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

BARBARA R. TUTWILER, Plaintiff, vs. SANDOZ INC., Defendant.	)	2:16-cv-01246-LSC

MEMORANDUM OF OPINION AND ORDER

Plaintiff Barbara Tutwiler ("Plaintiff") brought this products liability action against Defendant Sandoz Inc. ("Defendant"), alleging that a drug manufactured by Defendant caused her to suffer pulmonary injuries. This Court previously dismissed Plaintiff's claims but allowed her an opportunity to amend her complaint to address the pleading deficiencies. (Doc. 20.) Before this Court is Defendant's motion to dismiss the amended complaint. (Doc. 22.) For the reasons stated more fully herein, the motion is due to be granted.

I. BACKGROUND

The facts of this case, as derived from the initial complaint, are more fully set out in this Court's previous Memorandum of Opinion and Order. (Doc. 20.) The amended complaint is substantially similar. It alleges that Plaintiff's physician

prescribed amiodarone to Plaintiff for the treatment of her non-life-threatening atrial fibrillation. Defendant manufactures a generic version of amiodarone that was supplied to Plaintiff when she filled the prescription at her local pharmacy. Although amiodarone was not approved by the federal Food and Drug Administration ("FDA") for the treatment of non-life-threatening atrial fibrillation, its brand-name manufacturer marketed it extensively for this "off-label" use. Defendant "took advantage of" the brand-name manufacturer's promotional efforts and engaged in its own marketing campaign to tout the drug as an appropriate treatment for non-life-threatening atrial fibrillation. The combination of these promotional efforts misled physicians and caused them to prescribe amiodarone to patients with atrial fibrillation. Plaintiff further alleges that she was not personally informed of the risks associated with her use of amiodarone because Defendant did not distribute the FDA-mandated Medication Guide to her pharmacy, and as a result she did not receive the Medication Guide with her filled prescriptions.

II. Standard of Review

A pleading must, in general, present "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In order to withstand a motion to dismiss, however, the complaint "must contain

sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Lord Abbett Mun. Income Fund, Inc. v. Tyson*, 671 F.3d 1203, 1207 (11th Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). The plaintiff need not put forth "detailed factual allegations" in support of the claim, but there must be enough to "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

In evaluating the complaint, this Court must first "identif[y] pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* at 679. Next, this Court assumes the veracity of any well-pleaded factual allegations in order to "determine whether they plausibly give rise to an entitlement to relief." *Id.* The plaintiff is not required "to specifically plead every element of his cause of action" against the defendant, but "a complaint must still contain enough information regarding the material elements of a cause of action to support recovery under some 'viable legal theory.'" *Am. Fed'n of Labor & Cong. of Indus. Orgs. v. City of Miami*, 637 F.3d 1178, 1186 (11th Cir. 2011) (quoting *Roe v. Aware Woman Ctr. for Choice, Inc.*, 253 F.3d 678, 683–84 (11th Cir. 2001)). Mere "labels and conclusions" in the absence of concrete factual allegations that "raise a

right to relief above the speculative level" are insufficient to satisfy Rule 8(a)(2). *Twombly*, 550 U.S. at 555–56.

III. Discussion

A. Failure-to-Warn Claims

This Court previously dismissed with prejudice Plaintiff's failure-to-warn claims based on Defendant's failure to provide a Medication Guide to her pharmacy, holding that such claims were either preempted under federal law or subject to Alabama's learned-intermediary doctrine. Plaintiff's amended complaint nonetheless includes failure-to-warn causes of action alleging that Defendant failed to provide a Medication Guide to Plaintiff's pharmacy. These causes of action claim that Defendant's failure to provide the Medication Guide violates the "duty of sameness." This duty, which is imposed by FDA regulations, requires the labeling for generic medications to be the same as the labeling for the brand-name product. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011). However, even if Defendant's failure to provide a Medication Guide to Plaintiff's pharmacy for distribution runs afoul of these regulations, Plaintiff's failure-to-warn claims are nonetheless subject to Alabama's learned-intermediary doctrine.

In Alabama, "a prescription-drug manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the

[physicians] who prescribe the drug." *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 673 (Ala. 2014). "[I]f the warning to the [physician] is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient." *Id.* To overcome the learned-intermediary doctrine and hold the manufacturer liable, "[t]he patient must show 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. Plaintiff does not allege that if her physician had been aware of the risks of prescribing amiodarone to treat non-life-threatening atrial fibrillation, he would not have prescribed the drug to her. Instead, her failure-to-warn claims are based on Defendant's failure to warn *her* personally. But it does not follow from the Alabama Supreme Court's description of the learned-intermediary doctrine that if the manufacturer inadequately warns the physician, it owes an independent duty to warn the patient directly. This is the reason why this Court previously stated that "it appears unlikely that Plaintiff can state a failure-to-warn claim based on Defendant's failure to provide a Medication Guide to her pharmacy that avoids the application of both the learned-intermediary doctrine and *Mensing*" and dismissed

the failure-to-warn claims with prejudice. (Doc. 20 at 8.) The substantially similar claims alleged in the amended complaint are also due to be dismissed.

B. Off-Label Promotion Claims

This Court also previously dismissed Plaintiffs' off-label marketing causes of action without prejudice because the allegations in the initial complaint did not satisfy the heightened pleading standard for fraud under Fed. R. Civ. P. 9(b). Although Plaintiff's amended complaint alleges a cause of action for "negligent marketing and sale," she still claims that Defendant engaged in a "concerted and systemic effort to persuade physicians . . . that amiodarone was not only safe and efficacious for the treatment of atrial fibrillation but also approved for that use." (Doc. 21 at 42–43, ¶ 118.) As this Court held in dismissing Plaintiff's initial complaint, this allegation sounds in fraud. Further, Alabama law defines even *negligent* misrepresentations as legal fraud. Ala. Code § 6-5-101 ("Misrepresentations 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." (emphasis added)).

Plaintiff's claim for negligent marketing and sale is therefore subject to the pleading standard in Fed. R. Civ. P. 9(b), which requires the plaintiff "to plead the

who, what, when, where, and how of the allegedly false statements and then allege generally that those statements were made with the requisite intent." *Mizzaro v. Home Depot, Inc.*, 544 F.3d 1230, 1237 (11th Cir. 2008). To satisfy this standard, the complaint must include (1) precisely what statements were made in what documents or oral representations or what omissions were made; (2) the time and place of each such statement and the person responsible for making it; (3) the content of such statements and the manner in which they misled the plaintiff; and (4) what the defendant obtained as a consequence of the fraud. *Id.* (quoting *Tello v. Dean Witter Reynolds, Inc.*, 494 F.3d 956, 972 (11th Cir. 2007)). Plaintiff's amended complaint suffers from the same defect as her initial complaint because it similarly "fails to identify a single statement in any promotional material to support [Plaintiff's] contention that Defendant unlawfully promoted amiodarone for the treatment of atrial fibrillation." (Doc. 20 at 12.) The alleged fraud is not described with the requisite particularity, and Plaintiff's claim for negligent marketing and sale is due to be dismissed.

IV. Conclusion

For the reasons stated above, Defendant's motion to dismiss (Doc. 22) is hereby GRANTED and the amended complaint DISMISSED. Costs are taxed to Plaintiff.

DONE and **ORDERED** on August 3, 2017.

L. Scott Coogler
United States District Judge

186289