UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS SAN ANTONIO DIVISION

JO ANN MONK, Individually and as Personal Representative of the Estate of JESSE MONK,	§	
Plaintiff,	§	Civil Action No. SA-16-CV-1273-XR
v.	§	
WYETH PHARMACEUTICALS, INC., ET AL.,	§	
Defendants.	§	

ORDER

On this date, the Court considered Defendant Teva Pharmaceuticals' Motion to Dismiss (Docket no. 21), Defendants Eon Labs and Sandoz Inc.'s Motion to Dismiss (Docket no. 22), and the corresponding responses and replies. After careful consideration, the motions to dismiss are GRANTED IN PART AND DENIED IN PART.

BACKGROUND

I. Plaintiff's Factual Allegations

Jesse Monk had atrial fibrillation. Docket no. 18 at 6. Doctors prescribed amiodarone as a treatment. *Id*. He never received a Medication Guide describing certain risks associated with his use of amiodarone and his pharmacy did not have Medication Guides to provide to him. *Id*. at 7. After taking amiodarone as prescribed for approximately eight years, Monk died in January 2015. *Id*. at 1, 6. His autopsy revealed that the cause of death was amiodarone poisoning. *Id*. at 8. Monk's spouse, Jo Ann Monk, is the plaintiff in this lawsuit, and brings claims individually and as personal representative of Jesse Monk's estate. *Id*. at 1. Defendants Teva Pharmaceuticals USA, Inc., Eon Labs, Inc., and Sandoz, Inc. are distributors of a generic form of amiodarone. *Id*.

at 6. Defendants are required by Food and Drug Administration ("FDA") regulations and the Food, Drug, and Cosmetics Act ("FDCA") to provide Medication Guides to Monk via his pharmacy. *Id* at 7–8; *see* 21 C.F.R. § 280.24(b).

Jesse Monk was prescribed amiodarone "off label"—that is, for a use for which it was not fully approved by the FDA. *Id*. at 6. In particular, amiodarone was approved by the FDA through a limited "special needs" process, meaning that it was only approved "as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies." *Id*. at 5–6. Despite being approved only for these purposes, doctors prescribed amiodarone to Monk for treatment of atrial fibrillation. *Id*.

When Monk had his prescription filled at a local Walgreen's pharmacy, he was never given a Medication Guide. *Id*. at 7. According to the complaint, Monk did not know that he was prescribed amiodarone off label or of 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*.

Plaintiff's live complaint asserts causes of action for negligence, negligence per se, and gross negligence:

> [Defendants] have a duty to market amiodarone in such a way as to avoid unreasonable harm to patient consumers. [Defendants] were required to provide a Medication Guide . . . They failed to comply with that requirement and in doing so breached parallel Texas State law duties. [Defendants'] failure to provide amiodarone Medication Guides as required breached the Texas state common law duty to adequately warn of risks association with prescription medicines.

Id. at 11.

Defendant Teva filed a motion to dismiss on March 14, 2017. Docket no. 21. Defendants Eon and Sandoz filed a similar motion that same day. Docket no. 22.

II. The FDA's Drug Approval Framework[1]

Brand-name prescription drugs must be approved by the FDA before they go to market. Docket no. 18 at 5. To begin this process, the sponsor of a drug submits a new drug application ("NDA"). *Id*. NDAs include a litany of information relating to a drug's safety, effectiveness, proposed uses, warnings, and potential adverse reactions. *Id*. In 1984, Wyeth, a pharmaceutical company that was initially named as a defendant in this lawsuit but has since been voluntarily dismissed by Plaintiff, sponsored approval of amiodarone under the brand name Cordarone. *Id*. at 5; *see also* Docket no. 20. In doing so, however, Cordarone obtained FDA approval under an abbreviated "special needs" process whereby a drug is not subject to the full rigor of an NDA but is approved only for certain, limited "special needs." Docket no. 18 at 5. As such, Cordarone "was approved only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies." *Id*. at 5–6.

