UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

MARK BLACKBURN,	}	
	}	
Plaintiff,	}	
	}	
v.	}	**Case No.: 2:16-CV-963-RDP**
	}	
SHIRE US, INC., et al.,	}	
	}	
Defendants.	}	

MEMORANDUM OPINION

I. Introduction

This matter is before the court on Defendants' Motion to Dismiss Plaintiff's First Amended Complaint. (Doc. # 44). In their motion and accompanying memorandum of law (Doc. # 45), Defendants argue that Plaintiff's Amended Complaint is due to be dismissed in its entirety. Defendants' motion is fully briefed. (Docs. # 45, 51, 52). For the reasons stated below, Defendants' Motion is due to be granted in part and denied in part.

II. Factual Background[1]

Defendants engage in the distribution, marketing, and sale of the drug known as LIALDA. (Doc. # 41 at ¶ 8). In November 2013, Plaintiff was prescribed LIALDA for treatment of his Crohn's disease. (*Id.* at ¶ 39). Plaintiff took LIALDA, as prescribed, from November 2013 until February 2015. (*Id.*). In September 2015, Plaintiff was diagnosed with Stage IV renal failure and severe chronic interstitial nephritis. (*Id.* at ¶ 45). Plaintiff contends that LIALDA causes toxicity to build up in the kidneys over time, and he alleges that his kidney injuries were a direct result of his continued use of LIALDA. (*Id.* at ¶¶ 43-47).

[1] For purposes of evaluating Defendants' Motion to Dismiss, the court assumes the veracity of Plaintiff's well-pleaded factual allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Plaintiff asserts that LIALDA's label contained a defect, which was present both in January 2007 (when LIALDA was initially approved by the FDA), and in November 2013 (when Plaintiff was first prescribed LIALDA). (*Id.* at ¶¶ 17, 18). He contends that LIALDA's defective label caused his injuries. (*Id.* at ¶¶ 36, 47). LIALDA's label warned of the possibility that a consumer may develop kidney damage from use of the product. Indeed, the LIALDA label in use at the time Plaintiff was prescribed the drug[2] warned that "[r]enal impairment, including minimal change nephropathy, acute and *chronic interstitial nephritis*, and rarely, *renal failure*, has been reported in patients given products such as LIALDA that contain mesalamine or are converted to mesalamine." (*Id.* at ¶ 18) (emphasis added). Accordingly, Plaintiff does not contend that Defendants failed to warn that use of LIALDA may result in kidney injury.

Instead, he takes issue with the following language, also from LIALDA's label: "[i]t is recommended that patients have an evaluation of renal function prior to initiation of LIALDA therapy and periodically while on therapy." (*Id.*). Plaintiff alleges that this recommended "periodic" evaluation constitutes a defective and unsafe instruction for use of LIALDA. (*Id.* at ¶ 22). He contends that the term "periodic," as generally used in drug labels, refers to either semi-annual or annual testing. (*Id.*). However, he asserts that an appropriate LIALDA label should include instructions recommending "evaluation of renal function by a simple serum (blood) test of creatinine levels on a monthly basis for the first three months after initiation of therapy and then on a quarterly basis for at least one year." (*Id.* at ¶ 25). Plaintiff asserts that Defendants' recommendation of only "periodic" testing, as opposed to the more specific testing regimen detailed in his Amended Complaint, proximately caused his kidney injury. (*Id.* at ¶ 26).

[2] Plaintiff quotes language from both LIALDA's 2007 and 2013 labels, but asserts that, with respect to the language made the basis of his complaint, the two are "substantively identical." (Doc. # 41 at ¶ 19).

Plaintiff asserts claims for failure to warn under the Alabama Extended Manufacturers Liability Doctrine ("AEMLD"), fraud, suppression and concealment, and breach of express warranty.

III. Standard of Review

The Federal Rules of Civil Procedure require only that the complaint provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Still, the complaint must include enough facts "to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Pleadings that contain nothing more than "a formulaic recitation of the elements of a cause of action" do not meet Rule 8 standards, nor do pleadings suffice that are based merely upon "labels and conclusions" or "naked assertion[s]" without supporting factual allegations. *Twombly*, 550 U.S. at 555, 557. In deciding a Rule 12(b)(6) motion to dismiss, courts view the allegations in the complaint in the light most favorable to the nonmoving party. *Watts v. Fla. Int'l Univ.*, 495 F.3d 1289, 1295 (11th Cir. 2007).

