimately causing his heart damage. Rodriguez's claims sound in: (a) negligence (breach of duty to make product reasonably safe through testing and warning); (b) product liability-defective design; (c) product liability-marketing defect (failure to warn); (d) breach of express warranty; and (e) breach of implied warranty. D.E. 1-2. Despite the number of theories, there are two categories of complaints: (1) the product was not safely designed; and (2) the product was not accompanied by sufficient warnings or did not live up to the literature used to market it. Neither in his pleading nor in his response to the motion has Rodriguez articulated a theory of liability that falls outside these two groups.[1]

[1] Product liability claims are generally stated in three categories: design, manufacturing, and marketing defects. While Rodriguez's pleading does reference "manufacturing" defects, there are no factual allegations that, liberally construed, can be deemed to be associated with that category of claims. Without any related fact pleadings at all, any such claim cannot survive a Rule 12(b)(6) review. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Gilead seeks dismissal of all of Rodriguez's claims related to a defective design, whether couched as negligence, strict product liability, or breach of warranty, because Rodriguez failed to allege facts that would support a finding of a safer alternative design. With respect to failure to warn or inform, again under any theory, Gilead claims that it is insulated by the learned intermediary doctrine and the presumption of non-liability associated with FDA oversight.

DISCUSSION

A. Standard of Review

Under a motion to dismiss predicated upon Rule 12(b)(6), the test of pleadings is devised to balance a party's right to redress against the interests of all parties and the court in minimizing expenditure of time, money, and resources. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 558 (2007). *See also*, *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). Federal Rule of Civil Procedure 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." Furthermore, "Pleadings must be construed so as to do justice." Rule 8(e). The requirement that the pleader show that he is entitled to relief requires "more than labels and conclusions[;] a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

Factual allegations are required, sufficient to raise the entitlement to relief above the level of mere speculation. *Twombly*, 550 U.S. at 555. Those factual allegations must then be taken as true, even if doubtful. *Id*. In other words, the pleader must make allegations that take the claim from "conclusory" to "factual" and beyond "possible" to

"plausible." *Id*., 550 U.S. at 557. The *Twombly* court stated, "[W]e do not require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face." 550 U.S. at 570.

The Court, elaborating on *Twombly*, stated, "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully. *Iqbal*, 556 U.S. at 678. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. In dismissing the claim in *Iqbal*, the Court stated, "It is the conclusory nature of respondent's allegations, rather than their extravagantly fanciful nature, that disentitles them to the presumption of truth." 556 U.S. at 681. These principles apply to Gilead's challenge to Rodriguez's design defect claims.

A motion to dismiss for failure to state a claim upon which relief can be granted can be based not only on an omission in a plaintiff's claims but on the inclusion of factual assertions that contradict a claim or support an affirmative defense, such as limitations. Even if some allegations support a claim, if other allegations negate the claim on its face, then the pleading does not survive the 12(b)(6) review.

> A complaint is subject to dismissal for failure to state a claim if the allegations, taken as true, show the plaintiff is not entitled to relief. If the allegations, for example, show that relief is barred by the applicable statute of limitations, the complaint is subject to dismissal for failure to state a claim; that does not make the statute of limitations any less an affirmative defense, *see* Fed. Rule Civ. Proc. 8(c). Whether a particular ground for opposing a claim may be the basis for dismissal for failure to state a claim depends on whether the allegations in the complaint suffice to establish that ground, not on the nature of the ground in the abstract.

Jones v. Bock, 549 U.S. 199, 215 (2007). This principle applies to Gilead's arguments regarding the learned intermediary doctrine and the presumption of non-liability arising from FDA regulation.

B. Failure to Plead a Safer Alternative Design

Gilead asserts that Rodriguez is required to plead a safer alternative design when stating a design defect claim under Texas law. The Supreme Court of Texas has held that, according to the Texas products liability statute, "Section 82.005 reflects the trend in our common-law jurisprudence of elevating the availability of a safer alternative design from a factor to be considered in the risk-utility analysis to a requisite element of a cause of action for defective design." *Hernandez v. Tokai Corp*., 2 S.W.3d 251, 256 (Tex. 1999). *See also, Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995) (holding that evidence of a safer alternative design is necessary to a finding that a product is unreasonably dangerous for product liability purposes); *Brockert v. Wyeth Pharmaceuticals, Inc*., 287 S.W.3d 760, 769 (Tex. App.—Houston [14th Dist.] 2009, no pet.). *See also Dyer v. Danek Medical, Inc*., 115 F. Supp. 2d 732, 738 (N.D. Tex. 2000) (acknowledging *Tokai* as governing authority). According to Gilead, Rodriguez failed to plead any facts that would support a finding that there was a safer alternative design. Having failed to satisfy this pleading requirement, Gilead seeks dismissal of all design defect claims, however cast.

Rodriguez argues that the cases upon which Gilead relies were cases that evaluated the evidence either at summary judgment or after trial and that they state a

proof requirement rather than a pleading requirement. There is certainly a difference in the respective purposes of pleading and proof requirements. However, the proof requirement, insofar as it prescribes an element of a claim under Texas law, mandates the way in which such a claim must be pled under federal law, consistent with *Twombly* and *Iqbal*. Rodriguez does not dispute that a safer alternative design is a necessary component to a design defect claim.

