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

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

MICHAEL W. ALLAIN, as Executor of the Estate of ROBERT EARL DREHER, SR., Deceased,	)	
Plaintiff,	)	**Case No. 2:14-cv-00280-KOB**
v.	)	
WYETH PHARMACEUTICALS, INC., et al.,	)	
Defendants.		

MEMORANDUM OPINION

On February 14, 2014, Plaintiff Michael Allain, as executor of the estate of Robert Earl Dreher Sr., brought suit against Defendants Wyeth Pharmaceuticals, Inc., Sandoz Pharmaceuticals Corp., Novartis Pharmaceuticals Corp., and Upsher-Smith Laboratories, Inc.,[1] asserting a claim for wrongful death. (Doc. 1). On January 14, 2015, this court dismissed without prejudice Mr. Allain's Complaint as insufficiently pled and for failing to state a claim against the Defendants. (Doc. 32). Mr. Allain subsequently filed his First Amended Complaint, again asserting a wrongful death claim against Upsher-Smith, Sandoz, and Wyeth.[2] (Doc. 34). This matter is now before the court on Upsher-Smith and Sandoz's ("Generic Defendants") motions to dismiss. (Docs. 38 & 45). Also before the court is brand-name manufacturer Wyeth's motion to dismiss. (Doc. 36).

[1] Defendant Upsher-Smith Laboratories, Inc. is incorrectly identified in the First Amended Complaint as "Upsher-Pharmaceuticals, Inc."

[2] In his First Amended Complaint, Mr. Allain did not assert a claim against Novartis, and the court subsequently dismissed Novartis from the case. (*See* Doc. 35).

In their current motions, the Defendants contend that Mr. Allain's First Amended Complaint fails to cure the deficiencies in his initial Complaint and that it still fails to state a claim. For the reasons discussed below, the court will GRANT the Generic Defendants' motions and GRANT IN PART and DENY IN PART Wyeth's motion.

I. Standard of Review

A Rule 12(b)(6) motion to dismiss attacks the legal sufficiency of the complaint. Generally, the Federal Rules of Civil Procedure require only that the complaint provide "'a short and plain statement of the claim' that will give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957) (quoting Fed. R. Civ. P. 8(a)). A plaintiff must provide the grounds for his entitlement, but Rule 8 generally does not require "detailed factual allegations." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley*, 355 U.S. at 47). It does, however, "demand[] more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 566 U.S. 662, 678 (2009).

The Supreme Court explained that "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). To be plausible on its face, the claim must contain enough facts that "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal,* 556 U.S. at 678. 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*. (internal quotation omitted). "Where a complaint pleads facts that are merely consistent with a defendant's liability,

it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (internal quotation omitted).

II. Background

FDA Regulatory Framework

Pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Food and Drug Administration regulates the approval of both brand-name and generic drugs. *See* 21 C.F.R. § 314.50(c)(2)(1) (brand-name drugs); 21 C.F.R. § 314.94(a)(8) (generic drugs). Under the FDCA, the requirements for obtaining FDA approval vary greatly depending on whether the manufacturer is seeking approval for a new drug or is applying to manufacture a generic version of an already approved drug. A manufacturer seeking approval of a new drug must demonstrate that the drug is safe and effective, and that the proposed labeling of the drug is accurate and adequate. *See* 21 U.S.C. § 355(b); 21 U.S.C. § 352(f)(2). In contrast, a generic manufacturer seeking FDA approval must only demonstrate that the generic drug is chemically and practically the bioequivalent of the brand-name drug and that the labeling is the same as that approved for the brand-name drug. *See* 21 U.S.C. 355(j)(4)(G).

Statement of Facts

The following facts are taken from Mr. Allain's First Amended Complaint and are accepted as true for the purposes of the motions to dismiss.

FDA Approval of Cordarone

In 1985, Wyeth Pharmaceuticals received FDA approval to begin manufacturing and selling Cordarone in the United States. Cordarone is a prescription drug approved as a "drug of last resort" for patients suffering from life-threatening ventricular fibrillation or ventricular

tachycardia and is only to be used in situations where the patient's condition would not respond to other available drugs and therapies. Wyeth was the sole manufacturer of Cordarone from 1985 until Upsher-Smith and Sandoz received FDA approval to begin manufacturing and selling generic versions of Cordarone in 1998. Upsher-Smith produced a generic version of Cordarone known as Pacerone, and Sandoz produced a generic version known by the drug's chemical name, amiodarone hydrochloride. Both of the generic versions were the bioequivalent of Cordarone and mirrored the warning labels of Cordarone.

