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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 Estates of ROBERT EARL DREHER, SR., Deceased	)	
Plaintiff,	)	
v.	)	**Case No. 2:14-CV-00280-KOB**
WYETH PHARMACEUTICALS, INC.	)	
Defendant.	)	

MEMORANDUM OPINION

This matter is before the court on Defendant Wyeth Pharmaceuticals, Inc.'s Motion for Summary Judgment. (Doc. 96). Plaintiff Michael Allain, as executor of the estate of Robert Earl Dreher, Sr., sued Defendant Wyeth Pharmaceuticals for failure to warn, failure to provide medication guides to Mr. Dreher's pharmacy, and "off-label" promotion of the drug Cordarone, alleging each of these actions contributed to Mr. Dreher's wrongful death. On June 29, 2015, this court dismissed all Mr. Allain's claims against Wyeth except for the claim regarding the off-label promotion of Cordarone. (Doc. 58).

As explained more fully below, the court now finds no genuine dispute as to any material fact in this case and Wyeth is entitled to judgment as a matter of law. Therefore, the court will enter summary judgment in favor of Wyeth and against

Mr. Allain regarding his only remaining claim.

I. FACTUAL BACKGROUND

Mr. Allain has not responded to Wyeth's motion for summary judgment. Therefore, whenever Allain has failed to dispute one of Wyeth's facts by not responding to the motion, the court will review Wyeth's cited evidence, and, if it in fact fairly supports Wyeth's factual assertion, it will accept Wyeth's fact as true.

In 1985, Wyeth Pharmaceuticals received FDA approval to begin manufacturing and selling Cordarone in the United States. (Doc. 34 at 8). 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. (*Id.* at 3–4). Wyeth was the sole manufacturer of Cordarone from 1985 until the FDA granted other companies approval to begin manufacturing and selling generic versions in 1998. (*Id.* at 10). Sandoz Pharmaceuticals Corporation then produced a generic version, which is the bioequivalent of Cordarone, known by the drug's chemical name, amiodarone hydrochloride. (*Id.* at 11).

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. (*Id.* at 9). According to Mr. Allain, Wyeth's marketing campaign misled "an entire generation of physicians," *id.*, and Wyeth's promotional activities "would have greatly affected" Mr. Dreher's physicians' decisions to prescribe generic versions of Cordarone to Mr. Dreher. (*Id.* at 12).

In February of 2011, Mr. 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. (*Id.* at 11). 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."

Dr. Smith is a member of the American College of Cardiology, the governing board in the United States for cardiology, and relies upon the organization's guidelines concerning how to treat atrial fibrillation patients. (Doc. 97-1 at 21–22). He also testified that those guidelines recommend the off-label use of amiodarone to treat such patients, especially when those patients have a structural abnormality, like Mr. Dreher had. (*Id.*at 22). Dr. Smith further testified that he prescribed the amiodarone knowing the risks involved and understanding that it was for the purpose of an off-label use. (*Id.* at 23).

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. (Doc. 34 at 16–17). Mr. Dreher's condition continued to deteriorate, and, on February 15, 2012, Mr. Dreher passed away at the age of eighty four. (*Id.* at 17). Mr. Allain alleges that Mr. Dreher died as a result of taking amiodarone. More specifically, Mr. Allain argues Wyeth's promotion of Cordarone's "off-label" use "was a producing and proximate cause" of Mr. Dreher's death. (Doc. 34 at 13).

II. STANDARD OF REVIEW

When a district court reviews a motion for summary judgment, it must determine two things: whether any genuine issues of material fact exist, and whether the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56.

The court must "view the evidence presented through the prism of the substantive evidentiary burden" to determine whether the non-moving party presented sufficient evidence on which a jury could reasonably find for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). The court must not weigh the evidence and make credibility determinations because these decisions belong to a jury. *See id.* at 254.

Further, all evidence and inferences drawn from the underlying facts must be viewed in the light most favorable to the non-moving party. *See Graham v. State Farm Mut. Ins. Co.*, 193 F.3d 1274, 1282 (11th Cir. 1999). The court must grant

the motion *only if* no genuine issues of material fact exist *and if* the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56.

