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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

FRANCES ELLIOTT, as Executor of the Estate of CHARLES EDWARD ELLIOTT, Deceased,	}	
Plaintiff,	}	**Case No.: 2:16-cv-00861-RDP**
v.	}	
SANDOZ, INC.,	}	
Defendant.	}	

MEMORANDUM OPINION

I. Introduction

This case is before the court on Defendant's Motion to Dismiss Plaintiff's Complaint (Doc. # 5), filed July 5, 2016. The Motion is fully briefed. (Docs. # 6, 12, 14). After careful review, and for the reasons stated below, the court concludes that the Motion is due to be granted.

II. Background Facts and Procedural History[1]

Plaintiff filed her complaint on behalf of her deceased husband's estate on May 25, 2016, alleging a wrongful death claim against Defendant based on Defendant's failure to warn, off-label promotion,[2] negligence, and failure to provide Medication Guides to the decedent. (Doc. # 1). Defendant is a New Jersey corporation with its principal place of business in New Jersey.

[1] "A Rule 12(b)(6) motion questions the legal sufficiency of a complaint; therefore, in assessing the merit of a Rule 12(b)(6) motion, the court must assume that all the factual allegations set forth in the complaint are true." *Mays v. United States Postal Service*, 928 F. Supp. 1552, 1557-58 (M.D. Ala. 1996). Thus, for the purpose of resolving Defendant's Motion, the court treats the facts alleged in the Complaint as true.

[2] "Off-label" refers to the use of a drug for a purpose other than its FDA approved use. (Doc. # 1 at ¶ 30).

(Doc. # 1 at ¶ 19). It is involved in the manufacture, distribution, marketing, sale, labeling, and design of amiodarone both in the State of Alabama and throughout the United States. (*Id.*).

Charles E. Elliott ("Decedent"), resided in Vincent, Alabama before his death on June 8, 2015. (Doc. # 1 at ¶ 17). Plaintiff, Decedent's widow and Executor of his Estate, resides in Vincent, Alabama. (*Id.* at ¶ 18). Decedent was diagnosed with atrial fibrillation but the condition was not considered to be life threatening. (*Id.* at ¶ 33). Beginning in March 2015, and continuing through May 2015, Dr. Christopher King (a non-party to this case) prescribed him a course of 200 mg amiodarone hydrochloride ("amiodarone") tablets for treatment of his non-life threatening atrial fibrillation. (*Id.* at ¶ 34). Amiodarone is the generic for Cordarone®, a medication initially produced by the brand manufacturer (and non-party) Wyeth. (*Id.* at ¶ 28). Decedent filled the prescription at (non-party) The Medicine Chest Pharmacy and ingested the drug according to his physician's instructions. (*Id.*). He did not receive a Medication Guide from his pharmacist because, Plaintiff avers, Defendant did not provide them to The Medicine Chest Pharmacy. (*Id.*). Decedent was unaware that his use of the amiodarone was for an off-label use. (*Id.* at ¶¶ 36, 39).

Decedent's prescription for the amiodarone tablets were marked with the numbers 00185-0144-60 which identified the tablets as manufactured, marketed, and distributed by Defendant. (Doc. # 1 at ¶ 35). After taking the amiodarone tablets, Decedent began experiencing the following side-effects (which are the side-effects listed in the Medication Guide): lung damage, shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. (*Id.* at ¶¶ 38, 43). The effects of amiodarone are extremely long lasting, and can continue to affect patients long after they cease to use the drug, and cause serious pulmonary injuries. (*Id.* at ¶ 40). Decedent was

admitted to St. Vincent's East in May 2015, with severe pulmonary issues. (*Id.* at ¶ 45). He subsequently died from complications arising from the amiodarone tablets in June 2015. (*Id.* at ¶ 1).