To survive a motion to dismiss, a complaint must "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although "[t]he plausibility standard is not akin to a 'probability requirement,'" the complaint must demonstrate "more than a sheer possibility that a defendant has acted unlawfully." *Id.* A plausible claim for relief requires "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence" to support the claim. *Twombly*, 550 U.S. at 556. The Supreme Court has recently identified "two working principles" for a district court to use in applying the facial plausibility standard. First, in evaluating motions to dismiss, the court must assume the veracity of well-

pleaded factual allegations; however, the court does not have to accept as true legal conclusions when they are "couched as . . . factual allegation[s]." *Iqbal*, 556 U.S. at 678. Second, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 679.

Application of the facial plausibility standard involves two steps. Under prong one, the court must determine the scope and nature of the factual allegations that are well-pleaded and assume their veracity; and under prong two, the court must proceed to determine the claim's plausibility given the well-pleaded facts. That task is context specific and, to survive the motion, the allegations must permit the court based on its "judicial experience and common sense . . . to infer more than the mere possibility of misconduct." *Id.* If the court determines that well-pleaded facts, accepted as true, do not state a claim that is plausible, the claims are due to be dismissed. *Id.*

IV. Analysis

Defendants' brief in support of their Motion to Dismiss makes a number of arguments which purport to establish bases to dismiss Plaintiff's Amended Complaint. The court will address Defendants' arguments in turn.

A. Impossibility Preemption

It is axiomatic that "[u]nder the Supremacy Clause, state laws that require a private party to violate federal law are pre-empted and, thus, are 'without effect.'" *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). However, "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated… in a field which the States have traditionally occupied,' … we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Medtronic, Inc. v. Lohr*, 518

U.S. 470, 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Here, Defendants argue that Plaintiff's state law claims, which allege that LIALDA's label is inadequate under state law, are preempted by federal law related to the labelling of prescription drugs. (Doc. # 45 at pp. 13-18).

While Plaintiff alleges that Defendants had a duty under Alabama state law to issue adequate testing requirements and warnings (*see* Doc. # 41 at ¶ 150), federal law imposes more complex drug labeling requirements. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011). Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), drug manufacturers must gain approval from the United States Food and Drug Administration ("FDA") before marketing any drug in interstate commerce. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013); *see* 21 U.S.C. § 355(a). This premarket approval of a new drug application ("NDA") requires FDA approval of the exact text contained in the drug's proposed label. *See* 21 U.S.C. § 355; 21 C.F.R. §314.105(b). The FDA may approve of an NDA only if the drug in question is "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labelling thereof." 21 U.S.C. § 355(d).

Generally, "a manufacturer may only change a drug label after the FDA approves a supplemental application." *Wyeth v. Levine*, 555 U.S. 555, 568 (2009); 21 C.F.R. § 314.70. However, there are certain instances in which a drug manufacturer may unilaterally make changes to a drug's label without the FDA's prior approval. Under the "changes being effected" ("CBE") regulation, a manufacturer may unilaterally change the label of its drug to "add or strengthen a contraindication, warning, precaution, or adverse reaction" without waiting for FDA approval. § 314.70(c)(6)(iii)(A).

In those instances when state and federal law conflict, and it is "impossible for a private party to comply with both state and federal requirements," state law is preempted. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (internal quotation marks omitted). Given their obligations under the FDCA, Defendants argue that it would be impossible for them to comply with federal labelling requirements as well as the state duty Plaintiff contends LIALDA's label breached. The court disagrees.

In circumstances such as those presented here, "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA, Inc.*, 564 U.S. at 620. And, in a case involving facts similar to those here, the Supreme Court found that a plaintiff's state law claims were not preempted by federal labelling requirements. *Wyeth*, 555 U.S. at 573. In *Wyeth*, the plaintiff filed suit against a brand name drug manufacturer claiming that a drug that it manufactured did not contain an adequate warning. *Id.* at 565. In conducting its "impossibility" analysis, the Court noted that the CBE regulation permitted the defendant to strengthen its drug's warning before receiving the FDA's approval. *Id.* at 571. Because the defendant could "unilaterally strengthen its warning… the mere fact that the FDA approved [the drug in question's] label does not establish that it would have prohibited such a change." *Id.* at 573.

