UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

ALBERT MARTINEZ,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION H-18-2017
	§	
TEVA PHARMACEUTICALS USA, INC., *et al.*	§	
	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Pending before the court are motions to dismiss filed by defendants Mayne Pharma Inc., individually and as successor to Libertas Pharma, Inc. (Dkt. 22), Sandoz Inc. (Dkt. 25), Teva Pharmaceuticals USA, Inc. (Dkt. 27), and Taro Phamaceuticals (USA), Inc. (Dkt. 49) (collectively, "Defendants").[1] Plaintiff Albert Martinez responded. Dkts. 28– 29, 32, 50. Defendants replied. Dkt. 39, 40, 46, 57. Defendants supplemented their motions with additional authority. Dkts. 56, 61. Having considered the motions, responses, replies, and applicable law, the court is of the opinion that the motions should be DENIED.

I. BACKGROUND

This is a pharmaceutical case.[2] Dkt. 1 at 2. Defendants manufacture, market, and sell amiodarone, a generic medication. *Id.* The United States Food and Drug Administration ("FDA") approved amiodarone "only as a treatment of last resort for life-threatening ventricular fibrillation

[1]Because Defendants advance the same grounds in support of their individual motions, the court will address the motions together.

[2]For purposes of the motion to dismiss, the court accepts all of Martinez's allegations as true. *Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc.*, 677 F.2d 1045, 1050 (5th Cir. 1982).

or ventricular tachycardia that could not be controlled with any other FDA approved option." *Id.* "[E]ach consumer [must] receive an FDA-approved Medication guide each time an [a]miodarone prescription is filled." *Id.* at 13. According to Martinez, Defendants "did not validate the efficacy of their Medication Guide distribution process, and knew or should have known that their Medication Guides were not reaching patients like [him]." *Id.* at 10.

Two doctors prescribed amiodarone to Martinez "for a use never approved by the FDA." *Id.* at 2, 9. Martinez filled the prescription and received amiodarone manufactured by each of the four defendants. *Id.* at 2. He ingested the drug every day from September 26, 2015, to April 4, 2016. *Id.* at 8. He never received a Medication Guide. *Id.* at 8. If he had received one when he filled his prescription, "he would have read it, understood the risks of [a]miodarone [as well as] the approved uses of [a]miodranone, and would not have taken [it]." *Id.*

Martinez alleges he did not receive a Medication Guide because Defendants negligently designed, implemented, and validated a process for distributing those guides. *Id.* at 9. According to Martinez, Defendants "failed to take reasonable measures to provide [him] or his dispenser with the Medication Guides for [a]miodarone as required by federal and parallel state law" each time he filled his prescription.[3] *Id.* at 9, 15. He alleges that amiodarone proximately caused his injuries, including: pulmonary toxicity, Parkinson's disease, visual disturbances, vocal disturbances, and muscle weakness. *Id.* at 2. Martinez sued Defendants to recover in negligence and gross negligence. *Id*.

[3]According to Martinez, "[t]he overarching intent of federal prescription drug regulation and parallel Texas state law requirements is protecting patients from drugs that are ineffective, unsafe[,] or both . . . and ensuring that . . . consumers are provided required information before each . . . decides to . . . use a drug." Dkt. 1 at 2. He also asserts that "[t]his is . . . the basis for the duty the states impose on drug makers under both their common law and drug regulatory programs." *Id.*

II. LEGAL STANDARD

"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,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955 (2007) (internal quotations omitted). In considering a motion to dismiss under Rule 12(b)(6), courts accept the factual allegations contained in the complaint as true. *Kaiser*, 677 F.2d at 1050. The court does not look beyond the face of the pleadings to determine whether the plaintiff has stated a claim under Rule 12(b)(6). *Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999). The complaint "does not need detailed factual allegations, [but] a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 556 (internal citations omitted). The factual allegations must be: (1) enough to "raise a right to relief above the speculative level"; and (2) plausible—enough to raise a reasonable expectation that discovery will reveal further supporting evidence. *Id.*

III. ANALYSIS

Defendants move to dismiss Martinez's claims under Rule 12(b)(6). Defendants attack Martinez's claims as: (1) preempted; (2) barred by the learned intermediary doctrine; and (3) failing to allege sufficient facts. Because each of these grounds fail, the court DENIES each of the motions.

