Cook v. Wyeth Pharmaceuticals, Inc et al Doc. 95

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

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

HEATHER MOORE COOK, *as Executor of the Estate of* MAL M. MOORE, *deceased*,	}	
Plaintiff,	}	**Case No.: 2:15-cv-00529-MHH**
v.	}	
PAR PHARMACEUTICAL, INC,	}	
Defendant.	}	

MEMORANDUM OPINION[1]

This Alabama wrongful death action is before the Court on defendant Par Pharmaceutical, Inc.'s motion for summary judgment. (Doc. 78). Par, the manufacturer of a generic anti-arrhythmic heart medication known as amiodarone, argues that federal law preempts, and Alabama's learned-intermediary doctrine bars, plaintiff Heather Moore Cook's negligence *per se* claim against Par concerning Par's alleged failure to provide medication guides to the pharmacist who distributed

[1] The Court is issuing this opinion during a declared national emergency concerning COVID-19. To enable parties to pursue their rights during this emergency, the Court is continuing its work. For information about the timing of appeals, please review the information provided in the conclusion of this opinion. The Court is including this procedural information in each opinion that it issues during the national emergency.

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amiodarone to Ms. Cook's father, Mal Moore. For the reasons explained below, the Court grants Par Pharmaceutical's motion for summary judgment.

I. STANDARD OF REVIEW

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). To demonstrate that there is a genuine dispute as to a material fact that precludes summary judgment, a party opposing a motion for summary judgment must cite "to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." Fed. R. Civ. P. 56(c)(1)(A). "The court need consider only the cited materials, but it may consider other materials in the record." Fed. R. Civ. P. 56(c)(3).

When considering a summary judgment motion, a district court must view the evidence in the record and draw reasonable inferences in the light most favorable to the non-moving party. *Asalde v. First Class Parking Sys.*, 898 F.3d 1136, 1138 (11th Cir. 2018). Accordingly, in this opinion, the Court describes the record in the light most favorable to Ms. Cook.

II. FACTUAL AND PROCEDURAL BACKGROUND

In 1985, Wyeth Pharmaceuticals, Inc., the original manufacturer of

amiodarone, received FDA approval to market and sell the anti-arrhythmic heart medication under the brand name Cordarone®. (Doc. 47, ¶ 21).[2] The FDA's approval of Cordarone was a "special needs" approval that did not require the typical "rigorous . . . double-blind, randomized clinical trials." (Doc. 73, pp. 4–5, ¶ 13). Wyeth has not conducted the "customary and rigorous randomized clinical trials now required by the FDA for all new drug applications." (Doc. 73, pp. 4–5, ¶ 13).

The FDA approved Cordarone® "only 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. 73, p. 5, ¶ 14). According to Ms. Cook, despite the "special needs" purpose for which the FDA approved Cordarone®, Wyeth aggressively and successfully marketed Cordarone® for off-label uses as a "first line anti-arrhythmic therapy." (Doc. 73, p. 5, ¶ 14). Ms. Cook maintains that Wyeth engaged in an active promotional campaign and touted to physicians the anti-arrhythmic benefits of Cordarone®. (Doc. 73, p. 5, ¶ 15).

Ms. Cook alleges that Wyeth's campaign "focused on use of the drug for atrial fibrillation and failed to warn prescribing physicians of the potential dangers associated with amiodarone toxicity and dangers to atrial fibrillation patients."

[2] Ms. Cook initially named Wyeth as a defendant in this lawsuit. (Doc. 1). The Court has dismissed with prejudice Ms. Cook's claims against Wyeth. (Doc. 42).

(Doc. 73, pp. 5–6, ¶ 15). Ms. Cook alleges that physicians wrongfully turned to Cordarone® as a first-line therapy for atrial fibrillation because Wyeth misled the physicians about the potential dangers associated with the drug. (Doc. 73, pp. 5–6, ¶ 15).

In response to Wyeth's marketing efforts, the FDA issued warnings letters to Wyeth to stop promoting Cordarone® in a way that downplayed the risks and encouraged use of the drug as a first line anti-arrhythmic therapy. Ms. Cook alleges that the FDA warned Wyeth that it was unlawful to promote any drug for a use not described in the approved labeling of the drug. (Doc. 73, p. 6, ¶ 15). According to Ms. Cook, the FDA's warnings to Wyeth "began as early as 1988." (Doc. 73, p. 6, n. 2).

In 1999, Par received FDA approval to produce generic amiodarone. (Doc. 49-1, pp. 3–4). Par's generic version of amiodarone is "subject to the same advertising, marketing, and promotional requirements and restrictions set forth by the FDA for Wyeth in their advertising, marketing, and promotion of Cordarone®." (Doc. 47, ¶ 24). Par must provide to patients prescribed amiodarone "all FDA-approved labels, warnings, and Medication Guides with information exactly as required of the brand formulation manufacturer and as updated as directed by the FDA." (Doc. 73, p. 6, ¶ 16).

Before being prescribed amiodarone, Mr. Moore was diagnosed with non-life-

threatening atrial fibrillation. (Doc. 73, p. 6, ¶ 17). According to Ms. Cook, Mr. Moore "was not in a medical situation of 'last resort' as to the management of his atrial fibrillation." (Doc. 73, p. 6, ¶ 17). In January 2008, Mr. Moore's doctor, William Hill, prescribed a 90-day course of 200mg amiodarone tablets to treat Mr. Moore's atrial fibrillation. (Doc. 73, pp. 6–7, ¶ 18). Ms. Cook alleges that "Defendant's scheme of promoting amiodarone as a treatment for atrial fibrillation . . . has been so pervasive and insidious that it [has] wrongfully influence[d] the decisions of medical professionals, including [Mr.] Moore's doctor." (Doc. 73, p. 2, ¶ 4).