Although the FDA approved the sale of Cordarone and its generic equivalents, Cordarone was known to cause numerous side effects, the most serious of which is pulmonary lung disease. Cordarone can cause two different types of lung disease. First, it can produce a pneumonia like condition, which can cause shortness of breath and coughing. This condition usually improves once the patient stops ingesting the drug. Second, it can cause stiffening of the lungs that restricts a patient's breathing. This condition can occur years after a patient finishes taking Cordarone and can be fatal. Because of the serious side effects of Cordarone, the FDA required that manufacturers of Cordarone and its generic counterparts either (1) provide 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," or (2) provide "the means to produce Medication Guides in sufficient numbers" for the distributor of the drug to provide the guides to the consumers. *See* 21 C.F.R. § 208.24(b).

Mr. Dreher's use of Generic Amiodarone

In February of 2011, Robert Dreher's physician, Dr. Macy Smith, prescribed him a ninety-day course of generic amiodarone tablets manufactured by Sandoz to treat Mr. Dreher's

atrial fibrillation. Because Mr. Dreher suffered from atrial fibrillation, not ventricular fibrillation, and because his condition was not life threatening, his use of the drug was considered "off-label." At the time Mr. Dreher filled his prescription, the pharmacy should have provided Mr. Dreher with a medication guide. However, the pharmacy allegedly failed to do so because Sandoz had not provided the medication guide to the pharmacy, as required by the FDA. Because he did not receive a medication guide, Mr. Dreher was not informed of the risks of amiodarone or that his use of the drug was considered "off-label."

In August of 2011, Mr Dreher received a second prescription for a ninety-day course of amiodarone from a physician at the Veterans Affairs office. That doctor prescribed Mr. Dreher a ninety-day course of Pacerone manufactured by Upsher-Smith. Mr. Dreher's use of Pacerone was also "off-label." When Mr. Dreher filled his prescription for Pacerone at his pharmacy, the pharmacy again failed to provide a medication guide to Mr. Dreher warning of the risks of Pacerone. This time, the pharmacy allegedly failed to do so because Upsher-Smith had failed to fulfill its FDA mandated duty to provide the medication guides to the pharmacy.

From February 2011 to January 2012, Mr. Dreher experienced many of the symptoms associated with amiodarone use, including shortness of breath, wheezing, trouble breathing, coughing, and tiredness. Mr. Dreher's condition continued to deteriorate, and, on February 15, 2012, Mr. Dreher passed away at the age of eighty four. Mr. Allain alleges that Mr. Dreher died as a result of taking amiodarone.

Wyeth's Off-Label Promotion of Cordarone

In 1985, the same year that the FDA approved Cordarone, Wyeth began aggressively marketing the drug. Although Wyeth was aware of the serious side effects of Cordarone and that

Cordarone was approved only as a "drug of last resort," it nevertheless promoted Cordarone for "off-label" use —i.e. for a purpose other than that approved by the FDA. According to Mr. Allain, "an entire generation of physicians" were misled by Wyeth's marketing campaign and Wyeth's promotional activities "would have greatly affected" Mr. Dreher's physicians' decisions to prescribed generic versions of Cordarone to Mr. Dreher. In addition to his allegations against Wyeth, Mr. Allain also alleges that "Sandoz and Upsher Defendants' and/or its agents' pharmaceutical sales representatives actively promoted their generic amiodarone in the stream of commerce for the 'off-label' uses openly promoted by Defendant Wyeth." (Doc. 34, at 27). Mr. Allain, however, fails to identify any specific methods by which the Generic Defendants promoted the off-label use of amiodarone.

III. Discussion

Following Mr. Dreher's death, Mr. Allain, the executor of Mr. Dreher's estate, brought suit against the Defendants, asserting a single count of wrongful death. In that count, Mr. Allain asserts that Mr. Dreher's death was caused by "the negligent actions of Defendant Wyeth in the long term promotional and marketing activities associated with the sale of amiodarone and the failure to adequately inform physicians of the potential dangers associated with the drug" as well as "the negligent actions of Defendants Sandoz and Upsher for their failure to provide up to date labeling and to provide Medication Guides to distributors for the ultimate distribution of the Medication Guides to patients as required by FDA rules and regulations." (Doc. 34, at 37).

