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 Plaintiff's Motion to Reinstate Shire Development LLC as a Party Defendant (Doc. # 79) and Plaintiff's Motion for Reconsideration (Doc. # 91). Both the Motion to Reinstate (Docs. # 79, 81, 82) and the Motion for Reconsideration (Docs. # 91, 94, 96) are fully briefed. For the reasons stated below, the Motion to Reinstate (Doc. # 79) is due to be denied, and the Motion for Reconsideration (Doc. # 91) is due to be denied.

II. Background

Defendants Shire US Inc. and Shire LLC 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). On June 10, 2016, Plaintiff filed a complaint against Shire US Inc., Shire LLC, Shire Development LLC, Shire Pharmaceutical Development, Inc., and Shire Pharmaceuticals LLC. (Doc. # 1).

On October 5, 2016, Defendants moved to dismiss Plaintiff's claims. (Docs. # 26, 27). Plaintiff filed an opposed motion to amend his complaint on October 24, 2016. (Doc. # 36).

After the court ordered Defendants to file a brief in support of its opposition to Plaintiff's motion to amend (Docs. # 37-38), the court granted Plaintiff leave to amend on November 1, 2016. (Doc. # 40). On November 2, 2016, Plaintiff filed a First Amended Complaint. (Doc. # 41). In that amended pleading, Plaintiff asserted that Defendants' recommendation of only "periodic" renal testing while using Lialda, as opposed to the more specific testing regimen detailed in his First Amended Complaint, proximately caused his kidney injury. (*Id.* # 41 at ¶ 26). Specifically, Plaintiff asserted claims for failure to warn under the Alabama Extended Manufacturers Liability Doctrine ("AEMLD") (Count One), fraud (Count Two), suppression and concealment (Count Three), and breach of express warranty (Count Four). (Doc. # 41).

On November 16, 2016, Defendants moved to dismiss Plaintiff's First Amended Complaint. (Docs. # 44, 45). On May 8, 2017, the court dismissed Counts Two, Three, and Four with prejudice and denied Defendants' motion to dismiss Count One without prejudice. (Docs. # 53, 54). After granting Defendants' motion to dismiss for lack of personal jurisdiction on May 12, 2017, the court dismissed Defendants Shire Development LLC, Shire Pharmaceutical Development, Inc., and Shire Pharmaceuticals LLC without prejudice. (Doc. # 56). On June 29, 2017, Plaintiff filed a Motion to Alter or Amend Order and Motion to Amend Complaint (Doc. # 64), which the court denied. (Docs. # 85, 86).

Plaintiff's Motion to Reinstate Shire Development LLC as a Party Defendant (Doc. # 79) and Plaintiff's Motion for Reconsideration (Doc. # 91) are currently pending before the court. In the Motion to Reinstate, Plaintiff argues that the court should grant him leave to amend his complaint to add Shire Development LLC as a defendant in this case because Shire Development LLC is the holder of the New Drug Application ("NDA") for Lialda. (Doc. # 79). In the Motion for Reconsideration, Plaintiff asks the court to reconsider its denial (Docs. # 85, 86) of his

Motion to Alter or Amend Order (Doc. # 64) and to allow Plaintiff to file a Second Amended Complaint. (Doc. # 91). During an on-the-record conference held on November 16, 2017, the court asked the parties to brief Plaintiff's Motion for Reconsideration so that the court, at Plaintiff's request, could take a fresh look at Plaintiff's proposed Second Amended Complaint (Doc. # 64-1). (Doc. # 94-1 at p. 30). The court explores the merits of both pending motions, which are essentially motions to amend, in turn.

III. Standard of Review

Rule 15 of the Federal Rules of Civil Procedure governs amended and supplemental pleadings. Absent circumstances not relevant here, a party may amend the pleadings only by leave of the court or by written consent of the adverse party. *See* Fed R. Civ P. 15(a)(2). "The court should freely give leave when justice so requires." *Id*. "Ordinarily, a party must be given at least one opportunity to amend before the district court dismisses the complaint." *See Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005). That is, "[u]nless a substantial reason exists to deny leave to amend, the discretion of the District Court is not broad enough to permit denial." *Fla. Evergreen Foliage v. E.I. DuPont De Nemours and Co.*, 470 F.3d 1036, 1041 (11th Cir. 2006) (quotation marks omitted).

