FILED
2015 Jan-14 AM 11:08
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

The matter comes before the court on Defendant Wyeth Pharmaceuticals, Inc.'s[1] motion to dismiss, (Doc. 21), and Defendant Upsher-Smith Laboratories, Inc.'s[2] motion to dismiss, (Doc. 7). Plaintiff Michael Allain, as executor of the estate of Robert Earl Dreher Sr., asserts a wrongful death claim against Defendants Wyeth Pharmaceuticals, Inc., Sandoz Pharmaceuticals Corp., Bovartis Pharmaceuticals Corp., and Upsher-Smith Laboratories, Inc. (Doc. 1). In its motion to dismiss, Wyeth argues that Plaintiff's complaint should be dismissed pursuant to Rule 8(a)(2) and 12(b)(6) for failure to state a claim. (Doc. 21). Similarly, Upsher-Smith contends that the plaintiff's complaint should

[1] Defendant Wyeth Pharmaceuticals, Inc. is incorrectly identified in the complaint as Wyeth-Ayerst Laboratories, Inc.

[2] Defendant Upsher-Smith Laboratories, Inc. is incorrectly identified in the complaint as "Upsher-Pharmaceuticals, Inc.

be dismissed pursuant to Rule 12(b)(6) for failure to state a claim. For the reasons discussed below, the court will grant Wyeth's and Upsher-Smith's motions.

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). 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 merely based upon "labels or conclusions" or "naked assertions" without supporting factual allegations. *Twombly*, 550 U.S. at 555, 557.

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).

The Supreme Court has identified "two working principles" for the district court to use in applying the facial plausibility standard. The first principle is that, 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 even when "couched as [] factual allegation[s]" or "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Iqbal*, 556 U.S. at 677–78. The second principle is that "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 679. Thus, under prong one, the court determines the factual allegations that are well-pleaded and assumes their veracity, and then proceeds, under prong two, 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 a 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 claim must be dismissed. *Id*.

II. STATEMENT OF FACTS

Cordarone is an anti-arrhythmic heart medication, which is manufactured and distributed by Defendant Wyeth Pharmaceuticals, Inc. The FDA first approved Cordarone for use within the United States starting in 1985. Unlike most prescription drugs, the FDA approved Cordarone under a special needs approval process that did not require a randomized clinical trials process. The FDA approved Cordarone for use "as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies." (Doc. 1).

In 1998, Defendant Upsher-Smith Pharmaceuticals Inc. applied for and received FDA approval to market, manufacture, and sell a generic version of Cordarone, called Pacerone. That same year, in 1998, Defendants Sandoz Pharmaceuticals, Inc. and Novartis Pharmaceuticals Corp. also received FDA approval to manufacture and sell a generic version of Cardarone called amiodarone hydrochloride, the drug's chemical name. (Doc. 1).

Although Cordarone, Pacerone and the other generic formulation known as amiodarone hydrochloride were only approved as drugs of last resort, Defendants were aware that many amiodarone prescriptions were written for "off-label" purposes. To combat this off-label use, the FDA between 1985 and 2004 required Wyeth to repeatedly modify Cordarone's labeling and warnings. During this time period, the FDA also sent a letter to Wyeth instructing the company to stop endorsing the drug in a manner that

"downplayed the risks and promoted the drug as a first line anti-arrhythmic therapy." (Doc. 1 at ¶ 33). In 1989, 1992, and 1998, the FDA determined that Wyeth violated its regulations by disseminating false and misleading materials to physicians and the public without adequate risk information concerning the use of Cordarone. (Doc. 1).

