

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ALABAMA  
MIDDLE DIVISION**

<b>DAVID JAMES MILLER,</b>		
<b>Plaintiff,</b>		
<b>v.</b>		<b>4:13-CV-01687-KOB</b>
<b>PFIZER INC.,</b>		
<b>Defendant.</b>		

**MEMORANDUM OPINION**

This matter comes before the court on “Pfizer Inc.’s Motion for Judgment on the Pleadings.” (Doc. 12). Plaintiff David James Miller brings this suit against Defendant Pfizer Inc., alleging that Pfizer failed to warn Plaintiff and his physician of the potential side effects of the pharmaceutical product Lipitor and that Plaintiff suffered injuries as a result of ingesting Lipitor. (Doc. 1). Defendant’s motion for judgment on the pleadings argues that the complaint is due to be dismissed because Lipitor’s FDA-approved label included warnings about the very conditions that Plaintiff experienced as a result of taking Lipitor. (Doc. 12). For the following reasons, the court finds that Plaintiff’s complaint is due to be **DISMISSED WITHOUT PREJUDICE** with leave to amend within 30 days.

**I. FACTS**

According to Plaintiff’s complaint, Lipitor is a pharmaceutical drug used for managing and lowering blood cholesterol levels and is developed and marketed by Defendant. The United States Food and Drug Administration approved Lipitor for sale in 1996 and Defendant

maintained its name-brand marketing and sales until November 2011. (Doc. 1, ¶ 6).

In 2011, Plaintiff's doctor gave him sample packages of name-brand Lipitor to maintain and lower his blood cholesterol levels. Plaintiff ingested the Lipitor as prescribed by his doctor and as intended by Defendant. Around September 2011, Plaintiff began experiencing unexplained muscle pain and weakness. Upon investigation by his medical providers, Plaintiff discovered that his injuries were because he ingested Lipitor. (Doc. 1, ¶¶ 7-9).

As a result of ingesting Lipitor, Plaintiff experienced muscle weakness, pain, myopathy, neuropathy<sup>1</sup>, and rhabdomyolysis<sup>2</sup>. Plaintiff continues to suffer from these problems on a daily basis and his injuries require him to visit multiple medical specialists and incur significant medical expenses that are expected to continue through the remainder of Plaintiff's life. (Doc. 1, ¶ 9).

According to the Lipitor labels provided by Defendants—which we consider under the incorporation by reference doctrine, discussed below—the Lipitor label in effect in 2011 stated in the “Warnings and Precautions” section: “**Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with LIPITOR . . . .** Atorvastatin,

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<sup>1</sup>The Mayo Clinic defines neuropathy, or “peripheral neuropathy” as “a result of nerve damages, [that] often causes weakness, numbness and pain, usually in your hands and feet, but it may also occur in other areas of your body.” Mayo Clinic Staff, *Peripheral neuropathy*, MAYO CLINIC, <http://www.mayoclinic.org/diseases-conditions/peripheral-neuropathy/basics/definition/con-20019948> (last visited May 8, 2014).

<sup>2</sup>“Rhabdomyolysis is the breakdown of muscle tissue that leads to the release of muscle fiber contents into the blood. These substances are harmful to the kidney and often cause kidney damage.” U.S. National Library of Medicine and National Institutes of Health, MEDLINE PLUS: TRUSTED HEALTH INFORMATION FOR YOU, *Rhabdomyolysis*, <http://nlm.nih.gov/medlineplus/ency/article/000473.htm> (last visited May 22, 2014).

like other statins, occasionally causes myopathy, defined as muscle aches or muscle weakness . . . .” (Doc. 11-1, pg. 6) (emphasis in original). The label also included other warnings specific to rhabdomyolysis and myopathy.

## II. STANDARD OF REVIEW

Rule 12(c) provides that “[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings.” Fed. R. Civ. P. 12(c). “Judgment on the pleadings is appropriate when material facts are not in dispute and judgment can be rendered by looking at the substance of the pleadings and any judicially noticed facts.” *Bankers Ins. Co. v. Florida Residential Prop. & Cas. Joint Underwriting Ass’n*, 137 F.3d 1293, 1295 (11th Cir. 1998). A Rule 12(c) motion “is subject to the same standard as a motion to dismiss under Rule 12(b)(6).” *American United Life Ins. Co. v. Bell*, No. 2:09-cv-907-TFM, 2010 WL 1995034 at \*2 (M.D. Ala. May 18, 2010) (quoting *Doe v. Myspace, Inc.*, 528 F.3d 413, 418 (5th Cir. 2008)); *see also Horsley v. Feldt*, 304 F.3d 1125, 1134 (11th Cir. 2002) (noting the similarities between Rule 12(c) and Rule 12(b)(6)).