The court, however, need not allow an amendment that would be futile. *See Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001). An amendment is futile when "the complaint as amended is still subject to dismissal." *Hall v. United Insurance Co.*, 367 F.3d 1255, 1263 (11th Cir. 2004) (citing *Burger King Corp. v. Weaver*, 169 F.3d 1310, 1320 (11th Cir. 1999)). A court also need not allow an amendment where there has been undue delay, bad faith, dilatory motive, or repeated failure to cure deficiencies by amendments previously allowed or where allowing the amendment would cause undue prejudice to the opposing party. *See Halpin v. Crist*, 405 Fed.

App'x 403, 408-09 (11th Cir. 2010) (quoting *Corsello*, 428 F.3d at 1014); *see also Maynard v. Bd. of Regents of Div. of Univs.*, 342 F.3d 1281, 1287 (11th Cir. 2003) (holding that the district court did not abuse its discretion in denying a motion to amend filed on the last day of discovery because granting the motion "would have produced more attempts at discovery, delayed disposition of the case, likely prejudice . . . [and] there seems to be no good reason why [the movant] could not have made the motion earlier"). A district court may, in the exercise of its inherent power to manage the conduct of litigation before it, deny leave to amend a complaint, "so long as it does not outright refuse to grant the leave without any justifying reason." *Equal Rights Center v. Niles Bolton Assocs.*, 602 F.3d 597, 603 (4th Cir. 2010); *see also Reese v. Herbert*, 527 F.3d 1253, 1263 (11th Cir. 2008).

IV. Analysis

As explained below, because all of Plaintiff's proposed amendments would be futile, both motions are due to be denied. *See Bryant*, 252 F.3d at 1163.

A. Motion for Reconsideration

As an initial matter, and as more fully detailed in the court's prior Memorandum Opinion (Doc. # 85) denying Plaintiff's Motion to Alter or Amend Order (Doc. # 64), a plaintiff represented by counsel is not entitled to the opportunity to amend his complaint without leave of court or agreement of opposing counsel when the plaintiff has already previously amended his complaint. *See Eiber Radiology, Inc. v. Toshiba Am. Med. Sys., Inc.*, 673 F. App'x 925, 930 (11th Cir. 2016) ("[The Eleventh Circuit has] never required district courts to grant counseled plaintiffs more than one opportunity to amend a deficient complaint, nor have we concluded that dismissal with prejudice is inappropriate where a counseled plaintiff has failed to cure a deficient pleading after having been offered ample opportunity to do so."); *see also Henley v. Turner*

Broad. Sys., Inc., 267 F. Supp. 3d 1341, 1364 (N.D. Ga. 2017) ("The Court also concludes it is unnecessary to allow Plaintiffs, who are represented by counsel, the opportunity to file a further amended complaint."). Although the court explained to Plaintiff's counsel why his proposed Second Amended Complaint was futile, the court permitted the parties to brief Plaintiff's Motion for Reconsideration. (*See* Doc. # 94-1). The court now (and, once again) explains why Plaintiff's proposed Second Amended Complaint does not cure the deficiencies the court recognized in its previous Memorandum Opinion (Doc. # 53) dismissing Plaintiff's breach of express warranty and fraud-based claims.

1. The Proposed Second Amended Complaint Does Not Cure Plaintiff's Breach of Express Warranty Claim

Plaintiff claims that his Second Amended Complaint properly states a breach of express warranty claim. (Doc. # 96 at p. 8). The proposed Second Amended Complaint points to § 5.1 of the Warnings and Precautions in the 2013 Label and contends that this section provides instructions for safe use that form the basis of the bargain. (Docs. # 64-1 at ¶¶ 268-79; 96 at p. 9). Defendants counter that the additional language in the proposed Second Amended Complaint referencing § 5.1 of the 2013 Label do not alter Plaintiff's breach of express warranty allegation contained in his First Amended Complaint. (Doc. # 94 at p. 22-23). The court agrees with Defendants. The court has already examined the 2013 Label in the context of a breach of express warranty claim and found that the 2013 Label "cannot to be construed as an express warranty of safeness." (Doc. # 53 at p. 17-18). The court further noted that, to the extent that the Lialda Label could be construed as a description of goods, its "description" is contrary to an express warranty for safeness because it expressly states that its use may cause a number of side effects. (*Id.* at p. 18). Plaintiff's additional language in the proposed Second Amended Complaint highlighting § 5.1 of the 2013 Label does not change this conclusion. Rather, the

proposed amendment simply highlights language that the court has already considered. (*Compare* Doc. # 64-1 at ¶¶ 268-79 *with* Doc. # 53 at p. 17-18). As such, Plaintiff's proposed amended breach of express warranty claim does not cure the deficiencies noted in the court's Memorandum Opinion (Doc. # 53 at p. 17-18) and is futile. *See Hall*, 367 F.3d at 1263.