Wyeth received FDA approval to market and sell Cordarone® only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia. (*Id.* at ¶¶ 9, 29). Wyeth's FDA approval did not require the usual mandated, rigorous trials; rather, the FDA approved double-blind, randomized clinical trials. (*Id.* at ¶¶ 28, 73). Wyeth has never conducted such trials. (*Id.*). The FDA approval for Cordarone® is a "special needs" approval. (*Id.* at ¶ 28)

Wyeth aggressively and successfully marketed Cordarone® for off-label uses as a "first line anti-arrhythmic therapy." (*Id.* at ¶ 29). The campaign for making Cordarone® a "first-line" anti-arrhythmic drug was so successful that it prompted the FDA to warn Wyeth that promoting an off-label use of the drug is unlawful. (*Id.* at ¶ 30). In 1998, Wyeth received approval for the manufacturing, marketing, sale, and distribution of the generic formulation of Cordarone®, amiodarone hydrochloride. (*Id.* at ¶ 31).

Defendant began producing the generic amiodarone in 1988. (Doc. # 1 at ¶¶ 3, 31). Defendant's generic drug is subject to the same advertising, marketing, and promotional requirements and restrictions set forth by the FDA for Wyeth in their advertising, marketing, and promotion of Cordarone®. (*Id.* at ¶ 31, citing 21 U.S.C. § 355(j)). One of these requirements is Defendant's production of a Medication Guide, which contains the appropriate and up-to-date warning labels, to ultimately be given directly to patients in order to ensure that patients have access to important side-effect information. (Doc. # 1 at ¶ 41 (citing 21 C.F.R. § 208.24)).

Pursuant to 21 C.F.R.. § 208.24 a manufacturer of a drug (such as Defendant) is required to ensure 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.

Decedent did not receive a Medication Guide from Defendant. (Doc. # 1 at ¶ 37). Because neither Defendant nor Decedent's pharmacist provided a Medication Guide, Decedent was not aware that amiodarone "should only be used in adults with life-threatening heartbeat problems called ventricular arrhythmias," and even then only when "other treatments did not work or were not tolerated." (*Id.* at ¶ 39, quoting the Medication Guide for amiodarone HCI[3]).

Plaintiff alleges Defendant has benefitted from Wyeth's marketing campaign. (Doc. # 1 at ¶¶ 31, 32). Defendant and its agents also "actively promoted" the amiodarone it manufactured for off-label use. (*Id.* at ¶¶ 3, 53-55, 61, 69). Its "pervasive" promotional scheme allegedly "involved and continues to involve a calculated and deceitful sales and promotional campaign" that was fraudulent in nature. (*Id.* at ¶¶ 5, 63-65, 67). There are strict FDA regulations about the form and contents of such promotions, and it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug. (*Id.* at ¶ 6). *See also* 21 U.S.C. §§ 331, 352. Plaintiff contends Defendant saw a significant profit potential in off-label promotion of amiodarone with the knowledge of its dangers when used off-label. (Doc. # 1 at ¶¶ 11-12).

Plaintiff asserts that Defendant was aware at the time of Decedent's death that amiodarone was being prescribed for off-label purposes. (Doc. # 1 at ¶ 13). She also alleges that

[3] The Medication Guide is available at http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf.

Defendant was and is aware, or should have been aware, of the risks and dangers of using amiodarone for its off-label purpose. (*Id.* at ¶¶ 47-49, 51, 60). Further, Plaintiff asserts that at all times, Defendant designed, created, tested, developed, labeled, sterilized, packaged, manufactured, marketed, promoted, advertised, distributed, sold, warned, and otherwise caused amiodarone to be placed into the stream of commerce. (*Id.* at ¶70). And, Plaintiff avers, but for Defendant's "negligent actions," Decedent would not have ingested amiodarone. (*Id.* at ¶ 88).

Plaintiff filed this lawsuit, seeking compensatory damages, applicable interest, costs of suit, attorneys' fees, and all other relief the court deems proper under a wrongful death claim. (Doc. # 1). Defendant responded by filing its Motion to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (Doc. # 5). In the Motion, Defendant argues that the claims against it should be dismissed because they are preempted by federal law and, in the alternative, are insufficiently pled. (Doc. # 6).

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 pleaser is entitled to relief." Fed. R. Civ. P. 8(a)(2). However, 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 non-moving party. *Watts v. Fla. Intl. 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.