The Eleventh Circuit has explicitly applied the *Twombly* standard to a Rule 12(c) motion, noting that dismissal is appropriate when “the complaint lacks sufficient factual matter to state a facially plausible claim for relief that allows the court to draw a reasonable inference that the defendant is liable for the alleged misconduct.” *Jiles v. United Parcel Service, Inc.*, 413 Fed. Appx. 173, 174 (11th Cir. 2011) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556, 570 (2007)).

The court has also extended the “incorporation by reference doctrine” of Rule 12(b)(6) to Rule 12(c). *Horsley v. Feldt*, 304 F.3d at 1134. Therefore, “the court may consider a document

attached to [the motion] without converting the motion into one for summary judgment if the attached document is (1) central to the plaintiff's claim and (2) undisputed. In this context, 'undisputed' means that the authenticity of the document is not challenged." *Day v. Taylor*, 400 F.3d 1272, 1276 (11th Cir. 2005). The court considers the labels submitted by Defendant because they are central to Plaintiff's claim and Plaintiffs do not dispute their authenticity.

### **III. DISCUSSION**

#### **A. Count One: Strict Liability/Failure to Warn**

Defendant argues that Count 1 should be dismissed because Plaintiff pleads the count as a strict liability claim, rather than under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") and because the warnings in the Lipitor label were present and adequate as a matter of law. (Doc. 11). Plaintiff does not address Defendant's argument on the AEMLD, but argues that although the Lipitor label "contains language on myopathy and related injuries . . . that very same label is inadequate in relaying the full weight of such risks." (Doc. 15-1, pg. 2).

Alabama law does not recognize a strict liability cause of action, but instead substitutes the judicially-created AEMLD. *See Casrell v. Altec Indus., Inc.*, 335 So. 2d 128, 132 (Ala. 1976). This court will construe Count 1 as an AEMLD claim, as have other courts, but notes that if Plaintiff repleads Count 1—as this court will ultimately dismiss it without prejudice on other grounds—he should plead it as an AEMLD claim, not a strict liability claim. *See Bodie v. Purdue Pharma Co.*, 236 Fed. Appx. 511, 517 n. 9 (11th Cir. 2007) (construing a strict liability claim as an AEMLD claim under Alabama law).

To state a claim under the AEMLD, a plaintiff must show:

[H]e suffered injury or damages to himself or his property by one who sells a

product in a defective condition unreasonably dangerous to the plaintiff as the ultimate user or consumer, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it [was] sold.

*Morguson v. 3M Co.*, 857 So.2d 796, 800 (Ala. 2003). “[I]n the case of an ‘unavoidably unsafe’ yet properly prepared prescription drug, the adequacy of the accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous.” *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301, 1304 (Ala. 1984). The Alabama Supreme Court has established that the issue of adequate warning is not an affirmative defense, but “pertains to the initial establishment of liability.” *Id.*

Count 1 of Plaintiff’s complaint alleges that Lipitor “was not accompanied by proper warnings regarding all possible adverse side effects associated with the use of Lipitor.” (Doc. 1, ¶ 20). The complaint continues to say that “Lipitor was unaccompanied by warnings of its dangerous propensities” and that “Defendant failed to warn of the known or knowable likelihood of injury including, not limited to, the likelihood of developing rhabdomyolysis, neuropathy or myopathy.” (Doc. 1, ¶ 21).

To the extent that the complaint alleges that the warnings were inadequate because they were non-existent, the Lipitor labels that were incorporated into the complaint by reference show that such a claim is not true. The Lipitor label specifically discusses the risk of rhabdomyolysis, myopathy, and accompanying symptoms.<sup>3</sup> Plaintiff’s response, however, does not dispute the existence of these warnings. Instead, Plaintiff argues that the label is “inadequate in relaying the

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<sup>3</sup>Plaintiff lists “neuropathy” as one of his injuries. Although the Lipitor label does not specifically use this term, it refers to weakness and pain, the symptoms that define the condition of neuropathy.

full wight of such risks.” (Doc. 15-1).

With any pleading, the complaint must contain more than “a formulaic recitation of the elements of a cause of action” and cannot be based merely upon “labels or conclusions” or “naked assertions” without supporting factual allegations. *Twombly*, 550 U.S. at 555, 557. As applied in this situation, a mere statement that a warning is “inadequate” without facts supporting this assertion is insufficient.