The same is true here. Defendants note that an NDA holder may only utilize the CBE supplement process when "newly acquired information" becomes available which would support the change sought to be made. (Doc. # 45 at p. 19 (citing *In re: Celexa and Lexapro Marketing and Sales Practices Litigation*, 779 F.3d 34, 37 (1st Cir. 2015); 21 C.F.R. § 314.70(c)(6)). However, in his Amended Complaint, Plaintiff has alleged the existence of "newly acquired information."

> Newly acquired information is data, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3. In *Wyeth*, the Court rejected a "cramped reading of the CBE regulation" and noted that "newly acquired information" is not limited to new data, but includes new analyses of previously submitted data. *Wyeth*, 555 U.S. at 569, 570.

Here, Plaintiff has plausibly pled the existence of "newly acquired information" which could warrant the use of the CBE supplementation process. Plaintiff's Amended Complaint extensively pleads the existence of (1) recently reported information regarding potential adverse health effects of LIALDA, and (2) recommendations of specific testing regimens similar to the one described in Plaintiff's Amended Complaint. (*See* Doc. # 41 at ¶¶ 29-35, 74-78, 79-82, 83-88, 89-96, 97-115, 120). While Plaintiff notes that evidence of the renal toxicity of LIALDA and his proposed testing regimen existed prior to LIALDA's FDA approval, he alleges that the post-2007 literature and adverse event reports (AERs) (*Id.* at ¶¶ 83-88, 97-115) constitute "newly acquired information" which would have permitted Defendants to change LIALDA's label to recommend his proposed testing regimen. And indeed, at least one article has been published between the initial approval of LIALDA and November 2013 (when Plaintiff was prescribed LIALDA) which specifically proposed the testing regimen which Plaintiff alleges should have been added to LIALDA's label. (*Id.* at ¶ 86). Moreover, approximately fifty additional articles addressing the renal toxicity of mesalamine (the active ingredient in LIADLA) have been published after LIALDA's initial approval and prior to November 2013. (*Id.* at ¶ 88).

And, since LIALDA's initial approval, more than one thousand AERs have been compiled relating to individuals who took LIALDA and later reported a renal disorder. (*Id.* at ¶

109). Plaintiff's allegations regarding this expanding body of information detailing LIALDA's potential to adversely affect users' kidneys, coupled with his allegations about additional research suggesting the benefits of a testing regimen consistent with the one Plaintiff proposes, plausibly plead the existence of evidence which could qualify as "newly acquired information" for FDCA purposes.

That evidence of LIALDA's potential renal toxicity existed prior to its approval in 2007 does not alter this conclusion.[3] Plaintiff readily pleads that evidence of LIALDA's renal toxicity, as well as his proposed testing regimen, existed prior to LIALDA's approval. (Doc. # 41 at ¶¶ 59-78). He also pleads, however, that the growing body of evidence relating to LIALDA's potential renal toxicity and his proposed testing regimen constitutes newly acquired information sufficient to support use of the CBE process. (Doc. # 41 at ¶ 139). Newly acquired information is not limited to data which is submitted to (or available to) the FDA for the first time – it also includes new analyses of previously existing data. 21 C.F.R. § 314.3; *Wyeth*, 555 U.S. at 569, 570. Indeed, such evidence can have a cumulative effect, and the continued increase of AERS and/or medical literature can constitute "newly acquired information." *See Newman v. McNeil Consumer Healthcare*, 2012 WL 39793, at *10 (N.D. Ill. Jan. 9, 2012) (finding that AERs reported after 2005 could constitute new information that might change the FDA's analysis, where the FDA had considered the existence of AERs prior to 2005 and rejected their significance). Such is the case here. While evidence of LIALDA's possible renal toxicity and Plaintiff's proposed testing regimen certainly existed prior to LIALDA's approval, Plaintiff has

[3] In addition to the specific articles Plaintiff specifically mentions in his Amended Complaint, he has attached a list of medical articles relating to the nephrotoxicity of mesalamine as an exhibit to his complaint. (Doc. # 41-5). The court may consider this exhibit in ruling on Defendants' motion to dismiss. *Page v. Postmaster Gen. and Chief Exec. Officer of the U.S. Postal Serv.*, 493 Fed. Appx. 994, 995 (11th Cir. 2012). ("[E]xhibits attached to the complaint are treated as part of the complaint for Rule 12(b)(6) purposes" and may be considered without converting a motion to dismiss into a motion for summary judgment). Many of the articles included in this list were published prior to LIALDA's approval in 2007.

plausibly pled facts which would show that evidence supporting his proposed testing regimen increased following the FDA's approval of LIALDA. Assuming the facts pled in Plaintiff's amended complaint to be true, as the court must under these circumstances, this expansion of research and evidence regarding the need for, and efficacy of, Plaintiff's proposed testing regimen allegations plausibly indicates the existence of newly acquired information which was available and counseled in favor of a change to the renal testing recommendation included on LIALDA's label.