The above procedure applied only to the initial approval of a Wyeth's *brand-name* formulation of amiodarone, but the remaining defendants in this action are manufacturers of a *generic* form of amiodarone. *Id*. at 5. As such, they are governed by a slightly different regulatory process:

> In 1984, through the Hatch–Waxman Amendments, Congress modified these procedures for generic drug manufacturers, creating an expedited process for approving generic drugs. *See* DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984, Pub. L. 98–417, 98 Stat. 1585 (codified in scattered sections of 21 and 35 U.S.C.). In essence, these amendments allow a generic drug manufacturer to piggy-back on the FDA approval of a brand name drug—greatly accelerating the process for receiving approval—provided that the generic drug has active ingredients and labeling identical to that of the FDA-approved brand name drug. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612–13, n. 2 (2011). After the

[1] This background is taken from prior case law and the allegations in Plaintiff's live complaint; it is meant merely to provide context for the factual and legal contentions in this case and not as a comprehensive primer on FDA requirements and regulations.

> generic drug receives approval, the generic manufacturer is prohibited from making changes to the drug itself or from unilaterally changing the drug's label. *See Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013).

Eckhardt v. Qualitest Pharm., Inc., 751 F.3d 674, 676 (5th Cir. 2014) (citations modified).

Defendants all received FDA approval to manufacture, market, sell, and distribute their generic formulas of amiodarone. Docket no. 18 at 6. Accordingly, they were required by the FDA and FDCA to provide certain labels, warnings, and information. *Id*. Most notably for purposes of this lawsuit, the FDCA and its regulations require generic drug manufacturers to disseminate Medication Guides:

> (b) Each manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients by either:
>
> > (1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or
> >
> > (2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product. . . .
>
> (e) Each authorized dispenser of a prescription drug product for which a Medication Guide is required under this part shall, when the product is dispensed to a patient (or to a patient's agent), provide a Medication Guide directly to each patient (or to the patient's agent) unless an exemption applies under 208.26.

21 C.F.R. § 208.24(b), (e); *see also McLeod v. Sandoz, Inc.*, 4:16-CV-01640-RBH, 2017 WL 1196801, at *9 (D.S.C. Mar. 31, 2017) ("Specifically, 21 C.F.R. § 208.24 provides that '[e]ach manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients.'").

DISCUSSION

Defendants attack Plaintiff's state law claims in three ways. First, they argue that these claims are preempted by federal law under *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001). Second, they argue that Plaintiff has not pled the existence of a duty under Texas law because the learned intermediary doctrine requires pharmaceutical distributors to give warnings only to prescribing physicians rather than directly to patients. Third, they argue that Texas law does not recognize a negligence per se claim based on alleged violations of the FDCA or FDA regulations. More generally, Defendants also argue that Plaintiff's complaint does not meet federal pleading standards because it does not differentiate its allegations as between the three defendants.

For the following reasons, most of these arguments fail. The only one of Defendants' arguments that succeeds is that Plaintiff's negligence per se claims should be dismissed; to this extent, the motions to dismiss are GRANTED. In all other respects, the motions are DENIED.

I. Standard of Review

"To survive a motion to dismiss, a complaint 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)). A claim for relief must contain: (1) "a short and plain statement of the grounds for the court's jurisdiction"; (2) "a short and plain statement of the claim showing that the pleader is entitled to the relief"; and (3) "a demand for the relief sought." FED. R. CIV. P. 8(a). In considering a motion to dismiss under Rule 12(b)(6), all factual allegations from the complaint should be taken as true, and the facts are to be construed favorably to the plaintiff. *Fernandez-Montez v. Allied Pilots Assoc.*, 987 F.2d 278, 284 (5th Cir. 1993). To survive a 12(b)(6) motion, a complaint must

contain "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 555.