At some undisclosed time, Mr. Dreher was diagnosed with atrial fibrillation and chronic renal failure. Both conditions were manageable and not deemed to be life threatening. In February of 2011, Dr. Macy Smith prescribed Mr. Dreher a 90-day course of 200mg amiodarone tablets to treat his atrial fibrillation. These specific tablets of amiodarone were the generic version of Cardarone that were manufactured, marketed, and distributed by Defendants Sandoz and Novartis. Mr. Dreher ingested the drug according to the instructions. Because Mr. Dreher was not in a situation of last resort as to his atrial fibrillation, his use of amiodarone was considered an off-label use of the drug. Mr. Dreher was unaware that his use was off-label, and he did not receive a Medication Guide accompanying the drug. (Doc. 1). Plaintiff alleges that had Mr. Dreher been provided with a Medication Guide, he "would not have taken amiodarone." (Doc. 1 at ¶ 40).

In the spring of 2011, after taking amiodarone, Mr. Dreher experienced many of the serious side effects outlined in the Medication Guide, including lung damage, shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. (Doc. 1). In August of 2011, Dr. Vance Plumb prescribed Mr. Dreher a 90-day course of 200mg

tablets of Pacerone® manufactured by Defendant Upsher. (Doc. 21). Again, Mr. Dreher was not provided with a Medication Guide or the appropriate and up-to-date warning labels. In August 2011, Mr. Dreher fell in his garden, fractured a rib, and suffered a puncture wound that never fully healed. In September of 2011, Dr. Plumb lowered Mr. Dreher's dosage of amiodarone. (Doc. 1).

According to the complaint, "[f]rom February 2011 to January 2012, [Mr. Dreher] continuously told his family, 'I don't feel right. I'm out of breath all of the time, even when just walking to get the mail.'" (Doc 1 at ¶ 47). Prior to ingesting the drug, Mr. Dreher participated in normal day-to-day activities. However, during the time that he was taking the drug, Mr. Dreher "experienced symptoms of shortness of breath, productive cough, which eventually produced signs of blood, longer than normal healing of wounds, paler than normal pigment of skin, and signs of gout, sunken in cheeks and face." (Doc. 1 at ¶ 48). Mr. Dreher's last month to preform activities was December 2011, ten months after he began taking amiodarone. Mr. Dreher died on February 15, 2012, at the age of eighty-four. (Doc. 1).

III. LEGAL DISCUSSION

A. Plaintiff's Claims are not Pled with Sufficient Particularity

Plaintiff asserts a wrongful death claim against all the Defendants, sounding in negligence, strict liability, and fraud. Plaintiff's pleadings, however, are rife with vague and conclusory statements and fail to satisfy the requirements of Rule 8, more less the heightened pleading requirements of Rule 9. Plaintiff consistently lumps the Defendants

into an undifferentiated group and makes broad sweeping allegations against all Defendants, failing to cite any specific factual instances for support. Such "naked assertions" without supporting factual allegations are insufficient to survive a motion to dismiss. *See* Fed. Rules Civ. Proc., Rule 8(a) & 9(b); *Lane v. Capital Acquisitions & Mgmt., Co.*, No. 04-60602-CIV, 2006 WL 4590705, at *5 (S.D. Fla. April 16, 2006) ("By lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct, [plaintiff] fails to satisfy the minimum standard of Rule 8."); *Petrovic v. Princess Cruise Lines, Ltd.*, No. 12-21588-CIV, 2012 WL 3026368, at *3 (S.D. Fla. July 20, 2012); *see also Ambrosia Coal & Constr. Co. v. Pages Morales*, 482 F.3d 1309, 1317 (11th Cir. 2007) (plaintiffs must present specific factual allegations that are sufficient to "inform each defendant of the nature of his alleged participation in the fraud"); *United States ex rel. Clausen v. Lab. Corp. Of Am., Inc.*, 290 F.3d 1301, 1308 (11th Cir. 2002) ("[U]nder Rule 9(b)[,] allegations of fraud must include facts as to time, place, and substance of the defendant's alleged fraud.") (internal quotations omitted). Thus, Plaintiff's complaint is due to be dismissed for failure to plead his claims with sufficient particularity.