In considering a motion to dismiss, a court should "1) eliminate any allegations in the complaint that are merely legal conclusions; and 2) where there are well-pleaded factual allegations, 'assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.'" *Kivisto v. Miller, Candield, Paddock & Stone, PLC*, 413 Fed. Appx. 136, 138 (11th Cir. 2011) (quoting *Am. Dental Assn. v. Cigna Corp.*, 605 F.3d 1283, 1290 (11th Cir. 2010)). 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." *Twombly*, 550 U.S. at 556. Further, "courts may infer from the factual allegations in the complaint 'obvious alternative explanation[s],' which suggest lawful conduct rather than the unlawful conduct the plaintiff would ask the court to infer." *Am. Dental* , 605 F.3d at 1290 (quoting *Iqbal*, 556 U.S. at 682). 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. *Twombly*, 550 U.S. at 556.

IV. Analysis

Plaintiff brings a wrongful death cause of action, claiming (1) a failure to warn by

Defendant (based upon Decedent not receiving a Medication Guide), and (2) negligently fraudulent marketing. (Doc. # 1). Under Alabama's wrongful death statute, the personal representative of a deceased individual can bring suit to recover damages for "the wrongful act, omission, or negligence of any person, persons, or corporation" that resulted in the Decedent's death. Ala. Code § 6-5-410. Fraud in Alabama is committed when "[m]isrepresentations of a material fact made willfully to deceive, or recklessly without knowledge, and acted on by the opposite party, or if made by mistake and innocently and acted on by the opposite party." Code of Ala. § 6-5-101.

Defendant makes two arguments in its Motion to Dismiss. First, it contends that Plaintiff's claims are preempted by federal law under the precedent set forth in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013), *Guarino v. Wyeth, LLC*, 719 F.3d 1245 (11th Cir. 2013), and *Metz v. Wyeth LLC*, 525 Fed. Appx. 893 (11th Cir. 2013) (*per curiam*). Second, and alternatively, Defendant contends that Plaintiff's claims are insufficiently pled.

A. Plaintiff's Failure To Warn Claims Are Preempted

A court may dismiss a complaint when the claim hinges on a dispositive issue of law and a defendant shows it is entitled to judgment as a matter of law based on a plaintiff's pleadings. *Marshall County Bd. Of Educ. v. Marshall County Gas Dist.*, 992 F.2d 1171, 1174 (11th Cir. 1993). Defendant argues that *Mensing* and its progeny preempt Plaintiff's claims because Plaintiff's "allegations necessarily contend Defendant's labeling should have contained different or additional warnings." (Doc. # 6, pp. 8-9).

The Supreme Court held in *Mensing* that when state laws require stricter warning labels on generic drugs than federal regulations permit, the Supremacy Clause causes the federal

regulations to preempt the state law. *Mensing*, 131 S. Ct. at 2577. Subsequently, in *Bartlett*, the Court reaffirmed the holding of *Mensing*, ruling that New Hampshire's de facto additional warning requirements were preempted by federal regulations.[4] *Bartlett*, 133 S. Ct. at 2470.

The Eleventh Circuit expanded the scope of *Mensing* in its *Guarino* decision. In *Guarino* , our circuit rejected an argument that would have required generic drug manufacturers to notify pharmacists and doctors of required label changes. *Guarino*, 719 F.3d at 1249 ("Were we to accept the failure-to-communicate theory, generic manufacturers such as Teva would need to take affirmative action to notify consumers, doctors, or pharmacists of FDA-approved changes to the drug label in order to avoid liability. Yet '[b]ecause the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead.'"), quoting *Morris v. Pliva, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013). In *Metz*, a panel, citing *Guarino*, recognized *Mensing* as the law of the land. *See Metz*, 525 Fed. Appx. at 893.

In order to determine if *Mensing* preempts Plaintiff's claims here, the court must examine Plaintiff's stated cause of action. Plaintiff explains her cause of action as follows:

> The death of Charles Elliott was directly and proximately caused by the negligent actions of [Defendant] in the off-label and other negligent promotional and marketing activities associated with the sale of amiodarone and the negligent actions of Defendant . . . for their failure to warn by providing up to date and required labeling and to provide Medication Guides to distributors for the ultimate

[4] Specifically, the Court wrote:

> New Hampshire law imposes a duty on manufacturers to ensure that the drugs they market are not unreasonably unsafe, and a drug's safety is evaluated by reference to both its chemical properties and the adequacy of its warnings. Because Mutual was unable to change sulindac's composition as a matter of both federal law and basic chemistry, New Hampshire's design-defect cause of action effectively required Mutual to change sulindac's labeling to provide stronger warnings. But, as this Court recognized just two Terms ago in [*Mensing*], federal law prohibits generic drug manufacturers from independently changing their drugs' labels. Accordingly, state law imposed a duty on Mutual not to comply with federal law. Under the Supremacy Clause, state laws that require a private party to violate federal law are pre-empted and, thus, are without effect.