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 decedents death. Ala. Code § 6-5-410.

In the present case, Mr. Allain's wrongful-death claim is premised on three alleged instances of misconduct. First, Mr. Allain alleges that the Defendants failed to warn Mr. Dreher of the dangers of amiodarone. Second, Mr. Allain alleges that the Defendants promoted amiodarone for off-label use. Finally, Mr. Allain alleges that the Defendants are liable for Mr. Dreher's death because they failed to provide the Medication Guides to the pharmacy as required by FDA regulations. This court will address each of Mr. Allain's allegations in turn.

Adequacy of Amiodarone's Warning Labels

Throughout his First Amended Complaint, Mr. Allain challenges the adequacy of the warnings labels on the generic versions of amiodarone, he states:

> [T]he Cordarone®/amiodarone/Pacerone®, manufactured and/or supplied by Defendants was and is *unaccompanied* by *proper* warnings regarding all possible adverse side effects . . . . (Doc. 34, at 28) (emphasis added)
>
> Defendants *failed to warn of material facts* regarding the safety and efficacy of Cordarone®/amiodarone/Pacerone®, such that this drug would likely have never been approved, and no physician would have been able to prescribe this drug for use in the United States. (Doc. 34, at 28) (emphasis added)
>
> [T]he *warnings* for Cordarone®/amiodarone/Pacerone®, in effect during the relevant time period were vague, incomplete, and/or otherwise *wholly inadequate* . . . . (Doc. 34, at 30) (emphasis added).

Based on that language, Mr. Allain appears to assert a claim for wrongful death based on failure to warn and predicated on the alleged inadequacy of the Defendants' warning labels. However, in his response to the Defendants' motions, Mr. Allain states he "does not allege that the contents of the label should have been changed, but that the warnings in the form of the Medication Guide were not provided in accordance with the FDA mandate." (Doc. 42, at 13). Thus, although the language in his First Amended Complaint indicates that he is asserting a claim for failure to warn, Mr. Allain's response establishes that he has disavowed any claim

against the Defendants premised on the adequacy or content of the warnings. As such, to the extent that the First Amended Complaint could be read as asserting a failure-to-warn claim, it is due to be dismissed with prejudice.

Additionally, even if Mr. Allain had not withdrawn such a claim against the Generic Defendants, the claim would be preempted under *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). In *Mensing*, the Supreme Court addressed impossibility preemption in the context of failure-to-warn claims asserted against a generic-drug manufacturer. *See id* at 2573. The plaintiff in *Mensing* argued that state law required the generic manufacturer to provide a stronger warning on its drug label than the warning provided on the brand-name drug label. In addressing the plaintiff's argument, the Court noted that under the FDCA, generic-drug manufacturers "have an ongoing federal duty of 'sameness,'" requiring generic-drug manufacturers to match the equivalent brand-name manufacturer's labeling. *Id.* at 2575. Because the FDCA limits a generic manufacturer's ability to provide additional warnings on its drug, the Court held that failure-to-warn claims against a generic manufacturer are preempted by federal law. *See id.* at 2577–78. Thus, *Mensing* squarely precludes any suit against the Generic Defendants based on the alleged inadequacy of amiodarone's warnings, and Mr. Allain's failure-to-warn claim against the Generic Defendants would be due to be dismissed even if he had not withdrawn it.

Off-label Promotion of Amiodarone

Next, Mr. Allain asserts that the "Defendants" collectively "engaged in a massive and fraudulent marketing and promotional scheme in which they aggressively and fraudulently promoted Cordarone®/amiodarone for [off-label use]." (Doc. 34, at 29). Although Mr. Allain alleges that both Wyeth and the Generic Defendants are liable for their participation in the

alleged off-label promotion of amiodarone, the specific factual allegations Mr. Allain asserts against the Generic Defendants vary greatly from the allegations against Wyeth. As such, this court will address Mr. Allain's claim against the Generic Defendants separately from his claim against Wyeth.

The Generic Defendants' Off-Label Promotion of Amiodarone

The Generic Defendants contend that Mr. Allain's claims against them for the off-label promotion of amiodarone are preempted by *Mensing*. According to the Generic Defendants, Mr. Allain's claims are, at their core, failure-to-warn claims, and, as such, are barred by *Mensing*. In response, Mr. Allain argues that *Mensing* only dealt with "*label warnings* and the inability of a generic manufacturer to change the federally dictated labeling of the brand manufacturer." (Doc. 48, at 11) (emphasis added). Because his allegation of "off-label" promotion does not relate to the labeling of amiodarone, Mr. Allain contends that his claims are not barred by *Mensing*.