In *Bailey v. Janssen Pharmaceutica, Inc.*, the Eleventh Circuit examined a pleading brought under an analogous provision of Florida law. 288 Fed. Appx. 597 (11th Cir. 2008). The complaint stated: “The defective [drugs] were not accompanied by adequate instructions and/or warnings to fully apprise the prescribing physicians ... of the full nature or extent of the risks and side effects associated with its use.” *Id.* at 608. The Court determined that this statement was insufficient to plead a failure to adequately warn theory, noting that “[n]owhere does the complaint recite the contents of the warning label or the information available to [plaintiff’s] physician or otherwise describe the manner in which the warning was inadequate.” *Id.* at 609.

Although Count 1 of the complaint briefly mentions that the warnings were inadequate, it does not explain *why* they were inadequate. The facts alleged to support Count 1 focus on the *non-existence* of warnings and do not provide any factual support for an allegation that the necessary warnings were present but inadequate.

Defendant argues that even the adequacy of the warnings can be decided as a matter of law by the court. (Docs. 11 & 16). Plaintiff contests the issue, arguing that the adequacy of a warning is a question of fact that can only be decided by a jury. Although the court need not decide this issue today because it will dismiss the complaint for Plaintiff’s failure to state how

the Lipitor warnings were insufficient, it does note that even *if* this issue could be decided as a matter of law, most—if not all—of the cases that Defendant cited to the court in their briefs involved the court deciding the issue at the summary judgment stage, not at the motion to dismiss stage.

Because the complaint does not state how the Lipitor warnings were inadequate, the court will GRANT Defendants motion and DISMISS Count 1 of the complaint WITHOUT PREJUDICE.

**B. Count Two: Strict Liability/Design Defect**

Defendant applies all of its arguments concerning Count 1 to Count 2 as well. Like Count 1, Count 2 alleges strict liability, which the court will interpret as a claim under the AEMLD. Although the Plaintiff labels Count 2 as a “Design Defect” claim, whereas he labels Count 1 as a “Failure to Warn” claim, the design defect alleged in Count 2 is in fact the inadequate warnings. Therefore, the court’s analysis on Count 1 applies to Count 2 in its entirety and the court will GRANT Defendants motion and DISMISS Count 2 of the complaint WITHOUT PREJUDICE.

**C. Count Three: Negligence**

Defendant argues that Count 3 should be dismissed because Plaintiff failed to allege either a cognizable duty or breach. Under Alabama law, to make a claim for negligence, the Plaintiff must alleged that the Defendant “(1) breached (2) a duty, which (3) proximately caused (4) plaintiff’s injury.” *E.R. Squibb & Sons, Inc. v. Cox*, 477 So. 2d 963, 969 (Ala. 1985).

Count 3 alleges, in part, that Defendant “held the affirmative duty to properly warn and inform consumers such as Plaintiff of the risk of injury.” (Doc. 1, ¶ 30). While Plaintiff also

alleges that Defendant had a more generic duty to “properly and safely design, manufacture, [etc.],” to the extent Count 3 alleges that Defendant had a duty directly to Plaintiff, the claim cannot be maintained. Defendant points out, and Plaintiff impliedly agrees, that under Alabama’s learned intermediary doctrine, “a [pharmaceutical] manufacturer’s duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product.” *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313 (11th Cir. 2000).

Count 3 alleges that Defendant breached its duty by “fail[ing] to disclose the known or knowable risks associated with the product . . . .” As previously discussed, to the extent that Plaintiff alleges that a warning about Plaintiff’s injuries was non-existent, that claim cannot be maintained. To the extent that he is alleging that the warnings were inadequate, the complaint provides insufficient factual support to maintain such a claim. Therefore, the court will GRANT Defendant’s motion as to Count 3 and DISMISS Count 3 WITHOUT PREJUDICE.

**D. Count Four: Breach of Implied Warranty**

Defendant argues that Plaintiff fails to state a claim for breach of implied warranty. “In an action for breach of an implied warranty, the plaintiff must prove the existence of the implied warranty, a breach of that warranty, and damages proximately resulting from that breach.”

*Barrington Corp. v. Patrick Lumber Co.*, 447 So. 2d 785, 787 (Ala. Civ. App. 1984). Plaintiff’s complaint alleges that Defendant breached the implied warranty by failing to provide warnings of the risks. As previously discussed, to the extent that Plaintiff alleges that a warning about Plaintiff’s injuries was non-existent, that claim cannot be maintained. To the extent that he is alleging that the warnings were inadequate, the complaint provides insufficient factual support to maintain such a claim. Therefore, the court will GRANT Defendant’s motion as to Count 4 and

DISMISS Count 4 WITHOUT PREJUDICE.