II. Plaintiff properly alleges that Defendants did not comply with the applicable federal regulations.

Initially, the Court dispenses with an argument asserted by Defendants Sandoz and Eon—that Plaintiff's complaint does not allege that Sandoz and Eon violated any FDA regulations. In particular, Sandoz and Eon argue that Plaintiff does not allege their non-compliance with § 208.24(b) because "[t]he mere allegation that [they] did not provide Medications Guides to the Decedent's pharmacy is not sufficient to allege a violation of this regulation." Docket no. 22 at 8. With reference to the regulatory language quoted above, they point out that one way a manufacturer complies with the regulations is by "[p]roviding the means to produce Medication Guides," meaning that their failure to provide Medication Guides itself does not violate the regulations. *See* 21 C.F.R § 208.24(b)(2).

Sandoz and Eon misread the allegations of the complaint. They focus narrowly on Plaintiff's allegation that "Medication guides were not provided to that pharmacy by . . . Eon, Sandoz, or any of their distributors." Docket no. 18 at 7. Plaintiff, however, goes further by adding the following allegations: "Defendants failed to provide a Medication Guide that would reach Jesse Monk," *id*. at 3; "Jesse Monk's pharmacy did not have Teva, Eon, or Sandoz Medication Guides to provide Jesse Monk as these defendants each failed to distribute them as required," *id*. at 7. Though the complaint does not track the regulatory language verbatim, the allegation that the pharmacy did not have the Medication Guides necessarily follows from the premise that the pharmacy lacked the Guides themselves and the means to produce them.

Sandoz and Eon also argue that § 208.24(e) imposes no legal obligation to ensure actual delivery of a Medical Guide to a patient. Instead, they argue, this regulation applies only to

authorized distributors, which the pharmacy is but they are not. Sandoz and Eon ignore that subsection (e) does not absolve manufacturers of the requirements of subsection (b) but instead imposes separate requirements on authorized distributors *in addition to* those imposed on manufacturers. As explained above, the complaint adequately alleges that Sandoz and Eon did not comply with subsection (b); thus, whether they also complied with subsection (e) is irrelevant. Accordingly, Sandoz and Eon's argument that the complaint does not adequately allege a violation of the applicable federal regulations is without merit.

III. Under state law, Plaintiff adequately alleges negligence claims but does not adequately allege negligence per se claims.

a. Plaintiff's state law claims are not preempted by *Buckman*.

Defendants argue that under the Supreme Court's decision in *Buckman*, Plaintiff's Texas law claims that are based on Defendants' failure to provide an FDA-required Medication Guide are preempted. 531 U.S. 341, 352–53 (2001); *see also* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States."). *Buckman* dealt with "fraud-on-the-FDA" claims involving a medical device manufacturer allegedly using fraudulent tactics to obtain FDA approval for a device and plaintiffs subsequently bringing private causes of action against that manufacturer for its misrepresentations to the FDA.[2] 531 U.S. at 345–46. 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. *Id*. at 348. The broader lesson from *Buckman*, which Defendants seek to invoke here, is that state law claims that exist "solely by virtue" of FDCA requirements are preempted. *Buckman*, 531 U.S. 341, 352–53 (2001); *see also Perdue v. Wyeth*

[2] After two failed attempts to obtain FDA approval for its device, the manufacturer split the device into component parts and obtained piecemeal FDA approval for these parts. *Buckman*, 531 U.S. at 345–46.

Pharm., Inc., 209 F. Supp. 3d 847, 851 (E.D.N.C. 2016) (holding that a state law claim is preempted under *Buckman* if "'the existence of these federal enactments is a critical element in [plaintiff's] case,' and [if] a plaintiff's claims 'exist solely by virtue of the FDCA . . . requirements.'" (quoting *Buckman*, 531 U.S. at 352)). Indeed, this preemptive effect of *Buckman* has been extended beyond the fraud-on-the-FDA context by some courts. *See, e.g.*, *Perdue*, 209 F. Supp. 3d at 851–52.

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. *Buckman*, 531 U.S. at 352–53; *see also Perdue*, 209 F. Supp. 3d at 847 (noting that a state law claim is not preempted under *Buckman* if it rests on "'traditional state tort law principles of the duty of care,' the establishment of which 'predated the federal enactments in question.' . . . In this manner, *Buckman* does not extend so far as to restrict 'certain state-law causes of actions that parallel federal safety requirements.'" (quoting *Buckman*, 531 U.S. at 352)). 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 that same concern.