Though both Mr. Allain and the Generic Defendants present *argument* in support of their positions, none of the parties point to any *binding precedent* addressing the impact of *Mensing* on claims premised on a generic manufacturer's promotion of its generic drug for off-label use. This court, however, need not address the issue because, assuming *arguendo* that such claims are not preempted by *Mensing*, Mr. Allain has still failed to plead sufficient factual allegations to survive a motion to dismiss.

Mr. Allain's First Amended Complaint suffers from the same deficiencies that led this court to dismiss his initial complaint. Once again, Mr. Allain frequently lumps the Defendants together and makes conclusory allegations that provide no basis for differentiating the alleged

misconduct of one Defendant from the other. For example, Mr. Allain makes the following allegations:

> At all material times, Defendants marketed Cordarone/amiodarone/Pacerone, as having approval, characteristics, uses, and benefits that the drug did not have.
>
> At all material times, Defendants respectively, jointly and severally, did design, create, test, develop, label, sterilize, package, manufacture, market, promote, advertise, distribute, sell, warn, and/or otherwise caused the product to be placed into the stream of commerce, and ultimately to be ingested by Robert Dreher, Sr.
>
> At all material times, Defendants willfully failed and refused to actively and affirmatively monitor Cordarone/amiodarone/Pacerone's "off-label," unapproved uses insofar that such uses causes catastrophic injuries and death. Defendants, however, continued to sell Cordarone/amiodarone/Pacerone for unapproved uses.

(Doc. 34, at 31–32). As this court informed Mr. Allain in its order dismissing his initial complaint, such allegations are insufficient to satisfy Rule 8 because they fail to allege *specific* instances of misconduct against *specific* defendants. (*See* doc. 31, at 6–7).

Even setting aside Mr. Allain's propensity to lump the Defendants together, Mr. Allain fails to assert any *factual* allegations in support of his claims against the Generic Defendants for the off-label promotion of amiodarone. In the First Amended Complaint, Mr. Allain states that "Sandoz and Upsher Defendants' and/or its agents' pharmaceutical sales representatives actively promoted their generic amiodarone in the stream of commerce for the 'off-label' uses openly promoted by Defendant Wyeth." (Doc. 34, at 27). Mr. Allain also alleges that Upsher-Smith and Sandoz "took advantage of the pervasive promotional activities of Defendant Wyeth and [Upsher-Smith and Sandoz]'s generic version[s] of the drug directly benefitted from the decades of marketing of the drug for 'off-label' uses by Defendant Wyeth." (Doc. 34, at 10–11). He 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. *Iqbal*, 556 U.S. at 678 (internal quotation omitted) (alteration in original).

In addition to being deficient under Rule 8, Mr. Allain's claim for fraudulent misrepresentation is also deficient under the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure. *See Ziemba v. Cascade Intern., Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001); *Inman v. Am. Paramount Fin*. 517 Fed. Appx. 744, 748 (11th Cir. 2013). When pleading a fraud claim, "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 [p]laintiff; 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) (internal citation omitted).

The allegations in Mr. Allain's First Amended Complaint fall well short of that standard. In his First Amended Complaint, Mr. Allain made the following allegations against the Generic Defendants:

> At all material time, [Defendants] simultaneously engaged in a massive and fraudulent marketing and promotional scheme in which they aggressively and fraudulently promoted Cordarone/amiodarone for uses never authorized by the FDA. In fact, Defendants Marketed, promoted, and "pushed" Cordarone/amiodarone/Pacerone, not as a drug of last resort, but as a drug suitable as an initial therapy and to treat non-life threatening heart conditions. (Doc. 34, at 29).
>
> At all material times, Defendants respectively, jointly and severally, also promoted Cordarone/amiodarone/Paceron for heart conditions less severe than life-threatening ventricular arrhythmia (the only purpose for which the drug originally received FDA approval). (Doc. 34, at 29).
>
> [U]pon information and belief, Sandoz and Upsher Defendants' and/or its agents' pharmaceutical sales representatives actively promoted their generic amiodarone in

> the stream of commerce for the "off-label" uses openly promoted by Defendant Wyeth. (Doc. 34, at 27).
>
> The Defendants . . . promoted and conspired together and with others to promote the use of amiodarone as an initial, first-line therapy for arrhythmia and other heart ailments. (Doc. 34, at 4).