Because of this newly acquired information, Plaintiff has properly alleged that Defendants were unilaterally able to change their label pursuant to the CBE supplementation process. Accordingly, there can be no impossibility preemption here "[a]bsent clear evidence that the FDA would not have approved a change." *Wyeth*, 555 U.S. at 571.

1. At This Stage, Defendants Have Not Shown "Clear Evidence" That The FDA Would Not Have Approved Plaintiff's Proposed Change

Defendants argue that even if they could have made changes to LIALDA's label pursuant to the CBE process (which they do not concede was possible), the FDA still would not have approved of Plaintiff's proposed label change. (Doc. # 45 at p. 15). Specifically, Defendants argue that the label change which Plaintiff proposes would require Defendants to change not only the "Full Prescribing Information" section of LIALDA's label, but also the "Highlights" section of the drug label.

The "clear evidence" standard is a difficult one to meet at the pleadings stage. Here, Defendants must show, on the Plaintiff's pleadings alone, that the FDA would not have approved the change which Plaintiff has suggested. *Wyeth*, 555 U.S. at 571. However, as is the case here, plaintiffs rarely plead the existence of facts which would undermine their case in that fashion. With the benefit of Rule 56 evidence, courts have found preemption based on "clear evidence"

provided by a defendant. *See Dobbs v. Wyeth Pharmaceuticals*, 797 F. Supp. 2d 1264 (W.D. Okla. 2011) (finding preemption of a plaintiff's failure to warn claim where the defendant provided undisputed evidence that the express type of warning the plaintiff claimed the manufacturer should have included had been previously considered and rejected by the FDA). However, while such evidence may exist in this case, it is not before the court on Defendants' present motion. Accordingly, Defendants argue here that the FDA regulations themselves, read in conjunction with the facts in Plaintiff's Amended Complaint, demonstrate that the FDA would not have approved Plaintiff's proposed label change.

As discussed above, the CBE regulation allows a drug manufacturer to change its label upon filing its supplemental application with the FDA; it need not wait for FDA approval. 21 C.F.R. § 314.70(c)(6); *Wyeth v. Levine*, 555 U.S. at 568. However, in almost all instances, any change to the Highlights section of an approved drug's label requires FDA approval. *See* 21 C.F.R. § 314.70(b)(2)(v)(C) (categorizing any change to the information required by § 201.57(a) -- the section detailing the specific requirements of the Highlights section -- as a "major change" which requires FDA approval before it can be made). Again, in circumstances such as these, a private party's claim is only preempted if the drug manufacturer was not able to act independently under federal law to do what state law requires. That is, preemption exists "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance." *PLIVA, Inc.*, 564 U.S. at 623-24. Such assistance "is dependent on the exercise of judgment by a federal agency," and as such "that party cannot independently satisfy those state duties for preemption purposes." *Id.* at 624. Accordingly, when sufficient newly acquired information exists in order to support a label change under the CBE process, as has been plausibly pled here, the claim is not preempted.

However, the same cannot be said with respect to Plaintiff's assertion that a change to the Highlights section would be permitted here. Where a private party seeks a label change which requires FDA approval, such as a change to the Highlights section, impossibility preemption exists. Plaintiff argues that even if his proposed change necessitated a change to the Highlights section, it would still not risk conflict preemption. (Doc. # 51 at p. 21). He argues that such a change would not be "impossible," because Defendants could have sought expedited FDA approval of the Highlights section change or asked the FDA to waive such an approval requirement by submitting a written waiver request to the FDA. (*Id.*). The court disagrees. This is precisely the sort of argument that the *PLIVA, Inc.* court rejected. *PLIVA, Inc.*, 564 U.S. at 623-24. The "impossibility" inquiry turns on a private party's ability to act independently. It is of no consequence that the FDA may have allowed a change to the Highlights section of LIALDA. Because Defendants could not have independently changed the Highlights section of LIALDA in order to conform to state law, any argument that begins with the theory that Defendants could (or should) have changed the Highlights section of LIALDA's label ends in preemption.