Bartlett, 133 S. Ct. at 2470 (internal citations and quotations omitted).

> distribution of the Medication Guides to patients as required by FDA rules and regulations and as generally related to the manufacture, marketing, distribution and sale of Cordarone®/amiodarone as described herein.

(Doc. # 1, p. 26). She argues that, correctly interpreted, her cause of action asserts a wrongful death claim based upon of Defendant's negligent failure to follow FDA regulations. Accordingly, she contends, *Mensing* and its progeny do not apply because Defendant is alleged to have violated both state and federal law. (Doc. # 12, p. 10). And, as the argument goes, because the suit arises from Defendant's failure to follow federal law, there is nothing to preempt. (*Id.*, citing *Whitener v. PLIVA, Inc.*, No. 10-cv-1552, 2012 WL 3948797 (E.D. La. Sept. 10, 2012)). The court disagrees.

Even if the court accepts *arguendo* that Plaintiff is correct and an exception to *Mensing* exists when a defendant violates FDA regulations, her argument runs into a different hurdle in the form of 21 U.S.C. § 337(a). Section 337(a) provides that "[e]xcept as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of [the Federal Food, Drug, and Cosmetic Act] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Subsection (b) allows a state to bring suit "in its own name and within in its jurisdiction proceedings" of concerning enforcement or violation of specified sections of Title 21 of the United States Code, in certain situations. *See id.* at § 337(b).

The Supreme Court has held that "that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Byckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). However, there has been discord in circuit and district courts as to whether *Byckman* and section 337(a) preclude a claim that is based on a defendant not following FDA regulations. *See Allain v. Wyeth Pharms., Inc*., No. 14-cv-280, 2015 WL 3948961, at *8 (N.D. Ala. June 29, 2015) ("Mr. Allain may not bring

suit against the Defendants for their alleged violation of the FDCA [to [provide Medication Guides] because 21 U.S.C. § 337(a) specifically prohibits enforcement of the FDCA's provisions by private litigants."); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 862 (W.D. Tenn. 2015) ("If Plaintiffs claim negligence based solely on Defendants' failure to comply with federal law or solely on illegal off-label promotion (i.e. negligence per se), Plaintiffs' claims are impliedly preempted under *Byckman*."); *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 990 (E.D. Mo. 2014) ("Although Missouri products liability law supports recovery under a negligence theory, the conduct plaintiff complains of relates to Medtronic's promotion of the Infuse device for the off-label uses, which is a negligence "claim [that] would not exist if the FDCA did not exist.") (quoting *Linegar v. Armour of America*, 909 F.2d 1150, 1152-53 (8th Cir. 1990)). *But see Bass v. Stryker Corp.*, 669 F.3d 501, 514 (5th Cir. 2012) ("*Purcel* also indicated that 21 U.S.C. § 337(a) did not preempt negligence and products liability causes of action under Texas law.").

The court finds the argument in favor of preemption is persuasive. Plaintiff seeks to sue Defendant for an alleged violation of federal law and regulations—that is, Defendant's failure to provide the Medication Guide. (*See* Doc. # 12, p. 1 ("[Plaintiff]'s complaint alleges common-law negligent failure-to-warn claims based on [Defendant]'s failure to provide the FDA required Medication Guide" to decedent.")). The duty of Defendant to provide Medication Guides to *pharmacies* (*i.e.*, "distributors, packers, or authorized dispensers") arises solely under federal law. *See* 21 C.F.R. § 208.24(b). (Defendant has no duty to provide Medication Guides to patients). Even if *Mensing* and its progeny do not apply in this case (which is doubtful because Plaintiff is ultimately arguing a "failure to communicate" theory reminiscent of that asserted in *Guarino*, 719 F.3d 1245), Plaintiff's claim that Defendant was negligent for failing to provide Medication Guides to Decedent is preempted by section 337(a).