These allegations satisfy neither the "precise statements" nor the "time, place, and person" requirements of Rule 9(b). Mr. Allain fails to point to any statements made by either of the Generic Defendants that misled Mr. Dreher, Mr. Dreher's physicians, or any physician for that matter. Without factual support, Mr. Allain's general allegations that the Generic Defendants engaged in a "massive and fraudulent marketing and promotional scheme" cannot survive a motion to dismiss.

In sum, the allegations in the First Amended Complaint related to the Generic Defendants' involvement in the off-label promotion of amiodarone are woefully deficient and satisfy neither Rule 8 or Rule 9. As such, Mr. Allain's claims against the Generic Defendants for their alleged off-label promotion of amiodarone are due to be dismissed. However, the court will dismiss the claims *without* prejudice because it is not clear that Mr. Allain cannot state such a claim against the Generic Defendants.

Wyeth's Off-Label Promotion of Amiodarone

Mr. Allain's allegations of off-label promotion against Wyeth in the First Amended Complaint are similarly vague. In the section entitled "Cordarone, Concealment, and the Off-Label Promotional Scheme by Defendant Wyeth," Mr. Allain sets forth an extensive list of alleged wrongdoings in support of his allegation that Wyeth promoted Cordarone for off-label use. (Doc. 34, at 17). Upon closer examination, however, the vast majority of these allegations are unrelated to the promotion of Cordarone. For instance, Mr. Allain begins that section by

reciting more than twenty instance in which the FDA required Wyeth to revise its Cordarone warning labels. Those label revisions, however, are irrelevant in the pending suit because, as stated in his response, Mr. Allain "does not allege that the contents of the label should have been changed." (Doc. 42, at 13). Mr. Allain also discusses the Australian government's decision to issue a warning regarding possible adverse effects caused by Cordarone as well as Wyeth's decision to stop distributing Cordarone in Canada in 1996. Again, Mr. Allain fails to shed any light on how those allegations relate to his claim against Wyeth his claim of off-label promotion of Cordarone.

Although much of Mr. Allain's allegations against Wyeth are unrelated to the off-label promotion of Cordarone, Mr. Allain does allege a few specific instances that *are* relevant to his claim against Wyeth. Specifically, Mr. Allain alleges that in 1989, 1992, and 1998, the FDA sent "violation communications" to Wyeth regarding Wyeth's dissemination of false and misleading materials to physicians. (Doc. 34, at 19). Additionally, Mr. Allain alleges that Wyeth sponsored a Continuing Medical Education conference in 1998 during which it distributed a "68-page official looking, peer review-appearing magazine" that downplayed the side effects of Cordarone and promoted the drug for off-label use. (Doc. 34, at 21). Thus, in contrast to his allegations against the Generic Defendants, Mr. Allain has articulated a specific method of how Wyeth promoted Cordarone to physicians for off-label use. These sufficient allegations survive a motion to dismiss. *See Ashcroft v. Iqbal*, 566 U.S. 662, 678 (2009).

Mr. Allain's First Amended Complaint also sufficiently alleges that Wyeth's off-label promotion of amiodarone *caused* Mr. Dreher's physicians to prescribe him amiodarone for off-label use. In his First Amended Complaint, Mr. Allain alleges that Mr. Dreher's physician was

"a victim of Defendant Wyeth's long term and successful promotional efforts" and that those efforts "would have greatly affected her decision to prescribe amiodarone to Robert Dreher Sr." (Doc. 34, at 11–12). Admittedly, these allegations are somewhat vague and dubious. Nevertheless, the court's role at this stage is simply to determine whether Mr. Allain's claim is plausible, not probable. *See Iqbal*, 566 U.S. at 678 ("[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim that is plausible on its face.'") (internal quotation omitted). Because his claim against Wyeth for the off-label promotion of amiodarone is plausible, Wyeth's motion to dismiss this claim is due to be denied.

The Defendants' Failure to Provide Medication Guides

Mr. Allain's final allegation of misconduct against the Defendants is that they failed to provide medication guides to Mr. Dreher's pharmacy. This claim, however, is barred by either 21 U.S.C. § 337(a) or Alabama's learned intermediary doctrine.