Recently, the Fifth Circuit addressed a claim similar to this one involving a pharmaceutical company's failure to provide FDA-required warnings. In *Eckhardt v. Qualitest Pharmaceuticals, Inc.*, the plaintiff attempted to assert a cause of action based on generic drug manufacturers' failure to provide the plaintiff or his physician with any FDA-approved warnings. 751 F.3d 674, 679 (5th Cir. 2014). Ultimately, the Fifth Circuit affirmed the district court's

dismissal of these claims because the plaintiff did not make adequate factual allegations. *Id*. 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." *Id*. (emphasis added).

Other decisions from this Court have followed *Eckhardt*. In *Mitchell v. Wyeth*, a case involving similar allegations based on generic amiodarone manufacturers' failure to provide Medication Guides, Magistrate Judge Mark Lane recommended that the district court deny the pharmaceutical defendants' motion to dismiss:

> [Defendant] argues that under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001), [plaintiff] does not have a private right of action to the manufacturer's duty to provide the Medication Guide. However, despite rejecting a variety of allegedly parallel state tort claims as preempted by *Mensing* and *Bartlett*, the Fifth Circuit recently held in *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 679 (5th Cir. 2014), that an allegation that generic drug manufacturers "failed to provide [plaintiff] or his physician with any of the FDA-approved warnings . . . would be a violation of both state and federal law, [and] this is a parallel claim that is not preempted." *Id*. at 679–80. . . .
>
> 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.

Case No. 1:16-CV-574-LY-ML, Docket no. 73 at 8–9 (W.D. Tex. Jan. 1, 2017) (some citations omitted). The district court summarily adopted this recommendation after a *de novo* review. *Id*. at Docket no. 75 (W.D. Tex. Feb. 9, 2017). Judge Lane previously made similar recommendations in two more amiodarone cases. *See Rusk v. Wyeth*, Case No. 1:14-CV-549-LY-ML, 2015 WL 3651434 (W.D. Tex. June 11, 2005);[3] *Priest v. Sandoz*, Case no. 1:15-CV-

[3] "Plaintiffs in this case allege that [defendant] was responsible for providing an FDA-mandated 'Medication Guide.' Plaintiffs further allege that [the decedent] never received the Medication Guide, and that 'the Pharmacies' assert 'no manufacturer' was providing the Guides to pharmacists or patients. To the extent Plaintiffs seek to allege that Sandoz failed to comply with its obligation to supply distributors with the FDA-required

822-ML-LY, Docket no. 65 (W.D. Tex. December 29, 2016).[4] As in *Mitchell*, the district court summarily adopted both of these recommendations after conducting a *de novo* review. *Rusk*, Case no. 1:14-CV-549-LY, Docket no. 46 (W.D. Tex. October 16, 2015); *Priest*, Case no. 1:15-CV-822-LY, Docket no. 67 (W.D. Tex. January 31, 2016).

Defendants challenge *Eckhardt* and its progeny for failing to provide reasoning based in Texas law to support the proposition that these Medication Guide claims allege a breach of a parallel duty under Texas law. Defendants ignore, though, 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." 751 F.3d at 679.

Defendants also seek to avoid the *Eckhardt* line of cases by arguing that "neither *Mitchell* nor *Eckhardt* contains any substantive preemption analysis under *Buckman* whatsoever." *E.g.*, Docket no. 30 at 8. In *Mitchell*, Judge Lane's recommendation addressed the argument that *Buckman* preempted the plaintiff's Medication Guide claim. *Mitchell*, Case No. 1:16-CV-574-LY-ML, Docket no. 73 at 8. Defendants may disagree with the analysis or object to its depth, but to say that the recommendation does not contain such an analysis is incorrect. As to *Eckhardt*, whether the court meant that the parallel claims were preempted under *Buckman* or under another source of preemption is irrelevant because the court found that "failing to provide FDA-

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Medication Guides, and this failure proximately caused [the decedent] to take amniodarone [sic] without knowledge of the FDA-approved warnings, such a claim would survive federal preemption under *Eckhardt's* reasoning." *Rusk*, 2015 WL 3651434 at *7 (citations omitted).