The balance of Plaintiff's claims are premised on the contention that LIALDA's label should recommend a specific kidney testing regimen, rather than recommend only "periodic" testing. And LIALDA's recommendation of "periodic" testing occurs both in the Full Prescribing Information and Highlights section of its label. The Highlights section of LIALDA's label notes: "[r]enal impairment may occur. Assess renal function at the beginning of treatment and *periodically during treatment*." (Doc. # 41-2 at p. 2) (emphasis added). The label then refers the reader to Section 5.1 of the Full Prescribing Information ("FPI") under "Warnings and Precautions," which includes a more detailed warning and again recommends testing of renal

function "periodically." (*Id.* at p. 2, 3). To the extent that Plaintiff's Amended Complaint seeks relief for an alleged defect in the FPI warning, there is no preemption at this stage of litigation, because Plaintiff has plausibly pled that Defendants could have utilized the CBE process.

However, LIALDA's label also recommends "periodic" testing in its Highlights section. (Doc. # 45 at p. 21). Because Plaintiff alleges that this recommendation is deficient under state law, Defendants contend that Plaintiff's Amended Complaint seeks relief which requires a change to the Highlights section of LIALDA's label, and as such is preempted pursuant to FDA regulations. (*Id.*). Plaintiff's retort, while perhaps tenuous, is sufficient at this stage to overcome Defendants' motion to dismiss. Plaintiff argues that the language in the Highlights section of a drug's label is not required to mirror the language found in the FPI section of that label. (Doc. # 51 at p. 19).[4] Accordingly, he argues that had Defendants changed the LIALDA Label in the "below the line" Prescribing Information to define 'periodically' to include his proposed testing regimen, no 'major change' to the Highlights section would have been required." (Doc. # 51 at p. 20). Essentially, he contends that if the term "periodically" were changed in the FPI section to reflect his proposed testing regimen, it would be no more than "a mere clarification or fleshing out of the term 'periodically,'" and would not require a change of the term "periodically" in the Highlights section of LIALDA's label. (*Id.* at n. 29). As such, his amended complaint alleges that Defendants could have changed the recommendation for "periodic" testing in the FPI section of LIALDA's label, but left recommendation for "periodic" testing in the Highlights section.

To be sure, this theory may place Plaintiff on shaky ground going forward. On the one hand, Plaintiff alleges that LIALDA's recommendation that users undergo "periodic" renal

[4] For support of his position, Plaintiff notes that certain required language included in every Highlights section -- "[t]hese highlights do not include all the information needed to use [LIALDA] safely and effectively" -- effectively demonstrates that changes made to the FPI section of a drug label need not always be reflected in the Highlights section as well. (Doc. # 51 at pp. 19-20 (citing 21 C.F.R. § 201.57(a)(1)).

testing was deficient to the point of violating state law. But on the other, he contends that his proposed recommended renal testing is no more than a clarification of the term "periodic" referenced in LIALDA's Highlights section. Defendants argue that this is an inconsistency which bars his claim on either state law or preemption grounds. (Doc. # 52 at p. 6, n.4). However, Plaintiff has plausibly, if just barely, pled a set of circumstances which survives both the state law and preemption hurdles raised in Defendants' motion to dismiss. Plaintiff's Amended Complaint specifically quotes from the FPI section of LIALDA's label (as opposed to the Highlights section), and states that the term "periodic" is defective because it typically connotes semi-annual or annual testing. (Doc. # 41 at ¶¶ 17-18, 22-23). And when detailing the factual basis for his AEMLD claim, Plaintiff again referenced only the language contained in the FPI section warning, and did not plead that the warning in the Highlights section was also defective. (*Id.* at ¶¶ 157-58). Plaintiff's AEMLD claim, then, is one brought on the basis of an alleged half-truth. Plaintiff does not allege that Defendants failed to warn of LIALDA's possible renal toxicity, or failed to recommend a renal testing regimen for LIALDA users. Rather, Plaintiff bases his AEMLD claim on the contention that the renal testing recommendation contained in the FPI section of LIALDA's label is inadequate. This allegation, at the motion to dismiss stage, is sufficient to satisfy Plaintiff's pleading requirements on both state law and preemption grounds.