A. Preemption

Defendants argue that Martinez's claims are impliedly preempted by federal law. *See, e.g.*, Dkt. 22 at 4–6; Dkt. 25 at 6, 10; Dkt. 27 at 15–27; Dkt. 49 at 18. They argue that Martinez's claims impermissibly intrude on the FDA's exclusive authority to enforce its medication guide regulation because his claims arise solely by virtue of those regulations. *See, e.g.*, Dkt. 22 at 4–6 (relying on

Buckman Co. v. Pls.' Legal Comm., 531 U.S. 341, 352, 121 S.Ct. 1012 (2001)); Dkt. 49 at 18 (relying on *Perdue v. Wyeth Pharms., Inc.,* 209 F. Supp. 3d 846, 850–54 (E.D.N.C. 2016)).

Martinez relies on two recent Texas federal district court cases to argue that his claims are not preempted: *Monk v. Wyeth Pharmaceuticals, Inc.*, No. 5-16-cv-1273-XR, 2017 WL 2063008, at *1 (W.D. Tex. May 11, 2017) (Rodriguez, J.), and *Mitchell v. Wyeth Pharmaceuticals, Inc.*, No. 1:16-cv-574-LY, 2017 WL 7361750, at *1 (W.D. Tex. Feb. 9, 2017) (Yeakel, J.) (adopting magistrate judge's recommendation). *See* Dkt. 28 at 7–11. Both of those amiodarone cases analyzed and rejected arguments that are almost identical to those the Defendants advance here. *Compare Monk*, 2017 WL 2063008, at *1, *and Mitchell*, 2017 WL 7361750, at *1, *with* Dkt. 22 at 4–6, *and* Dkt. 25 at 6, 10, *and* Dkt. 27 at 15–27, *and* Dkt. 49 at 18. And both cases relied on the Fifth Circuit's decision in *Eckhardt v. Qualitest Pharmaceuticals, Incorporated*, 751 F.3d 674, 679 (5th Cir. 2014). *See Monk*, 2017 WL 2063008, at *2; *see also Mitchell*, 2017 WL 7361750, at *5–7.

Monk determined that an estate's negligence and gross negligence claims were not preempted. 2017 WL 2063008, at *4. Like Martinez, the *Monk* doctors prescribed amiodarone for an off-label use and the decedent-patient never received a Medication Guide. *See id.* at *1. And, just like Martinez, the *Monk* patient "did not know . . . the risks of taking amiodarone, the Medication Guide would have given him this information, and he would not have taken amiodarone had he been fully informed." *Id.*

Monk analyzed *Buckman* and *Eckhardt* to determine that the estate's claims were not preempted. *Id.* *Monk* reasoned that: (1) *Buckman* does not preempt parallel claims;[4] and

[4]*Monk* explained:

> *Buckman* dealt with 'fraud-on-the-FDA' claims involving a medical device manufacturer allegedly using fraudulent tactics to obtain FDA

(*2*) *Eckhardt* "found that claims for failing to provide FDA approved warnings (like the Plaintiff's here) are indeed parallel claims."[5] *Id.* at *4, *6. *Monk* cited *Mitchell* and two other district court cases as following *Eckhardt*.[6] *Id.* at *5 (citing *Mitchell*, 2017 WL 7361750, at *5–7, and *Priest v.*

> approval for a device and plaintiffs subsequently bringing private causes of action against the manufacturer for its misrepresentations to the FDA. Recognizing that private, state law causes of action for fraud-on-the-FDA conflict with federal law because they skewed 'a somewhat delicate balance of statutory objectives' covered by the FDA, the Supreme Court found that these claims were preempted. The broader lesson from *Buckman* . . . is that state law claims that exist 'solely by virute' of the FDCA requirements are preempted.
> [. . .]
> Crucially, however, the *Buckman* court distinguished preempted 'fraud-on-the-agency' claims from those based on 'traditional state tort law principles of the duty of care,' recognizing that 'certain state-law causes of actions that parallel federal safety requirements are not preempted.' This distinction is logical . . . the reason for preempting 'fraud-on-the-agency claims is primarily to protect the 'somewhat delicate balance of statutory objectives' that could be skewed by interference from private enforcement but pre-existing state law tort principles alone do not implicate the same concern.