[4] "[D]espite rejecting a variety of allegedly parallel state tort claims as preempted . . . the Fifth Circuit recently held in *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 679 (5th Cir. 2014) that an allegation that generic drug manufacturers 'failed to provide [plaintiff] or his physician with any of the FDA-approved warnings . . . would be a violation of both state and federal law, [and] this is a parallel claim that is not preempted.' *Id.* at 679–80 . . . To the extent Plaintiff seeks to allege that [defendant] failed to comply with its 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." *Priest*, Case no. 1:15-CV-822-ML-LY, Docket no. 65 at 11–12 (W.D. Tex. December 29, 2016).

approved warnings would be a violation of state and federal law . . . [and] is a parallel claim." Because "certain state-law causes of actions that parallel federal safety requirements" are not preempted under the express language of *Buckman,* 531 U.S. at 353, and the Fifth Circuit in *Eckhardt* found that claims for failing to provide FDA approved warnings (like Plaintiff's here) are indeed parallel claims, this Court, at most, takes the simple step of connecting the rule of *Buckman* with the finding of *Eckhardt.*[5]

Other case law does not warrant a contrary result. Defendants cite a variety of cases from the Fifth Circuit dealing with other pharmaceutical claims, but none of these cases dealt with the potential preemptive effect of *Buckman* on state law negligence claims such as the ones here. A large number of these cases involved fraud-on-the-FDA claims, like those in *Buckman* that the Supreme Court found skewed the "somewhat delicate balance of statutory objectives" involved in FDA regulation. *See, e.g., Estes v. Lanx, Inc.*, 660 F. App'x. 260, 261 (5th Cir. 2016). Another case cited by Defendants, *Morris v. PLIVA, Inc.*, deals specifically with a pharmaceutical manufacturer's *labeling* of its products, and was not a barrier to the Fifth Circuit's subsequent decision in *Eckhardt* (or any of Judge Lane's recommendations). 713 F.3d 774, 777–78 (5th Cir. 2013). Defendants also cite a variety of cases from district courts outside the Fifth Circuit that have found similar claims to be preempted, but these cases interpret other states' laws and lack the binding guidance of a case like *Eckhardt*. *See, e.g., McDaniel v. Upsher-Smith Pharm., Inc.*, 216CV02604JPMCGC, 2017 WL 657778, at *4 (W.D. Tenn. Jan. 26, 2017) (interpreting Tennessee law and correctly characterizing *Eckhardt* as "only persuasive and not binding authority.").

[5] The court in *Eckhardt* may well have meant that *Buckman* does not preempt these claims, undermining Defendants' argument entirely. Still, Defendants are correct that the court did not mention *Buckman* by name. At most, it is possible that the court never analyzed whether *Buckman* would also warrant preemption in light of its finding that the state law claims there paralleled federal law.

In sum, the Court finds that Plaintiff's claims are not preempted because under *Buckman*, parallel claims are not preempted, and under *Eckhardt*, claims such as Plaintiff's are parallel claims.

b. The learned intermediary doctrine does not bar Plaintiff's claims at this stage.

Under Texas law, "[t]he elements of a negligence cause of action are the existence of a legal duty, a breach of that duty, and damages proximately caused by the breach." *IHS Cedars Treatment Ctr. of DeSoto, Tex., Inc. v. Mason*, 143 S.W.3d 794, 798 (Tex. 2004). Thus, in order to state a cause of action for negligence, Plaintiff must allege the existence of a legal duty under Texas law. Whether Plaintiff has done so turns on Texas' learned intermediary doctrine.