2. The Proposed Second Amended Complaint Does Not Cure Plaintiff's Fraud-Based Claims

The court previously dismissed Plaintiff's fraud-based claims in his First Amended Complaint because these claims "failed to plead the existence of a *material fact* to support [those] claims." (Doc. # 53 at p. 19) (emphasis in original). The court also noted that if Plaintiff had alleged that Defendants (1) "misrepresented (or concealed) the existence of certain adverse events or potential side effects of LIALDA" or (2) "made a 'sales pitch' or other representation regarding the safety of its recommended 'periodic' renal testing regimen.," then the court's analysis of these fraud-based claims may be different. (*Id.* at p. 19-20). But Plaintiff has not sufficiently made either of these allegations in his proposed Second Amended Complaint. Rather, Plaintiff argues that his proposed Second Amended Complaint cures the deficiencies of his fraud-based claims from his First Amended Complaint because it "explain[s] in detail why § 5.1 of the 2013 Label is a legally mandated statement of instructions for safe use and a material misrepresentation regarding safe use." (Doc. # 65 at p. 10) (citing Doc. # 64-1 at ¶¶ 188-205).

A fraud claim must comply with Federal Rule of Civil Procedure 9(b). Rule 9(b) requires that a party alleging fraud to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Under Rule 9(b), "a plaintiff must allege: '(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the statement; (3) the content and manner in which these statements misled the Plaintiffs; and (4) what the defendants gained by the alleged fraud.'" *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1291 (11th Cir.

2010) (quoting *Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1380-81 (11th Cir. 1997)). Of course, the heightened pleading requirements of Rule 9(b) must also satisfy the plausibility mandate set forth in *Twombly* and *Iqbal*. Plaintiff has failed to satisfy either requirement—in both his First Amended Complaint and Second Amended Complaint.

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). To proceed on his fraudulent suppression claim, 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). "In Alabama, a drug manufacturer 'may be held liable for fraud or misrepresentation (by misstatement or omission)' based on 'information and warning deficiencies' on a drug's labelling." *Houston v. Bayer Healthcare Pharm., Inc.*, 16 F. Supp. 3d 1341, 1350 (N.D. Ala. 2014) (quoting *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676 (Ala. 2014)). More specifically, a plaintiff "can base her fraud and misrepresentation claims on the defendant manufacturer's breach of its 'duty to warn . . . *about the risks associated with the long-term use of the drug' in its labeling*." *Id.* (quoting *Weeks*, 159 So. 3d at 655-56).

In this case, Plaintiff's First Amended Complaint and Second Amended Complaint simply do not allege that Defendants failed to warn *about the risks* associated with the long-term use of Lialda in its labeling. (*See* Docs. # 41, 64-1). Indeed, there is no question that Lialda's labels warned that a consumer may develop kidney damage from use of the product (as Plaintiff did). (Docs. # 41 at ¶ 18; 64-1 at ¶ 15). Rather than asserting that Defendants failed to warn

about the risks associated with the use of Lialda, both complaints allege that the recommended "periodic" evaluation failed to provide information regarding the safe use of Lialda, including proper testing. (*See* Docs. # 41 at ¶ 22, 175, 183; 64-1 at ¶ 182). Ultimately, Plaintiff is attempting to transform Lialda's warning into a safety warranty in order to support its fraud-based claims. And, for the reasons explained in the court's Memorandum Opinion, the warnings contained in § 5.1 of the 2013 Label "cannot to be construed as an express warranty of safeness." (Doc. # 53 at p. 17-18).