Ultimately, Plaintiff seeks recovery because she alleges Defendant violated FDA regulations. Although Plaintiff couches that claim under a negligence standard, granting relief would essentially hold Defendant liable for not following federal law and regulations. This amounts to an attempt to end run around section 337(a). Plaintiff's failure to warn claims fail as a matter of law.

B. The Learned-Intermediary Doctrine Bars Plaintiff's Failure To Warn Claims

Plaintiff asserts in her opposition brief that Defendant also failed to adequately warn the medical community, including Dr. King, of the dangers of the generic amiodarone. (Doc. # 12). That claim is derived from a mixture of Plaintiff's fraudulent marketing and failure to warn claim (analyzed above). Accordingly, the court concludes for the reasons stated above that any such failure to warn the medical community claim is preempted.

But even if Plaintiff's failure to warn claim were not preempted, it is barred as a matter of law for another reason: the learned-intermediary doctrine. "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 though 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.* (emphasis added). 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. In short, the patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient.

Id. at 673-74.

Here, the learned intermediary doctrine bars Plaintiff's failure to warn claim for two reasons. First, Plaintiff has not pleaded any plausible facts that show Defendant failed to adequately warn Dr. King of the dangers of amiodarone. Instead, she has made a conclusory statement that "Defendant failed to provide adequate and required warnings to physicians" (Doc. # 1 at ¶ 60), which the court disregards. Further, she has alleged general, conclusory statements concerning promotions, marketing, and education given to medical providers, but has not set

forth any facts suggesting Dr. King was the target of or influenced by any of these actions. (*See* Doc. # 1). Again, the court must disregard those conclusory allegations.

Second, Plaintiff has not shown that *Defendant* was the amiodarone manufacturer that allegedly failed to adequately warn Dr. King about the dangers of amiodarone. Again, the legal principle applicable here is that:

> FDA regulations require that a generic manufacturer's labeling for a prescription drug be exactly the same as the brand-name manufacturer's labeling. The Supreme Court in [*Mensing*] held that it would have been impossible for the generic manufacturers to change their warning labels without violating the federal requirement that the warning on a generic drug must match the warning on the brand-name version, preempting failure-to-warn claims against generic manufacturers.

Weeks, 159 So.3d at 677. Defendant owed a duty under FDA mandates to provide the same warning as that provided by Wyeth.[5] The court has determined that Plaintiff's claims that it failed to do so are preempted by *Mensing*.

Finally, as already noted, Defendant is not the only manufacturer of amiodarone. Wyeth is, of course, one such manufacturer. The court takes judicial notice that other generic manufacturers of amiodarone include Upsher-Smith Laboratories, Inc., Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc. *See Allain*, 2015 WL 3948961, at *1; *Stephens v. Teva Pharms., U.S.A.*, 70 F. Supp. 3d 1246, 1247 (N.D. Ala. 2014). Although Decedent's prescription was filled with amiodarone pills bearing a number indicating Defendant manufactured them, any of the foregoing amiodarone manufacturers may (or may not) have influenced or warned Dr. King (adequately or inadequately) concerning off-label use of amiodarone. The Complaint does

[5] To be sure, Defendant may have been able to provide *additional* information outside of drug labels to physicians to those required by the FDA, but the court is not convinced that it had any legal duty to do so, and is doubtful that it is even authorized to do so. *See Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (quoting *Mensing*, 131 S. Ct. at 2576) ("[I]f generic manufacturers, but not the brand-name manufacturer, sent [additional warnings such as a 'Dear Doctor' letters], that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'"). *Cf. also Morris*, 713 at 777 (observing that "it is logically incoherent to contend that PLIVA had a duty to apply the 2004 warning label when Appellants also assert repeatedly that no labels predating 2009 were adequate").

not provide any allegations that it was Defendant's failure to adequately warn Dr. King that proximately caused Plaintiff's death. Accordingly, the learned-intermediary doctrine also bars Plaintiff's failure to warn claim.[6]

C. Plaintiff's Off-Label Marketing Claim Is Due To Be Dismissed

Plaintiff has also alleged that Defendant engaged in a pervasive scheme of promotion and marketing amiodarone for off-label use, despite being aware of its dangers when so used. Although she characterizes her claim as one for negligent marking and negligent misrepresentations, the claim is pleaded in the nature of one for purposeful, knowing, or reckless fraud.