B. Complaint Fails to State a Claim

Even looking beyond the Rule 8 and Rule 9 pleading deficiencies in the complaint, Wyeth's and Upsher's motions to dismiss are due to be granted because Plaintiff fails to plead facts sufficient to state a claim for relief.

Plaintiff's claims against the Defendants are based on three instances of alleged misconduct. First, the Plaintiff alleges that the Defendants promoted amiodarone for "off-label" use, misleading physicians into prescribing amiodarone when they should not have done so. Second, Plaintiff alleges that the Defendants failed to ensure that Mr. Dreher received a Medication Guide informing him of the serious side effects of using amiodarone or that his use of the drug was for an "off-label" use. Finally, Plaintiff alleges that the warnings on the drug were inadequate.

Defendant's promotion of amiodarone for off-label use

As to Plaintiff's first claim, Plaintiff alleges that the Defendants misrepresented the risks associated with amiodarone and encouraged physicians to prescribe the drug for off-label use. In support to this contention, Plaintiff points to evidence of alleged labeling and promoting misconduct conducted by Defendant Wyeth between 1985 and 2004. Plaintiff alleges Wyeth's actions were misleading to physicians generally. However, Plaintiff fails to draw a connection between this alleged misconduct and the decision of Plaintiff's physicians, Dr. Smith and Dr. Plumb, to prescribe amiodarone to Mr. Dreher *in 2011.* Indeed, Plaintiff fails to allege that Mr. Dreher's prescribing physicians were misled about any aspect of amiodarone. Thus, even assuming that the Defendants engaged in misconduct prior to 2004, Plaintiff fails to allege facts showing that Mr. Dreher suffered any harm as a result of those actions. Plaintiff's failure to allege a causal connection between the Defendants' actions and Mr. Dreher's injury is fatal to this claim.

Defendants' failure to provide Mr. Dreher with a Medication Guide

As to Plaintiff's second allegation of misconduct, Plaintiff contends that the FDA required the Defendants to provide Mr. Dreher with a Medication Guide when Mr. Dreher purchased the amiodarone. Plaintiff, however, is mistaken as to Wyeth's and Upsher's duties.

First, as to Wyeth's duty, Wyeth points out that Mr. Dreher ingested two versions of amiodarone—Pacerone, manufactured by Upsher-Smith, and generic amiodarone, manufactured by Sandoz. Mr. Dreher never used Cordarone, the version of amiodarone manufactured by Wyeth. Thus, Wyeth contends that it did not owe Mr. Dreher any duty to provide him a Medication Guide. In response, Plaintiff alleges that Wyeth had a duty to provide a Medication Guide to Mr. Dreher under the Alabama Supreme Court's decision in *Wyeth, Inc. v. Weeks*, No. 1101397, 2014 WL 4055813 (Ala. 2014).

In *Weeks*, the Alabama Supreme Court held that "a brand-name-drug company may be held liable for *fraud or misrepresentation* . . . based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company." *Id.* at *23 (emphasis added). However, unlike the plaintiff in *Wyeth*, Plaintiff does not allege that the Medication Guide was false or deceptive. In fact, Plaintiff in his reply brief states that the "Medication Guide clearly and unequivocally states that 'off-label' and non-'drug of last resort' use of amiodarone should not occur and provides a clear warning of the dangers of death and severe injury." (Doc. 25-1, p. 11). Plaintiff instead faults Wyeth for failing to ensure that Mr. Dreher received the Medication Guide. *See*

(Doc. 25-1, p. 7). Thus, Plaintiff does not challenge the sufficiency of the warning but only that Mr. Dreher was not provided a Medication Guide. As such, *Weeks* does not control the case at hand.

Aside from *Weeks*, Plaintiff cites no law for the proposition that the manufacturer of a brand name drug has a duty to provide Medication Guides to consumers of competing generic version drugs. Finding no law imposing such a duty, this court concludes that Wyeth did not owe a duty to provide a Medication Guide to Mr. Dreher when he purchased Pacerone and generic amiodarone. Thus, Plaintiff's claim against Wyeth for failure to provide a Medication Guide lacks merit. Additionally, even assuming that Wyeth had a duty to warn Mr. Dreher, the claim would still be due to be denied for the reasons discussed in connection with Plaintiff's claim against Upsher.