This Court is bound to apply Texas law to substantive matters when sitting, as we are here, in diversity jurisdiction. In contrast, with respect to procedural matters including pleading requirements, this Court applies federal law. *E.g.*, *Hanna v. Plumer*, 380 U.S. 460, 471 (1965); *Erie R. Co. v. Tompkins*, 304 U.S. 64, 92 (1938); *Affholder, Inc. v. S. Rock, Inc.*, 746 F.2d 305, 310 (5th Cir. 1984). Recognizing that a safer alternative design is a necessary element to a substantive design defect claim under Texas substantive law, federal procedural law requires that the pleading allege sufficient facts to support the plausibility of that element. *Twombly, supra*. In defending against Gilead's challenge to his pleading, Rodriguez sets out a litany of conclusory allegations from his pleading, none of which relate to a safer alternative design. D.E. 32, p. 8. Instead, they address global dangerousness, poor quality, or marketing issues. Because Rodriguez has failed to plead any facts related to a safer alternative design, the Court **DISMISSES** all claims, under any theory, related to design defects.

Rodriguez has asked for an opportunity to amend and cure this defect in the event that the Court dismisses the claims as pled. Gilead opposes this request, faulting Rodriguez for failing to amend during the time that the motion has been pending. The

Court, cognizant that the Court had stayed the parties' briefing on this issue pending a ruling on the motion for remand and aware that Rodriguez drafted his pleading under Texas notice pleading rules, **GRANTS** Rodriguez's request and **ORDERS** Rodriguez to file any motion for leave to amend on or before ten days from the date of this Order. In connection with any such motion, the Court **ORDERS** Rodriguez to attach a copy of the amended complaint, highlighting or redlining those allegations that he contends satisfy the safer alternative design fact pleading requirements. In the event that such a motion is filed, the Court **ORDERS** Gilead to file any response it may have on or before ten days from the date that the motion is filed.

C. Learned Intermediary Doctrine

Gilead claims that it owes no duty to warn, under any theory, because its duty ran only to Dr. Lawitz and, on the face of the pleading, Rodriguez admitted that Dr. Lawitz had full knowledge of all information related to S/L. The Fifth Circuit has explained precisely how the learned intermediary doctrine is applied under Texas law:

> The learned-intermediary doctrine states that, in some situations, a warning to an intermediary fulfills a supplier's duty to warn consumers. *See Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591–92 (Tex. 1986). "In Texas, the most common use of this doctrine is in prescription drug cases." *Wyeth–Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 91 (Tex. App.—Texarkana 2000, no writ) (citations omitted). Under the doctrine, a patient-purchaser's doctor stands between the patient and the manufacturer, professionally evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use. *Id.* If the doctor is properly warned of the possibility of a side effect and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided. Accordingly, the doctrine excuses a drug

> manufacturer "from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers." *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467–68 (5th Cir. 1999).
> . . .
> Thus, "when the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user." *Alm*, 717 S.W.2d at 592.

Ackermann v. Wyeth Pharmaceuticals, 526 F.3d 203, 207 (5th Cir. 2008). This Fifth Circuit explanation of Texas law is consistent with, and was cited with approval in, the more recent Supreme Court of Texas opinion, *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140 (Tex. 2012), upon which both parties rely.

Central to the learned intermediary doctrine in the pharmaceutical context is a prescribing physician acting in the best interests of the patient through a physician-patient relationship. *Id*. at 166-67 (holding that a non-prescribing physician did not insulate the drug manufacturer through the learned intermediary doctrine). Rodriguez has pled that Dr. Lawitz was not a "prescribing physician" and was not acting within a physician-patient relationship during the clinical study but was rather an extension of Gilead, incentivized to act as a drug marketer rather than as a treating physician. While this Court has dismissed the claims against Dr. Lawitz as healthcare liability claims, that decision (pursuant to the statutory definition of a healthcare liability claim) did not require a finding that Dr. Lawitz was acting pursuant to a physician-patient relationship or was considered a qualifying "prescribing physician" at the time of the alleged injury to Rodriguez.

The parties have offered competing case law on the issue of whether a physician associated with a clinical trial qualifies as a learned intermediary. The *Centocor* court rejected liability as to a treating physician who did not prescribe, but administered, the medication. *Id*. at 166-67. Judge Ellison of this District made an *Erie* guess that Texas law would provide an exception to the learned intermediary doctrine where the evidence can show that the physician's medical judgment was compromised by a pharmaceutical company's incentives. *Murthy v. Abbott Laboratories*, 847 F. Supp. 2d 958, 971 (S.D. Tex. 2012) (declining to dismiss the case on the basis of the learned intermediary doctrine under Rule 12(b)(6) in favor of evaluating the evidence on the issue).