B. The Learned Intermediary Doctrine Does Not Bar Plaintiff's Claims

Defendants next argue that Plaintiff's claims are barred by the learned intermediary doctrine. (Doc. # 45 at p. 24). "Alabama's learned intermediary doctrine imposes on a prescription drug company a duty to provide warnings *solely* to the prescribing physician rather than to the patient directly." *Allain*, 2015 WL3948961, at *8 (citing *Stone v. Smith, Kline &*

French Labs., 447 So. 2d 1301, 1304 (Ala. 1984)) (additional citations omitted). The Alabama Supreme Court has stated that:

> [t]he principle behind the learned-intermediary doctrine is that prescribing physicians act as learned intermediaries between a manufacturer of a drug and the consumer/patient and that, therefore, the physician stands in the best position to evaluate a patient's needs and to assess the risks and benefits of a particular course of treatment for the patient.

Wyeth, Inc. v. Weeks, 159 So. 3d 649, 672-73 (Ala. 2014). This doctrine exists because consumers can obtain prescription drugs only through a physician or other qualified healthcare provider, and physicians are trained to understand the highly technical warnings required by the FDA in drug labeling. *Id.* at 673 (citing 21 U.S.C. § 353(b)(1); 21 C.F.R. § 201.56). The doctrine "recognizes the role of the physician as a learned intermediary between a drug manufacturer and a patient." *Id.*

"Under the learned intermediary doctrine the adequacy of [Defendant's] warning is measured by its effect on the physician, to whom it owe[s] a duty to warn, and not by its effect on the consumer." *Weeks*, 159 So. 3d at 673 (quoting *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313-14 (11th Cir. 2000)) (citations, quotations and changes omitted). "A prescription-drug manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug. Once that duty is fulfilled, the manufacturer has no further duty to warn the patient directly." *Id.* To be sure, "[h]owever, if the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient." *Id.* But, for this to be the case, a patient must make a specific showing: "that the manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury." *Id.* at 673-74.

Defendants argue that Plaintiff has not plausibly alleged facts indicating that Defendants failed to adequately warn his physician, Dr. Ferrante, of the dangers of LIALDA. Specifically, Defendants contend that Plaintiff has failed to properly plead any plausible facts that show: (1) Defendants failed to adequately warn Dr. Ferrante of the dangers of LIALDA; (2) Dr. Ferrante did not understand or appreciate LIALDA's warning; (3) Defendants failed to warn Dr. Ferrante of a risk "not otherwise known" to him; and (4) the alleged defect in LIALDA's label was the actual and proximate cause of his injury. The court disagrees.

Plaintiff's Amended Complaint pleads a number of facts which, taken as true, plausibly make out an AEMLD claim which survives Defendants' "learned intermediary" defense. Plaintiff pled that the term "periodic," as used in Defendants' LIALDA label, is generally used in drug labels to mean either semi-annual or annual testing. (Doc. # 41 at ¶ 22). Moreover, he pled that many physicians interpret and understand recommendations for "periodic" testing to mean testing at the patient's next physical examination, which could be a year or more after initiation of LIALDA's therapy. (*Id.* at ¶ 23). Plaintiff alleges that Dr. Ferrante is a gastroenterologist, and that the mesalamine-related medical literature and AERs which may have alerted him to Plaintiff's proposed testing regimen actually related to the field of nephrology, one with which he has no special knowledge. (*Id.* at ¶¶ 56-58).

Plaintiff has specifically pled that LIALDA's warning was inadequate, and that Dr. Ferrante reasonably relied on LIALDA's defective warning. (*Id.* at ¶¶ 155-60, 169). And, he has pled specific facts which bypass the learned intermediary doctrine. Plaintiff's Amended Complaint pleads that professionals such as Dr. Ferrante commonly assign a meaning to "periodic" which is different than the testing regimen he asserts is efficacious. (*Id.* at ¶¶ 22-23). As such, Plaintiff has plausibly pled that Defendants failed to adequately warn Dr. Ferrante, and

that Dr. Ferrante did not fully appreciate LIALDA's warning. Moreover, by distinguishing the fields of gastroenterology and nephrology, Plaintiff has, at least at this stage, plausibly pled that LIALDA's label, which did not include specific details regarding the implementation of a testing regimen in its recommendation, failed to warn Dr. Ferrante of a risk not otherwise known to him.