III. DISCUSSION

Mr. Allain's First Amended Complaint provided two instances potentially showing that Wyeth's promotion of Cordarone's off-label use *could* have caused Mr. Dreher's physicians to prescribe him amiodarone for off-label use. (Doc. 58 at 13–14). This court determined, at the motion to dismiss stage, those examples were barely sufficient to establish a plausible cause of action, but noted that while the allegations were "somewhat vague and dubious," the court's role at the motion to dismiss stage is simply to determine whether Mr. Allain's claim is *plausible*. (*Id.* at 14). Now, at the summary judgment stage, the court analyzes Mr. Allain's claim in light of the total body of evidence properly before the court.

Mr. Allain provides two incidents that may have been relevant to show that Wyeth's promotion of the off-label use of Cordarone caused Mr. Dreher's death. First, 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). While these alleged communications could perhaps indicate Wyeth's wrongful or fraudulent promotion of Cordarone, Mr. Allain never submitted any actual evidence of these communications—either as to their existence or as to how they establish that

Wyeth's conduct led to Mr. Dreher's death.

Second, Mr. Allain alleged 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. (*Id.* at 21). However, Mr. Allain never provided any further evidence showing how this magazine or any other conduct actually affected the decision-making regarding Mr. Dreher's amiodarone prescription. In contrast, Dr. Smith testified that he has never been exposed to any marketing materials regarding Cordarone or amiodarone.

Since Mr. Allain's First Amended Complaint, and despite this court's acknowledgment of its doubts regarding Mr. Allain's ability to establish causation, Mr. Allain has not provided any further evidence linking Wyeth's promotion of Cordarone's off-label use to Mr. Dreher's death. Of the relevant incidents that Mr. Allain cited in his First Amended Complaint, the most recent alleged event occurred in 1998, three years before Dr. Smith was licensed to practice medicine, and 13 years before he prescribed amiodarone to Mr. Dreher.

Also, Dr. Smith testified that he has never met with any pharmaceutical or marketing representatives regarding Cordarone, nor viewed any Cordarone marketing materials. (Doc. 97-1 at 10). He also testified that he based his decision to prescribe amiodarone on his own training and experience, along with the

American College of Cardiology's published guidelines. (Doc. 97-1 at 22). Notably, Dr. Smith admitted that he decided to prescribe the medication despite his awareness of the drug's inherent risks and that such use would be off-label.

Hence, the record reflects that Dr. Smith used his own medical judgment to determine that the potential benefits of amiodarone outweighed its risks. Because Mr. Allain provided no evidence to contradict Wyeth's evidence, nothing before the court supports his claim that Wyeth's marketing or promotional activity regarding the off-label use of Cordarone directly or proximately caused Mr. Dreher's death.

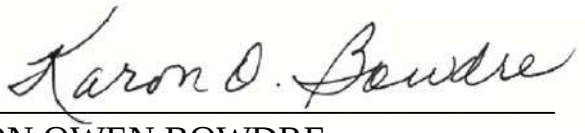
Therefore, even if Wyeth did engage in promotional campaigns—even improper or fraudulent campaigns—encouraging doctors to use Cordarone for off-label purposes, Mr. Allain has not provided any evidence showing how those alleged promotional campaigns and marketing influenced Mr. Dreher's physicians' decision to prescribe the drug to him. Without such evidence, Mr. Allain cannot establish that Wyeth's alleged improper promotion of Cordarone contributed to or caused Mr. Dreher's death. Wyeth is therefore entitled to judgment as a matter of law.

IV. CONCLUSION

For the reasons explained above, the court will GRANT Wyeth's motion for summary judgment, enter SUMMARY JUDGMENT in favor of Wyeth and

against Mr. Allain's only remaining claim in this case, and will DIRECT the Clerk to close the case. Costs are taxed as paid.

DONE this the 27th day of February, 2018.



KARON OWEN BOWDRE
CHIEF UNITED STATES DISTRICT JUDGE