The court agrees with Plaintiff that both AEMLD and fraud-based claims against drug manufactures can coexist under Alabama law (even if the substance of the fraud-based claim is essentially a products liability claim). *See Weeks*, 159 So. 3d at 656. However, that rule of law does not mean that a court cannot dismiss fraud-based claims that fail to satisfy the requirements of Rule 9(b) and the plausibility mandate set forth in *Twombly* and *Iqbal*.[1] As this court explained in its previous Memorandum Opinion when analyzing Plaintiff's fraud-based claims:

> 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.

[1] In its Motion to Dismiss, Defendants argued that all of Plaintiff's claims are barred based on preemption and the Learned Intermediary Doctrine. (Doc. # 45 at p. 17-27). Additionally, Defendants specifically challenged elements of Plaintiff's breach of express warranty, fraud, and concealment claims but did not include a similar elements-based challenge for Plaintiff's failure to warn claim. (Doc. # 45 at p. 27-31). Accordingly, the court did not specifically address the sufficiency of Plaintiff's failure to warn claim under *Twombly* and *Iqbal*.

(Doc. # 53 at p. 20 n.5). Plaintiff's proposed Second Amended Complaint continues to base its fraud-based claims on a naked assertion that the Lialda labels represented that Lialda therapy would be safe.[2] (Doc. # 64-1 at ¶ 170, 224). Therefore, the Second Amended Complaint does not cure the First Amended Complaint's deficiencies related to Plaintiff's fraud-based claims and is futile. *See Hall*, 367 F.3d at 1263.

Plaintiff is not entitled to leave to amend his complaint as a matter of right yet another time. *See Wagner v. Daewoo Heavy Indus. Am. Corp.*, 314 F.3d 541, 542-44 (11th Cir. 2002). And, even if the court had dismissed these claims without prejudice (instead of with prejudice) and had granted Plaintiff leave to file his proposed Second Amended Complaint, the proposed amendments would be futile. Accordingly, the Motion for Reconsideration (Doc. # 91) is due to be denied.

B. Motion to Reinstate

Plaintiff contends that the court should grant him leave to amend his complaint to add Shire Development LLC as a defendant in this case because Shire Development LLC is the holder of the NDA for Lialda. (Doc. # 79). Defendants counter that such leave should not be granted because this court does not have personal jurisdiction over Shire Development LLC (Doc. # 81). For the reasons explained below, the court agrees with Defendants.

"A plaintiff seeking the exercise of personal jurisdiction over a nonresident defendant bears the initial burden of alleging in the complaint sufficient facts to make out a prima facie case of jurisdiction." *United Techs. Corp. v. Mazer*, 556 F.3d 1260, 1274 (11th Cir. 2009). In

[2] The court notes that Plaintiff added language in his proposed Second Amended Complaint regarding Defendants' compliance with FDA regulations. (Doc. # 64-1 at ¶¶ 171-79). To the extent that Plaintiff is raising a claim that Defendants violated the FDCA, these claims are precluded by 21 USC § 337(a). *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions . . . .").

determining whether the exercise of personal jurisdiction over a nonresident defendant[3] is appropriate, the court first considers a state's long-arm statute. *See Cable/Home Communication Corp. v. Network Prods., Inc.*, 902 F.2d 829, 855 (11th Cir. 1990); *see also Alexander Proudfoot Co. World Headquarters L.P. v. Thayer*, 877 F.2d 912, 919 (11th Cir. 1989). Alabama's long-arm statute permits personal jurisdiction to the extent it "is not inconsistent with the constitution of this state or the Constitution of the United States." Ala. R. Civ. P. 4.2(b). Because Alabama's long-arm statute allows the exercise of personal jurisdiction to the full extent permissible under the U.S. Constitution, the court next determines whether sufficient minimum contacts exist to satisfy the Due Process Clause of the Fourteenth Amendment so that "maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (quoting *Milliken v. Meyer*, 311 U.S. 457, 463 (1940)); *see also Cable/Home Communication Corp.*, 902 F.2d at 855; *Alexander Proudfoot Co.*, 877 F.2d at 919.

Plaintiff does not argue that this court has general jurisdiction over Shire Development LLC. Accordingly, the court focuses on whether it has specific jurisdiction over Shire Development LLC. As the Supreme Court has explained:

> In order for a state court to exercise specific jurisdiction, the *suit* must arise out of or relate to the defendant's contacts with the *forum*. In other words, there must be an affiliation between the forum and the underlying controversy, principally, an activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation. For this reason, specific jurisdiction is confined to adjudication of issues deriving from, or connected with, the very controversy that establishes jurisdiction.