The duty of the Defendants to provide medication guides to Mr. Dreher's pharmacy arises solely under federal law. *See* 21 C.F.R. § 208.24(b). Indeed, Mr. Allain states in his First Amended Complaint that the Defendants' failure to provide the medication guides to the pharmacy was "a direct violation of the FDA's mandate to manufacturers of the drug . . . ." (Doc. 34, at 36). However, Mr. Allain may not bring suit against the Defendants for their alleged violation of the FDCA because 21 U.S.C. § 337(a) specifically prohibits enforcement of the FDCA's provisions by private litigants. *See* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be *by and in the name of the United States*."); *Buckman Co. v. Plaintiff's 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 [is] authorized to file suit for noncompliance with [its] provisions.").

Additionally, to the extent that Mr. Allain asserts that the Defendants violated Alabama law by failing to provide medication guides to Mr. Allain's pharmacy, the claim is barred by 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. *See Stone v. Smith, Kline & French Labs.*, 447 So. 2d. 1301, 1304 (Ala. 1984) (internal citation omitted); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 673–74 (Ala. 2014) (holding that once a prescription manufacturer warns the prescribing physician, "the manufacturer has no further duty to warn the patient directly"). Thus, the Defendants had no duty under Alabama law to directly warn Mr. Dreher of the dangers of amiodarone by providing a medication guide to him or to provide medication guides to Mr. Dreher's pharmacy. Instead, the Defendants' only duty under Alabama law is to provide adequate warnings to Mr. Dreher's *prescribing physician*. As such, Mr. Allain cannot assert a claim under Alabama law against the Defendants for failing to provide Mr. Dreher's pharmacy or Mr. Dreher himself with a medication.

Because Mr. Allain's claims against the Defendants for their alleged failure to provide medication guides to Mr. Dreher's pharmacy is barred by either section 21 U.S.C. § 337(a) or the learned intermediary doctrine, the claim is due to be dismissed with prejudice.[3]

[3] Even if this claim were not barred by the learned intermediary doctrine and 21 U.S.C. § 337(a), the claim would still be due to be dismissed against Wyeth as Mr. Dreher never ingested Cordarone, the version of amiodarone Wyeth manufactured, and therefore, Wyeth could not have owed a duty to provide a medication guide to Mr. Dreher when he ingested a different manufacturer's drug.

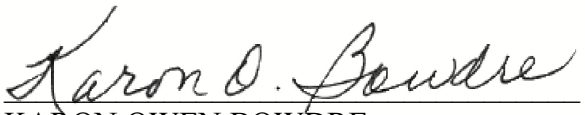
IV. CONCLUSION

For the reasons discussed above, the court **GRANTS** Upsher and Sandoz's Motions to Dismiss. The court **DISMISSES WITH PREJUDICE** Mr. Allain's claims against Upsher-Smith and Sandoz for failure to warn and failure to provide medication guides to Mr. Dreher's pharmacy. The court **DISMISSES WITHOUT PREJUDICE** Mr. Allain's claims against Upsher-Smith and Sandoz for their alleged promotion of amiodarone for off-label use.

Additionally, the court **GRANTS IN PART** and **DENIES IN PART** Wyeth's motion to dismiss. The court **GRANTS** Wyeth's motion as to Mr. Allain's claims against Wyeth for failure to warn and for failing to provide medication guides to Mr. Dreher's pharmacy, and **DISMISSES** those claims **WITH PREJUDICE**. The court **DENIES** Wyeth's motion only as to Mr. Allain's claim against Wyeth for the off-label promotion of Cordarone. This sole claim remains.

Within Mr. Allain's responses to the motions to dismiss, he requests leave to amend his First Amended Complaint to remedy any pleading deficiencies. Out of an abundance of patience, the court **GRANTS** Mr. Allain's motion to amend and allows Mr. Allain ***one more chance*** to amend his complaint to address the issues cited in this opinion regarding the claims dismissed without prejudice. Because Mr. Allain abandoned his failure-to-warn claim and because he cannot state a claim against the Defendants for their alleged failure to ensure Mr. Dreher received a medication guide, this court **GRANTS** Mr. Allain's motion to amend ***only*** as to his claim against the Generic Defendants for their alleged off-label promotion of amiodarone.

Done and **Ordered** this 29th day of June, 2015.



KARON OWEN BOWDRE
CHIEF UNITED STATES DISTRICT JUDGE