As to the scope of Upsher's duty, the relevant Code of Federal Regulations provides that the manufacturer of a drug has a duty to provide Medication Guides to the *distributor* of the medication, *not the end user*, so that the *authorized dispenser* can provided a medication guide to each patient. *See* 21 C.F.R. § 208.24(b).[3]

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[3] (b) Each manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients by either:

> (1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or
>
> (2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product.

Plaintiff's complaint does not allege that Upsher breached this duty, but only alleges that Mr. Dreher did not receive a Medication Guide. Plaintiff's complaint leaves open the possibility that Upsher fulfilled its duty to provide Medication Guides to the authorized distributor, but the authorized distributor simply failed to give the Medication Guide to Mr. Dreher. Thus, Plaintiff's complaint fails to establish "more than a sheer possibility that [Upsher] acted unlawfully." *Iqbal*, 556 U.S. at 678. Absent a well-founded allegation that Upsher breached its duty to provide the distributor with a Medication Guide, this claim is due to be dismissed. *See Stephens v. Teva Pharms. U.S.A., Inc.*, No. 5:13-cv-01357-IPJ, ECF No. 32, at *6 (Oct. 1, 2014) (dismissing claim because the "plaintiff's argument leaves open the possibility that the defendants met their obligations to furnish the Medication Guide [to the authorized distributor]").

The adequacy of the warnings provided on the amiodarone

Although Plaintiff in his reply brief states that he "does not allege that the contents of the label should have been changed," Plaintiff in his complaint states that "the warnings for Cordarone®/amiodarone/ Pacerone®, in effect during the relevant time period were vague, incomplete, and/or otherwise wholly inadequate . . . to alert prescribing physicians, pharmacists, consumer patients and Robert Dreher, Sr. of the actual risks associate with this drug." To the extent that this language claims the Defendants failed to provide medication guides to physicians, the court has already

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21 C.F.R. § 208.24(b).

addressed the Defendants' duty to provide guides to the authorized distributors, not directly to the prescribing physicians or consumers. To the extent that the complaint alleges the warnings themselves were inadequate, Plaintiff fails to specify in what way the "warnings to physicians" were inadequate. Plaintiff's "conclusory statements," devoid of additional factual support, are insufficient to insulate Plaintiff's complaint from a motion to dismiss. *See Iqbal*, 556 U.S. at 678 (citations omitted). Additionally, as Defendant Wyeth points out, even if Plaintiff's complaint were sufficiently pled, Plaintiff's claim would still be due to be dismissed under Alabama's learned-intermediary doctrine.

Under the learned-intermediary doctrine, a prescription drug manufacturer's duty to warn "is limited to an obligation to advise the *prescribing physician* of any potential dangers that may result from the drug's use." *Stone v. Smith, Kline, & French Labs.*, 447 So. 2d 1301, 1304 (Ala. 1984) (emphasis added) (internal quotation omitted). The prescribing physician then acts as a "learned intermediary" between the patient and the drug manufacturer. *See Nail v. Publix Super Markets, Inc.*, 72 So. 3d 608, 614 (Ala. 2011); *Batchelor v. Pfizer, Inc.*, 2013 WL 3873242, *2 (M.D. Ala. 2013) ("Defendant had no duty to warn Plaintiff, only to warn her physicians adequately and honestly, and Plaintiff offers no factual allegations to support the theory that there was an inadequate or dishonest warning."); *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1279 (11th Cir. 2002) ("[T]he learned intermediary doctrine is nearly universal; where drugs . . . are only available to the public by prescription from a physician or dentist, the products

manufacturer fulfills its duty to warn by advising the professional of the dangers of the product.") (internal quotation omitted).