Defendants' contention that Plaintiff's claims fail for lack of proximate cause is similarly off the mark. Defendants argue that Plaintiff has not alleged that a different warning would have altered Dr. Ferrante's decision to prescribe LIALDA to Plaintiff, and as such, Plaintiff has not pled that LIALDA's allegedly defective label caused his injury. (Doc. # 45 at p. 27). This is a typical way of assessing the proximate cause inquiry. *Weeks*, 159 So. 3d at 673-74. However, it is not the only way. Indeed, proof of proximate cause could take the form of evidence that, although the physician still would have prescribed the drug, the physician would have changed her behavior or treatment in some way that would have resulted in a different outcome for the plaintiff. *Barnhill v. Teva Pharm, USA, Inc.*, 819 F. Supp. 2d 1254, 1261 (S.D. Ala. 2011); *Fields v. Eli Lilly & Co.*, 116 F. Supp. 3d 1295, 1307 (M.D. Ala. 2015). Here, Plaintiff has not alleged that Dr. Ferrante would not have prescribed him LIALDA if the drug's label had been adequate. Instead, Plaintiff acknowledges that LIALDA's label warns of the risk of kidney damage, but contends that an adequate label would have recommended a specific method by which LIALDA users should test to determine whether they had developed kidney damage. (Doc. # 45 at ¶ 167). Here, Plaintiff has plausibly pled the existence of proximate cause. He has pled sufficient facts which purport to establish that if LIALDA's label were adequate, Dr. Ferrante would have recommended a specific renal testing regimen, which Plaintiff would have followed, which, in turn, would have detected potential impairment of his kidney function in the early stages of its development. (Doc. # 41 at ¶¶ 161-165). Accordingly, because Count One

(AEMLD) of Plaintiff's Amended Complaint is neither preempted by federal law nor barred by the learned intermediary doctrine, Defendants' motion to dismiss is due to be denied to the extent that it seeks dismissal of that count.

C. Plaintiff's Breach of Express Warranty Claim is Due to be Dismissed

In Count Four of his Amended Complaint, Plaintiff advances a claim for breach of express warranty. (Doc. # 41 at ¶ 210). Plaintiff alleges that LIALDA's label "constituted a warranty that compliance with [its recommended testing] would make use of the LIALDA product safe." (*Id.* at ¶ 215). However, he contends that LIALDA failed to conform to this express warranty because use of LIALDA in conformity with its warning label (which recommends only "periodic" testing) was unsafe. (*Id.* at ¶ 216). Defendants counter this assertion in their motion to dismiss, and argue that the language in the LIALDA label cannot be construed to represent an "express warranty of safeness," and as such Count Four of Plaintiff's amended complaint is due to be dismissed. (Doc. # 45 at p. 28). The court agrees.

In Alabama, "[a]ny description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description." Ala. Code §7-2-313(1)(b); *see also* Ala. Code §7-2-313(2) (noting that it is not necessary that the seller use formal words such as "warrant" or "guarantee" in order to create an express warranty). However, LIALDA's label simply does not embody any form of express warranty which Defendants have breached. LIALDA's label at the time it was prescribed to Plaintiff (which is attached to Plaintiff's amended complaint) lists a host of warnings and potential adverse consequences associated with the drug. (*See* Doc. # 41-2 at p. 2 (noting the potential that LIALDA users may experience mesalamine-induced acute intolerance syndrome, masalamine-induced cardiac hypersensitivity, hepatic failure, and GI tract obstruction, among other

potentially adverse reactions)). LIALDA's label specifically notes that the drug may cause renal impairment in both the Highlights section and FPI section of its label. (*Id.* at pp. 2, 3).

Even to the extent that LIALDA's label can be construed as a "description of goods" which creates an express warranty, that description cannot to be construed as an express warranty of safeness. To the contrary, LIALDA's label represents that it is intended to be used to treat ulcerative colitis, and that its use may cause a number of side effects, including renal impairment or failure. Plaintiff has failed to plead any breach of this purported warranty. Instead, Plaintiff's amended complaint pleads that he was prescribed LIALDA, he developed certain kidney ailments (of which LIALDA's label warned), and if LIALDA had utilized a different label his kidney ailments would have been discovered sooner. As addressed above, this set of facts plausibly pleads a failure to warn claim under the AEMLD. But, it does not plausibly plead a claim for a breach of express warranty. Accordingly, Defendants' motion to dismiss is due to be granted as to Count Four of Plaintiff's Amended Complaint, and that count is due to be dismissed.