Texas law has long limited a manufacturer or supplier's duty to warn end users of its products in certain situations where an intermediary separates the supplier from the end user. *See Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591 (Tex. 1986) ("[A] manufacturer or supplier may, in certain situations, depend on an intermediary to communicate a warning to the ultimate user of a product."). The Texas Supreme Court in *Alm*—a products liability case involving the manufacture of an aluminum bottle cap—hypothesized about the applicability of this doctrine in the prescription drug context while summarizing the reasoning and holdings from lower Texas courts:

> In some situations, courts have recognized that a warning to an intermediary fulfills a supplier's duty to warn ultimate consumers. For example, when a drug manufacturer properly warns a prescribing physician of the dangerous propensities of its product, the manufacturer is excused from warning each patient who receives the drug. The doctor stands as a learned intermediary between the manufacturer and the ultimate consumer. Generally, only the doctor could understand the propensities and dangers involved in the use of a given drug. In this situation, it is reasonable for the manufacturer to rely on the intermediary to pass on its warnings. However, even in these circumstances, when the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user.

Id. at 591–92 (citations omitted). The Texas Supreme Court ultimately found that there was some evidence in the record to support the jury's finding that the warnings given by the manufacturer of the bottle cap to the bottler (i.e., the intermediary) were inadequate. *Id*. at 593

Picking up on this language from *Alm*, the Texas Supreme Court later held that the learned intermediary doctrine applies to a pharmaceutical manufacturer's duty to warn consumers of dangers associated with prescription drugs. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 156 (Tex. 2012). Previously, the Texas Supreme Court "[had] not considered a case that squarely present[ed] the applicability of the learned intermediary doctrine within the context of prescription drug products-liability cases." *Id*. at 157. But in *Centocor*, the court extended the rule to such a situation:

> [W]e hold that a prescription drug manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, it has no further duty to warn the end users directly. *But as we have previously indicated, when the warning to the prescribing physician is inadequate or misleading, the prescription drug manufacturer remains liable for the injuries sustained by the patient*.

Id. at 15 (emphasis added).

Plaintiff correctly highlights the emphasized language from *Centocor*. Unlike Defendants' characterization of Plaintiff's argument, this language does not signify an exception to the learned intermediary doctrine, but rather is the rule itself. Where 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. Accordingly, the application of the learned intermediary doctrine does not bar Plaintiff's claims, as this Court recognized in *Mitchell*. Case No. 1:16-CV-574-LY-ML, Docket no. 73 at 8–9 ("Texas's learned intermediary doctrine also does not defeat this cause of action.").

Plaintiff has pled that Defendants failed to provide adequate warnings of the dangers of their products, and under Texas law, this sufficiently states a claim. 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 conducted discovery on the issue.

c. Plaintiff's negligence per se claims are dismissed.

Defendants argue that Plaintiff's negligence per se claim should be dismissed because Texas law does not recognize a cause of action for negligence per se based on alleged violations of the FDCA. Docket no. 21 at 14. The Court agrees.

"Negligence per se is a tort theory whereby courts use statutes or regulations to define the standard of reasonably prudent conduct." *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002) (citing *Carter v. William Sommerville & Son, Inc.*, 584 S.W.2d 274, 278 (Tex. 1979)). The Court has relatively little guidance on this question because neither the Fifth Circuit nor the Texas Supreme Court has stated whether a violation of the FDCA and FDA regulations can give rise to a negligence per se claim. *Hackett*, 246 F. Supp. 2d at 594.

To support their arguments, Defendants rely primarily on *Hackett*, where this Court found that Texas law did not recognize such a claim. 246 F. Supp. 2d at 546. The Court was persuaded by the thorough analysis of a Texas trial court, which found that under the applicable factors set forth by the Texas Supreme Court, the FDCA and FDA regulations did not give rise to a cause of action for negligence per se under Texas law. *Id.* (discussing and following *Baker v. Smith & Nephew Richards, Inc.*, Case No. 95-58737, 1999 WL 811334, at *8–11 (Tex. Dist.