In the present case, Plaintiff fails to allege that any of the physicians who prescribed Mr. Dreher amiodarone were uninformed or misled about the risks associated with the drug. Instead, Plaintiff vaguely alleges that "prescribing physicians" generally were misled about amiodarone. Plaintiff's failure to specifically allege that *Mr. Dreher's prescribing physicians* were misled and how they were misled is fatal to this claim. This failure is especially striking given that Plaintiff's counsel in a similar case involving amiodarone filed an almost identical complaint that was dismissed because it too failed to specifically allege that the plaintiff's prescribing physicians were misled. *See Stephens v. Teva Pharms. U.S.A., Inc.*, No. 5:13-cv-01357-IPJ, ECF No. 32, at *15–16 (Oct. 1, 2014).

Additionally, even if Plaintiff had sufficiently alleged facts showing that the Defendants breached a duty to adequately inform Mr. Dreher's prescribing physicians, this claim is still due to be dismissed because Plaintiff fails to plead facts sufficient to show causation. Under the learned intermediary doctrine, Plaintiff "must show that the manufacturer failed to warn the physicians 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." *Stone v. Smith Kline & French Labs.*, 447 So. 2d 1301, 1304 (Ala. 1984).

Plaintiff attempts to satisfy this requirement by stating that Mr. Dreher would not have taken the amiodarone if he had been provided with a Medication Guide. This argument, of course, presupposes that the warnings in the Medication Guide were

adequate to warn Mr. Dreher of the risks of amiodarone, which is at odds with Plaintiff's claim that the warnings were insufficient. Nevertheless, even assuming that Plaintiff has a reasonable explanation for this apparent inconsistency, the question under the learned intermediary doctrine is not whether the patient would have taken the medication if they had been adequately warned but whether the physician would have prescribed the medication. *See In re Traysol Prod. Liab. Litig.*, No. 08-MD-01928, 2011 WL 2117257, at *5 (S.D. Fla. May 23, 2011) ("The question [under the learned intermediary doctrine] is whether . . . an adequate warning would been read and heeded by [the plaintiff's] prescribing physician, and the injury would have been avoided.") (alterations supplied); *Barnhill v. Teva Pharm. USA, Inc.*, 819 F. Supp. 2d. 1254, 1260 (S.D. Ala. 2011) ("In cases such as these [involving prescription drugs and the learned intermediary doctrine], . . . the plaintiff[ ] must demonstrate that, had the defendant given an adequate warning, it would have been read and heeded by the *prescribing physician*[ ].") (internal quotations omitted) (alternations in original). In the present case, Plaintiff fails to allege that Mr. Dreher's physicians would not have prescribed the amiodarone to Mr. Dreher if they had been adequately informed of all the risks associated with the drug. Accordingly, Plaintiff fails to plead facts sufficient to show causation.

Because Plaintiff fails to allege facts sufficient to state any claim, Plaintiff's complaint is due to be dismissed against all Defendants in the case.

IV. CONCLUSION

For the reasons discussed above, Defendants' Motion to Dismiss is due to be **GRANTED**, and Plaintiff's claims against all Defendants are due to be **DISMISSED WITHOUT PREJUDICE**.

Within Plaintiff's response to the motion to dismiss, Plaintiff requests leave to amend his complaint. Because granting leave to amend would not prejudice Defendants, this court will **GRANT** Plaintiff's motion. Plaintiff must file an amended complaint by February 13, 2015. Upon the filing of such amended pleading, the court will reopen the case.

Additionally, if Plaintiff chooses to file an amended complaint, this court **ORDERS** Plaintiff to concurrently file a response to this court's previous order to show cause for why Defendants Sandoz Pharmaceuticals Corporation and Novartis Pharmaceuticals Corporation should not be dismissed pursuant to FRCP 4(m). (Doc. 29).

Done and Ordered this 14th day of January, 2015.

Karon O. Bowdre

KARON OWEN BOWDRE
CHIEF UNITED STATES DISTRICT JUDGE