D. Plaintiff's Fraud-Based Claims are Due to be Dismissed

Plaintiff asserts two fraud-based claims in his amended complaint: Count Two, a claim for fraud, and Count Three, a claim for suppression and concealment. In support of his fraud claim, Plaintiff asserts that "[t]he instructions for use in LIALDA's Label constituted a representation to physicians (and patients) that LIALDA therapy would be safe based upon Recommended Periodic Evaluation." (Doc. # 41 at ¶ 175). However, Plaintiff contends that this representation -- specifically, the "Warnings and Precautions" provision in Section 5.1 of LIALDA's label -- was false. (*Id.* at ¶ 176). Similarly, in support of his suppression and concealment claim, Plaintiff pleads that LIALDA's label failed to disclose the existence of his

proposed testing regimen, and instead only offered the "half-truth" that LIALDA users should undergo "periodic" testing of their kidneys while using the drug. (*Id.* at 199-201).

In order to proceed on his fraud claim Plaintiff must plausibly plead (1) a false representation (2) of a material existing fact (3) relied upon by the plaintiff (4) who was damaged as a proximate result of the misrepresentation. *Coastal Concrete Co. v. Patterson*, 503 So. 2d 824, 826 (Ala. 1987). And to proceed on his fraudulent suppression Plaintiff must plausibly plead the existence of the following elements: "(1) a duty on the part of the defendant to disclose facts; (2) concealment or nondisclosure of material facts by the defendant; (3) inducement of the plaintiff to act; (4) action by the plaintiff to his or her injury." *Lambert v. Mail Handlers Ben. Plan*, 682 So. 2d 61, 63 (Ala. 1996).

Both of Plaintiff's fraud-based claims fail for the same reason – Plaintiff has failed to plead the existence of a *material fact* to support his fraud claims. In order for Plaintiff's fraud and fraudulent suppression claims to proceed, he must plausibly allege that Defendants misrepresented a material fact and concealed a material fact. But Plaintiff's amended complaint alleges only deficiencies with the *recommendation* provided in LIALDA's label. Indeed, if Plaintiff alleged that Defendants misrepresented (or concealed) the existence of certain adverse events or potential side effects of LIALDA, the present analysis would be different. *See Brasher v. Sandoz Pharm. Corp.*, 2001 WL 36403362, at *11 (N.D. Ala. Sept. 21, 2001) (finding that a reasonable juror could have concluded that, in reporting 15 incidents of stroke in their package insert, Defendant fraudulently concealed the other 17 strokes that it knew occurred). These are facts which, when misrepresented or concealed, could form the basis of a fraud claim. Similarly, Plaintiff may have pled viable fraud-based claims had he alleged that Defendants made a "sales pitch" or other representation regarding the safety of its recommended "periodic" renal testing

regimen.[5] *See Brasher*, 2001 WL 36403362, at *10. This type of allegation also could potentially support a fraud claim.

But here, Plaintiff's fraud claims attack only the adequacy of LIALDA's recommendation that its users have their renal function assessed "periodically." And while this allegation does serve as a plausibly pled basis for a failure to warn AEMLD claim, it does not form the basis of a fraud claim. LIALDA's label recommends a certain course of treatment, and Plaintiff has argued that a more detailed "clarification" of that course of treatment should have been used. (Doc. # 51 at p. 20, n. 29). This allegation fails to plead the existence of a material fact which Defendants misrepresented or concealed. Accordingly, to the extent Defendants' motion seeks dismissal of Counts Two and Three of Plaintiff's amended complaint, it is due to be granted, and those counts are due to be dismissed.

V. Conclusion

For the reasons stated above, Defendants' Motion to Dismiss is due to be granted in part and denied in part. A separate order will be entered in accordance with this opinion.

DONE and **ORDERED** this May 8, 2017.

R. DAVID PROCTOR
UNITED STATES DISTRICT JUDGE

[5] While the court assumes the veracity of the facts contained within Plaintiff's amended complaint, the court is not required to afford "conclusions" or "naked assertion[s]" a presumption of truth when evaluating Defendants' motion to dismiss. *Twombly*, 550 U.S. at 555, 557. Here, Plaintiffs' assertion that LIALDA's label constituted a representation that LIALDA therapy would be safe is just such a conclusion. Moreover, it is a conclusion not supported by the facts in Plaintiff's amended complaint. Plaintiff attached LIALDA's 2013 label to his amended complaint. And, as addressed above, LIALDA's label addresses in detail a wide array of potential side effects that LIALDA users may endure and does not state that a LIALDA user would be free from injury if that user followed the label's recommended testing regimen.