Under Alabama law, "[m]isrepresentations of a material fact made willfully to deceive, or recklessly without knowledge, and acted on by the opposite party, or if made by mistake and innocently and acted on by the opposite party, constitute legal fraud." Ala. Code § 6-5-101. "A claim of fraudulent misrepresentation comprises the following elements: '(1) a false representation (2) concerning a material fact (3) relied upon by the plaintiff (4) who was damaged as a proximate result." *Weeks*, 159 So. 3d at 656 (quoting *Fisher v. Comer Plantation*, 772 So, 2d 455, 463 (Ala. 2000)) (additional citation omitted).

In federal court, a fraud claim must comply with Federal Rule of Civil Procedure 9(b). Pursuant to Rule 9(b), when a party alleges fraud or mistake, she "must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, or other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Accordingly, a plaintiff pursuing a fraudulent misrepresentation complaint must allege: "(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the

[6] Although Plaintiff requests leave to amend her Complaint in the instance the court determines it fails to state a claim, such an amendment would be futile for her failure to warn claims. Therefore, concerning these claims, Plaintiff's request is denied.

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 Assn. 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*. Unfortunately, Plaintiff has failed to satisfy either requirement.

First, Plaintiff has provided only conclusory allegations concerning Defendant's marketing and promotional activities. For example, Plaintiff simply claims that Defendant "took advantage of" and benefitted from Wyeth's promotions (Doc. # 1 at ¶¶ 31, 32, 53). Plaintiff also alleges, upon information and belief, that Defendant "and/or their agents' pharmaceutical sales representatives and materials and sources actively promoted their generic amiodarone in the stream of commerce for the 'off-label' uses openly promoted by Wyeth." (*Id.* at ¶ 54). She has "offered no facts to support these allegations, and, thus, these allegations are quintessential examples of the 'naked assertion[s] devoid of further factual enhancement' that the Supreme Court declared to be insufficient to survive a motion to dismiss." *Allain*, 2015 WL 3948961, at *6 (quoting *Iqbal*, 556 U.S. at 678) (alteration in original).

Further, Plaintiff's claim for fraudulent misrepresentation is also deficient under Rule 9(b). For example, in addition to the allegations discussed above, Plaintiff avers that "[a]t all material times, Defendant respectively, also promoted amiodarone for heart conditions less severe than life-threatening ventricular arrhythmia (the only purpose for which the drug originally received FDA approval)." (Doc. # 1 at ¶ 62). These allegations do not satisfy the "precise statements" or the "time, place, and person" requirements of Rule 9(b). Plaintiff fails to point to any statements made by Defendant (or its agents) that misled Decedent, Decedent's

physicians, or any physician. "[A] fraud claim fully accrues once any legally cognizable damage has proximately resulted, *i.e.*, once the plaintiff has 'detrimentally' relied on the fraud." *Weeks*, 159 So. 3d at 672 (quoting *Ex parte Haynes Downard Andra & Jones, LLP*, 924 So. 2d 687, 694 (Ala. 2005)) (alteration in original). Her Complaint does not set forth precisely when Defendant's alleged promotional and marketing scheme occurred and when Decedent, Decedent's physicians, or any other physicians may have heard or been influenced by that scheme (other than a start date in the 1980s when Wyeth began its marketing campaign).

In sum, the allegations in the Complaint related to Defendant's off-label promotion of amiodarone are "woefully deficient and satisfy neither Rule 8 or Rule 9." *Allain*, 2015 WL 3948961, at *7. Thus, Plaintiff's claims against Defendant for its alleged off-label promotion of amiodarone are due to be dismissed.

V. Conclusion

For these reasons, the court concludes that Defendant's Motion to Dismiss (Doc. # 5) is due to be granted. Plaintiff's failure to warn claims are due to be dismissed with prejudice, and her off-label promotion of amiodarone claims are due to be dismissed without prejudice. Plaintiff's request to amend her Complaint is due to be granted (in part) insofar as it related to an off-label promotion claim. At this point, it is not clear that Plaintiff cannot state such a claim against Defendant.

A separate order shall be entered.

DONE and **ORDERED** this August 18, 2016.

R. DAVID PROCTOR
UNITED STATES DISTRICT JUDGE