Id. (discussing *Buckman*, 531 U.S. at 352).

[5]*Monk* explained that the *Eckhardt* plaintiff sued generic drug manufacturers:

> for fail[ing] to provide the plaintiff *or* his physician with any FDA-approved warnings. Ultimately, the Fifth Circuit affirmed the district court's dismissal of these claims because the plaintiff did not make adequate factual allegations. Before doing so, however, the court indicated that because 'failing to provide FDA-approved warnings would be a violation of both state and federal law, this is a parallel claim that is not preempted.'

2017 WL 2063008, at *5 (discussing *Eckhardt*, 751 F.3d at 679) (emphasis added). Defendants argue that "*Eckhardt* has no bearing on this case . . . [because] plaintiff was alleging that his *prescribing physician* was not provided with adequate warnings." *See, e.g.*, Dkt. 27 at 21. This argument fails because Defendants disregard the *Eckhardt* estate also alleged that the patient did not receive adequate warnings. *See* 751 F.3d at 679.

[6]*Mitchell* "involv[ed] similar allegations based on generic amiodarone manufacturers' failure to provide Medication Guides." 2017 WL 2063008, at *6 (discussing *Mitchell*, 2017 WL 7361750,

Sandoz Inc., 1-15-cv-822-ML-LY, 2017 WL 8896188, at *2 (W.D. Tex. Dec. 28, 2017) (adopting magistrate judge's report and recommendation), and *Rusk v. Wyeth-Ayerherst Labs.*, No. 1-14-cv-549-LY, 2015 WL 11050913, at *1 (W.D. Tex. Oct. 26, 2015) (Yeakel, J.) (same)). The *Monk* court explained that it took "the simple step of connecting the rule of *Buckman* with the finding of *Eckhardt*." *Id.* at *7.

Defendants repeat the challenges the *Monk* defendants advanced against *Eckhardt*. *Compare id.*, *with* Dkt. 27 at 20, *and* Dkt. 57 at 5–8. But just as *Monk* explained: "Defendants ignore . . . that regardless of the explanation in *Eckhardt,* this Court is bound by Fifth Circuit precedent, which expressly recognizes that a claim for failure to provide FDA-approved warnings alleges a violation of both [Texas] and federal law and that such a claim is a parallel claim that is not preempted."[7] 2017 WL 2063008, at *6 (citing *Eckhardt*, 751 F.3d at 679) (internal quotations omitted); *cf.* Dkt. 63 (supplementing with *McDaniel v. Upsher-Smith Labs., Inc.*, 893 F.3d 941, 942 (6th Cir. 2018)); Dkt. 56 (supplementing with *Small v. Amgen, Inc.*, 723 F. App'x 722, 723 (11th Cir. 2018)). To the extent that Defendants ask this court to disregard *Eckhardt*, the court declines.

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at *8). *Mitchell* determined that "to the extent [plaintiff] seeks to allege that Defendants failed to comply with their obligation to supply distributors with the FDA-required Medication Guides, and this failure proximately caused [the decedent] to take amiodarone without knowledge of the FDA-approved warnings, such a claim would survive federal preemption under *Eckhardt's* reasoning." *Id.*

[7]Defendants assert that other Fifth Circuit cases require this court to conclude that Martinez's claims are preempted. *See, e.g.,* Dkt. 27 at 17 (citing *Morris v. Pliva, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (per curiam), and *Estes v. Lanx, Inc.*, 660 F. App'x 260, 262 (5th Cir. 2016) (per curiam)). Defendants argue that *Morris* extends to the distribution of FDA-mandated medication guides. Dkt. 27 at 17 (citing *Morris*, 713 F.3d at 777). Defendants urge the court to assume that the Fifth Circuit would treat federal labeling obligations as equivalent to FDA-mandated Medication Guides. *Id.* at 18. The court will not make that leap without further guidance from the Fifth Circuit. Defendants also argue that under *Estes*, Martinez has no private right of action. *See* Dkt. 27 at 15. *Estes* analyzed "fraud-on-the-FDA" claims. 660 F. App'x at 621. That is not what Martinez alleges here. *See* Dkt. 1 at 2.