June 7, 1999)[6]). At least two other federal district courts in Texas have relied on *Hackett* and *Baker* to summarily find that "Texas courts . . . refuse to recognize a cause of action for negligence per se based on violations of the [FDCA] and FDA regulations." *Holland v. Hoffman-La Roche, Inc.*, 3-06-CV-1298-BD, 2007 WL 4042757, at *3 (N.D. Tex. Nov. 15, 2007) (quoting *Hackett*, 246 F. Supp. 2d at 594); *see also Jackson v. Tae Jin Kim*, 2:02-CV-200, 2004 WL 6040969, at *4 (E.D. Tex. Sept. 27, 2004) (citing *Baker*, 1999 WL 811334 at *8). The Court is persuaded by the cases cited by Defendants, and agrees that Texas law likely does not recognize a cause of action for negligence per se based solely on the violation of the FDCA and FDA regulations.

Plaintiff's arguments to the contrary are unavailing. First, Plaintiff argues that the cases cited by Defendants were summary judgment decisions that came long after the pleadings stage. *Hackett*'s dismissal of the negligence per se claims, however, came on a Rule 12(c) motion for judgment on the pleadings. 246 F. Supp. 2d at 593–94. Further, all of these cases, despite being postured as summary judgment decisions, conducted a legal (not factual) analysis of negligence per se claims. Plaintiff next relies on an out-of-circuit decision interpreting Oklahoma law as recognizing a negligence per se claim in these circumstances, but this case is far from binding in any respect and is countered by other out-of-circuit decisions that reach the opposite result. *Compare* Docket no. 28 at 13 (citing *Howard v. Zimmer*, 718 F.3d 1209, 1210 (10th Cir. 2013) for the proposition that Oklahoma law recognizes FDA-based negligence per se claims) *with Talley v. Danek Medical, Inc.*, 179 F.3d 154, 157–61 (4th Cir. 1999) (finding that Virginia law did not permit plaintiff to enforce certain violations of FDA regulations through a negligence per se claim). Finally, Plaintiff argues that Judge Lane permitted similar negligence per se claims to

[6] *Baker* was affirmed, but the appellate court expressly withheld a ruling on this question. *See McMahon v. Smith & Nephew Richards, Inc.*, Case No. 14-99-00616-CV, 2000 WL 991697, at *3, n. 2 (Tex. App.—Houston [14th Dist.] July 20, 2000, no pet.).

proceed in his recommendations in *Rusk* and *Priest*, but as Defendants note, Judge Lane never analyzed these claims; the refusal to dismiss these claims *sua sponte*, especially in the absence of argument from the parties, is not an affirmation of the validity of these claims. Accordingly, Plaintiff's negligence per se claims are dismissed.

IV. Plaintiff's complaint is not deficient for failing to differentiate its allegations among the three defendants.

Finally, the Court dispenses with Defendants Sandoz and Eon's argument that Plaintiff's complaint is inadequate for failing to differentiate its allegations as to each of the three defendants. Docket no. 22 at 13. Though Plaintiff's complaint does not separate its allegations, it specifically identifies each defendant and specifically describes all Defendants' allegedly wrongful conduct. *See, e.g.*, Docket no. 18 at 6 ¶ 31; 7 ¶ 39; 7–8 ¶ 40; 11 ¶ 57–61. The fact that Plaintiff accuses all three defendants of the same wrongdoings is not a basis for dismissal.

CONCLUSION

For the foregoing reasons, Defendant Teva's motion to dismiss (Docket no. 21) and Defendants Sandoz and Eon's motion to dismiss (Docket no. 22) are GRANTED IN PART AND DENIED IN PART. In their Rule 26 Report, the parties indicated that they would provide a status report by May 22, 2017. Docket no. 27. In preparation for a status conference (which will be set at a later time) the parties are ORDERED to provide this status update by June 5, 2017. In addition, the parties are further ORDERED to provide scheduling recommendations in accordance with the Court's form (available at Docket no. 15) by June 5, 2017.

It is so ORDERED.

SIGNED this 11th day of May, 2017.

XAVIER RODRIGUEZ
UNITED STATES DISTRICT JUDGE