[3] It is undisputed that Shire Development LLC is incorporated in and has its principal place of business outside of Alabama, does not have any office or facilities in Alabama, and does not have a registered agent for service of process in Alabama. (*See* Doc. # 43-1).

Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty., 137 S. Ct. 1773, 1780 (2017) (emphasis in original) (internal citations, quotations, and brackets omitted). "[A] defendant's placing goods into the stream of commerce 'with the expectation that they will be purchased by consumers within the forum State' may indicate purposeful availment." *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 881-82 (2011) (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 298 (1980)). However, "[t]he defendant's transmission of goods permits the exercise of jurisdiction only where the defendant can be said to have targeted the forum; as a general rule, it is not enough that the defendant might have predicted that its goods will reach the forum State." *Nicastro*, 564 U.S. at 882. In analyzing specific jurisdiction, the court asks whether the defendant purposefully availed "itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws." *Id.*

Plaintiff argues that this court's exercise of specific jurisdiction over Shire Development LLC is appropriate because Shire Development LLC (as the NDA holder for Lialda) placed Lialda into the stream of commerce to reach Alabama consumers, such as himself. (Doc. # 79 at p. 7). Plaintiff does not dispute that Shire Development LLC has not *in actuality* manufactured, sold, or distributed Lialda. Rather, Plaintiff contends that Shire Development LLC, as the NDA holder, should also be considered a "manufacturer" for the purposes of this jurisdictional inquiry. (Doc. # 82 at p. 4). The court is skeptical of these semantics but, in any event, notes that the word used to describe Shire Development LLC is irrelevant to whether Shire Development LLC "targeted" the State of Alabama and has purposeful availment contacts within the State. *Cf. Nicastro*, 564 U.S. at 882.

Plaintiff advances several theories as to how Shire Development LLC targeted the State of Alabama. None of them have merit. First, Plaintiff claims that Shire Development LLC established sufficient minimum contacts with the State "[w]hen [it] sought permission from the FDA to manufacture, market and sell Lialda® in Alabama (and other states)." (Doc. # 82 at p. 8). But, simply seeking permission from the FDA or submitting an NDA does not rise to the level of targeting Alabama or invoking the benefits and protections of its laws (especially when none of these activities occurred within Alabama or were directed at Alabama). *See Nicastro*, 564 U.S. at 882. Second, Plaintiff argues that Shire Development LLC purposefully availed itself to Alabama by crafting a defective label that it knew would be purchased by Alabama residents and failing to enhance this allegedly defective label. (Doc. # 82 at p. 8). This argument also misses the mark as "it is not enough that the defendant might have predicted that its goods will reach the forum State." *Nicastro*, 564 U.S. at 882. Finally, Plaintiff appears to present an alter ego theory of liability, attributing the actions of the Shire entities that actually sold Lialda to Shire Development LLC. (Docs. # 79 at p. 9 n.13; 82 at p. 8). However, Plaintiff has not included any facts in his pleadings or any proposed added allegations in his briefing to support such a theory. Because Plaintiff has not provided the court with any support for the proposition that Shire Development LLC targeted the State or invoked the benefits and protections of its laws, there is no basis for the court to reinstate Shire Development LLC as a defendant in this action. *See Nicastro*, 564 U.S. at 882.

Defendants also argue that an amended complaint adding Shire Development LLC would be futile because Plaintiff cannot state a claim against Shire Development LLC under the AEMLD (the only remaining claim in this case). (Doc. # 81). The court finds it unnecessary to explore this argument because, as discussed above, Shire Development LLC has had no

purposeful availment contacts with the State that support this court's exercise of specific jurisdiction over it in this product liability action. Because reinstating Shire Development LLC would be futile, Plaintiff's Motion to Reinstate (Doc. # 79) is due to be denied.

V. Conclusion

For the reasons stated above, both the Motion to Reinstate (Doc. # 79) and the Motion for Reconsideration (Doc. # 91) are due to be denied. A separate Order will be entered in accordance with this Memorandum Opinion.

DONE and **ORDERED** this May 10, 2018.

R. DAVID PROCTOR
UNITED STATES DISTRICT JUDGE