Gilead has cited four cases, none of which are opinions of Texas courts or courts within this federal circuit. Each is distinguishable. In *Kernke v. The Menninger Clinic, Inc*., 173 F. Supp. 2d 1117, 1122 (D. Kan. 2001), the issue was evaluated on the basis of summary judgment evidence rather than on pleadings. Furthermore, in *Kernke* it was undisputed that the clinical investigators were acting as prescribing physicians. The court in *Tracy v. Merrell Dow Pharmaceuticals, Inc*., 569 N.E.2d 875, 878-79 (Ohio 1991), evaluated a challenge to a jury instruction on the learned intermediary doctrine. The court held that, despite allegations that the clinical trial investigating physicians were not acting consistent with a physician-patient relationship, the evidence was sufficient to support the jury's finding that there was such a relationship that supported the application of the learned intermediary doctrine.

The court in *Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. Ct. App. 1978) also considered the pharmaceutical company's duty to warn after full trial on the merits. The

opinion recites that there was no evidence that the warnings provided were inadequate. There appears to have been no issue regarding whether the investigating physician was an appropriately motivated prescribing physician. Last, in *Little v. Depuy Motech, Inc*., No. 96CV0393-L JAH, 2000 WL 1519962, *8-9 (S.D. Cal. June 13, 2000), the court evaluated summary judgment evidence and determined that the physician's mere participation in another manufacturer's study did not impair his independent medical judgment.

As outlined here, each of Gilead's cases arose out of summary judgment or trial proceedings where the question was whether the evidence supported the application of the learned intermediary doctrine. None of the cases rejected a plaintiff's claims at the pleading stage. Rather, because the decisions were made only at an evidentiary phase, they reinforce the conclusion that Judge Ellison reached: the matter is a question of fact, subject to determination on the basis of evidence. Consequently, the Court **DENIES** Gilead's motion to dismiss the failure to warn claims under Rule 12(b)(6) based on the learned intermediary doctrine where Rodriguez has pled a basis for challenging the intermediary's status under the doctrine.

D. Presumption of Non-Liability Through FDA Regulation

Last, Gilead points out that the clinical study in which Rodriguez participated was conducted pursuant to FDA regulation, including FDA approval of the warnings given to Dr. Lawitz and Rodriguez. Gilead claims the benefits of the presumption of non-liability provided by Tex. Civ. Prac. & Rem. Code § 82.007. While that presumption is rebuttable, Gilead asserts that Rodriguez has failed to plead any cognizable basis for

rebuttal. In response, Rodriguez argues that § 82.007 does not apply in a clinical trial scenario.

In relevant part, § 82.007 states:

> (a) 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, including a health care provider, manufacturer, distributor, and prescriber, 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 ***for a product approved*** under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended . . . .

§ 82.007 (emphasis added). Relying on a plain language statutory interpretation, Rodriguez argues that S/L was not "a product approved" by the FDA because it was still in pre-approval clinical trials. While it did ultimately receive marketing approval, that level of approval took place after Rodriguez was treated with, and allegedly injured by, S/L. D.E. 32, p. 12.

As Rodriguez acknowledges, statutory construction of Texas laws involves looking at the entire law, without isolating particular words or phrases. *Meritor Auto, Inc. v. Ruan Leasing Co*., 44 S.W.3d 86, 90 (Tex. 2001); Tex. Gov't Code Ann. § 311.011(a). Contrary to that principle, Rodriguez seeks to isolate the phrase "a product approved" and construe that as meaning only a product that receives final approval for

marketing to the public. Read in its entirety, the clause speaks of approval "under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended." Thus a plain language reading of the provision would indicate that any approval by the FDA, acting pursuant to the Act, would create the non-liability presumption in favor of Gilead.

The Federal Food, Drug, and Cosmetic Act refers to FDA approval of drugs for clinical trials. *See e.g.*, 21 U.S.C. § 355. However, in explaining the requirements for an "investigational new drug" clinical trial, the regulation speaks in terms of authorizations rather than approvals. *See e.g.*, 21 C.F.R. 312. Without deciding whether this is a distinction without a difference, the Court concludes that a fully informed decision of this matter requires evidence of precisely what materials were provided to the FDA and whether the warnings on which Gilead relies were "approved." For that reason, the Court declines to grant relief at the pleading stage of this case. Gilead's motion to dismiss Rodriguez's failure to warn claims under Rule 12(b)(6) on the basis of the presumption of non-liability is **DENIED**.

CONCLUSION

For the reasons set out above, the Court **GRANTS** Lawitz and TLI's motion to dismiss (D.E. 6), **GRANTS IN PART** Gilead's motion to dismiss (D.E. 5) with respect to the design defect claims, and **DENIES IN PART** Gilead's motion to dismiss (D.E. 5) with respect to the learned intermediary doctrine and statutory presumption of non-liability. The Court **ORDERS** that Rodriguez may file a motion to amend his pleading to include facts that support a design defect claim on or before the tenth day after the date of

this Order. In the event that such a motion to amend is filed, the Court **ORDERS** that Gilead file any response it may have to the motion on or before the tenth day after the date the motion is filed.

ORDERED this 16th day of January, 2015.

NELVA GONZALES RAMOS
UNITED STATES DISTRICT JUDGE