B. Learned intermediary doctrine

Defendants argue that the Texas's learned intermediary doctrine bars Martinez's claims. *See* Dkt. 22 at 7; Dkt. 27 at 9; Dkt. 40 at 7; Dkt. 49 at 7–8, 15–17. "Under Texas law, to prevail on a negligence cause of action, the plaintiff must prove the existence of a legal duty, a breach of that duty, and damages proximately caused by the breach." *Fret v. Melton Truck Lines, Inc.*, 708 F. App'x 824, 827 (5th Cir. 2017) (internal citations omitted). Under the learned intermediary doctrine, "the manufacturer of a pharmaceutical product satisfies its duty to warn the end user of its product's potential risks by providing an adequate warning to a 'learned intermediary,' who then assumes the duty to pass on the necessary warnings to the end user." *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 158 (Tex. 2012).

Defendants argue that the learned intermediary doctrine precludes the existence of duty and thus bars Martinez's claims. *See* Dkt. 22 at 7; Dkt. 27 at 9; Dkt. 40 at 7; Dkt. 49 at 7–8, 15–17. Martinez disagrees by relying on *Centocor*. Dkt. 28 at 12–13 (citing 372 S.W.3d at 158); Dkt. 32 at 6 (same).

Monk determined that the learned intermediary doctrine did not bar the plaintiff's claims. 2017 WL 2063008, at *7. The *Monk* court explained that "[w]here warnings to a learned intermediary are adequate, a drug manufacturer fulfills its duty to warn end users of its products under Texas law, but this result occurs *only if* the drug manufacturer provided adequate warnings." *Id.* (learned intermediary doctrine did not bar plaintiff's claims). In that case, the "[p]laintiff . . . pled that Defendants failed to provide adequate warnings of the danger of their products, and under Texas law, this sufficiently states a claim." *Id.*

Just as in *Monk*, Martinez has pled that Defendants did not provide adequate warnings of the risks of taking amiodarone by failing to ensure that Medication Guides reached him and patients like

him. *Compare id.*, *with* Dkt. 1 at 2, 8–9. Accordingly, the learned intermediary doctrine does not bar Martinez's claims at this stage. *Cf. Monk*, 2017 WL 2063008, at *7 ("Whether those warnings were in fact adequate—such that the learned intermediary doctrine would shield Defendants from liability—can be considered at the summary judgment phase after the parties have conduct discovery on the issue.").

C. Pleading deficiencies[8]

Defendants argue that Martinez fails to allege sufficient facts to survive Rule 8(b)(2). *See, e.g.*, Dkt. 22 at 3; Dkt. 49 at 19; Dkt. 57 at 12. Because Martinez's allegations raise a right to relief above a speculative level, the court disagrees. *See Twombly*, 550 U.S. at 555; *see also Kaiser*, 677 F.2d at 1050. Namely, Martinez alleges that: (1) the Medication Guide gave information about the risks of taking amiodarone; (2) he never received a Medication Guide; (3) had he received one, he would not have taken amiodarone; and (4) he suffered injuries because he took amiodarone. *See* Dkt. 1 at 2, 8–9. He also alleges that Defendants knew or should have known that patients like him: (1) were receiving off-label prescriptions; and (2) were not receiving Medication Guides. *Id.* And he alleges that Defendants did not ensure that pharmacies had enough Medication Guides to give to patients like Martinez. *Id.* These allegations satisfy Rule 8(a)(2).

IV. CONCLUSION

Defendants' motions to dismiss (Dkts. 22, 25, 27, 49) are DENIED.

Signed at Houston, Texas on July 31, 2018.

Gray H. Miller
United States District Judge

[8]Defendants argue that Martinez impermissibly combines allegations about the manufacturers together. *See, e.g.*, Dkt. 25 at 6, 17; Dkt. 49 at 21. "The fact that plaintiff accuses all . . . defendants of the same wrongdoings is not a basis for dismissal." *Monk*, 2017 WL 2063008, at *9.