**E. Count Five: Breach of Express Warranty**

A breach of express warranty claim, like a breach of implied warranty claim, requires a plaintiff to plead that the defendant breached the alleged warranty. *See Gordon v. Pfizer Inc.*, No. CV-06-RRA-703-E, 2006 WL 2337002, at \*8 (N.D. Ala. May 22, 2006). Count 5 of Plaintiff's complaint pleads that Defendant breached the warranty by failing to accompany Lipitor with "any adequate warnings of its dangerous propensities . . . ." (Doc. 1, ¶ 40). As previously discussed, to the extent that Plaintiff alleges that a warning about Plaintiff's injuries was non-existent, that claim cannot be maintained. To the extent that he is alleging that the warnings were inadequate, the complaint provides insufficient factual support to maintain such a claim. Therefore, the court will GRANT Defendant's motion as to Count 5 and DISMISS Count 5 WITHOUT PREJUDICE.

**F. Count Six: Fraud**

"The elements of fraud are (1) a false representation (2) of material existing fact (3) reasonably relied on by the plaintiff (4) who suffered damage as a proximate consequence of the misrepresentation." *Exxon Mobil Corp. v. Ala. Dept. of Conservation & Natural Resources*, 986 So. 2d 1093, 1114 (Ala. 2007) (internal quotations and emphasis omitted). Count 6 pleads that a false representation occurred when "Defendant did not disclose or warn users and their physicians about the known risk of injury in using Lipitor." (Doc. 1, ¶ 44). As previously discussed, to the extent that Plaintiff alleges that a warning about Plaintiff's injuries was non-existent, that claim cannot be maintained. To the extent that he is alleging that the warnings were inadequate, the complaint provides insufficient factual support to maintain such a claim.

Therefore, the court will GRANT Defendant's motion as to Count 6 and DISMISS Count 6 WITHOUT PREJUDICE.

**G. Count Seven: Negligent Misrepresentation**

“Under Alabama law, the elements of a claim of negligent misrepresentation are: (1) a misrepresentation (2) concerning a material fact (3) justifiably relied on by the plaintiff (4) and loss or damages proximately caused by such misrepresentation.” *Industrial Partners, Ltd. v. CSX Transp., Inc.*, 974 F.2d 153, 157 (11th Cir. 1992). Count 7 alleges that a misrepresentation occurred when “Defendant falsely represented to Plaintiff, his physicians, and the general public that Lipitor was safe for use to aid in treatment of high cholesterol.” (Doc. 1, ¶ 55). As previously discussed, to the extent that Plaintiff alleges that the drug was unsafe because Defendant did not warn of the risks at all, that claim cannot be maintained. To the extent that Plaintiff is alleging that the product was not safe because the warnings on the drug were inadequate, the complaint provides insufficient factual support to maintain such a claim. Therefore, the court will GRANT Defendant's motion as to Count 7 and DISMISS Count 7 WITHOUT PREJUDICE.

**H. Count Eight: Fraud by Concealment**

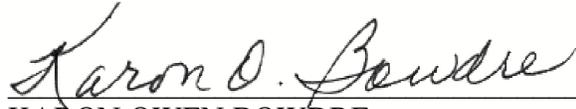
The elements of fraud by concealment, otherwise know as fraudulent suppression, are: “(1) the suppression of a material fact (2) that the defendant had a duty to communicate (3) because of a confidential relationship between the parties or because of the circumstances of the case and (4) injury resulting as a proximate consequence of the suppression.” *Ex parte Liberty Nat. Life Ins. Co.*, 797 So. 2d 457,465 (Ala. 2001); *see also Lee v. United Federal Sav. & Loan Assn.*, 466 So. 2d 131, 133 (Ala. 1985). Count 8 of the complaint alleges that Defendant

suppressed “the true facts concerning Lipitor, such as that it would cause severe, disabling painful injuries, such as rhabdomyolysis, neuropathy and myopathy.” (Doc. 1, ¶ 60). As previously discussed, to the extent that Plaintiff alleges that a warning about Plaintiff’s injuries was non-existent, that claim cannot be maintained. To the extent that he is alleging that the warnings were inadequate, the complaint provides insufficient factual support to maintain such a claim. Therefore, the court will GRANT Defendant’s motion as to Count 8 and DISMISS Count 8 WITHOUT PREJUDICE.

**IV. CONCLUSION**

For these reasons, the court finds that Plaintiff’s complaint is due to be DISMISSED WITHOUT PREJUDICE with leave to amend within 30 days.

DONE and ORDERED this 22nd day of May, 2014.

  
KARON OWEN BOWDRE  
CHIEF UNITED STATES DISTRICT JUDGE