Mr. Moore filled his prescription at Jim Myers Pharmacy and took amiodarone according to the instructions. (Doc. 73, p. 7, ¶ 19). Mr. Moore's prescriptions tablets were marked with the numbers 49884-0458-05, which identified the tablets as being manufactured, marketed, and distributed by Par. (Doc. 73, p. 7, ¶ 20; Doc. 73-1, p. 2). Ms. Cook alleges that Mr. Moore did not receive a "medication guide" when he filled his amiodarone prescription. (Doc. 73, p. 7, ¶ 19). According to Ms. Cook, Par "did not provide the Medication Guides to the distributor and pharmacists in a manner to ensure distribution" to Mr. Moore with his prescription consistent with Par's obligations under state and federal regulations. (Doc. 73, p. 7, ¶ 19). Ms. Cook alleges that because Mr. Moore did not receive a medication guide, he "was not aware that his use of the medication was for an off-

label use," and he "ingested a mislabeled drug as defined by Alabama law." (Doc. 73, p. 7, ¶ 19). Had he received a medication guide, Ms. Cook alleges, Mr. Moore would have known that "amiodarone should only be used in adults with life-threatening heartbeat problems called ventricular arrhythmias and, even then, only when other treatments did not work or were not tolerated." (Doc. 73, pp. 8–9, ¶ 23) (internal quotation marks omitted).

The amiodarone medication guide outlines the drug's potential side effects. (Doc. 73, p. 10, ¶ 26). In the summer of 2012, Mr. Moore began experiencing a number of these side effects, including lung damage, shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. (Doc. 73, pp. 10–11, ¶¶ 26–27). Mr. Moore's condition continued to deteriorate, and he "was admitted to Duke Medical Center with acute and chronic respiratory failure and pulmonary fibrosis." (Doc. 73, pp. 10–11, ¶¶ 27–28). Mr. Moore died on March 30, 2013. (Doc. 73, p. 11, ¶ 28).

Ms. Cook contends that had Par provided an amiodarone medication guide to the distributor or to Mr. Moore's pharmacist to ensure distribution to Mr. Moore, then Mr. Moore "would have been aware of the serious lung related side effects that would lead to his physical injuries and death." (Doc. 73, p. 8, ¶ 21). Had he been aware of those side effects, Ms. Cook alleges, Mr. Moore "would have had a

conversation about amiodarone with his doctor and his doctor would not have prescribed" the drug. (Doc. 73, p. 14, ¶ 39). And Ms. Cook alleges that, had Mr. Moore not taken amiodarone, he would not have suffered fatal coronary and pulmonary conditions. (Doc. 73, p. 11, ¶ 29).

Ms. Cook alleges that Par previously received information concerning deaths and serious injury resulting from the improper use of amiodarone:

> [Par] has received information concerning cases of severe medical conditions resulting from the use of amiodarone, including pulmonary toxicity, pulmonary fibrosis, lung damage, hepatic damage and failure, neurotoxicity, peripheral neuropathy, neonatal hypothyroidism, optic neuritis, toxic option neuropathy, blindness, serious exacerbation of arrhythmias, and congestive heart failure, such as that experienced by [Mr.] Moore.

(Doc. 73, p. 11, ¶ 31). According to Ms. Cook, Par did not disclose to healthcare professionals, consumers, Mr. Moore's doctors, or Mr. Moore the information the company possessed concerning the incidents and actual adverse medical events, injuries, and deaths suffered by amiodarone users. Ms. Cook maintains that Par failed to comply with its state and federal obligations "[s]o that it could continue selling amiodarone for dangerous off-label uses[.]" (Doc. 73, p. 3, ¶ 5). According to Ms. Cook, "[Par's] success in the market is totally dependent on the dangerous off-label use of amiodarone to treat atrial fibrillation . . . which it can only achieve by not adequately providing a Medication Guide." (Doc. 73, p. 2, ¶ 4). To that end, Ms. Cook alleges, Par has "continued to aggressively sell amiodarone" for off-label

uses. (Doc. 73, p. 12, ¶ 33).

III. ANALYSIS

Ms. Cook's negligence *per se* claim rests on Par's alleged failure to "ensure delivery of a Medication Guide, an essential part of the product label, to [Mr.] Moore" when he was prescribed amiodarone. (Doc. 73, p. 12, ¶ 36). Par argues that federal law preempts, (Doc. 79, p. 15), and Alabama's learned-intermediary doctrine bars, (Doc. 84, p. 16; Doc. 94, p. 3), Ms. Cook's claim. "Because preemption is a principle derived from the Supremacy Clause, U.S. Const. Art. VI, cl. 2," a district court should not resolve the constitutional question "'if there is also present some other ground upon which the case may be disposed of.'" *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1328 (11th Cir. 2017) (quoting *Slack v. McDaniel*, 529 U.S. 473, 485 (2000)). Therefore, the Court first examines Par's contention that the learned intermediary doctrine bars Ms. Cook's negligence *per se* claim.

Under Alabama law, negligence *per se* is a viable common law tort theory of recovery in a wrongful death action. *See Keeton v. Fayette County*, 558 So. 2d 884, 887–88 (Ala. 1989) (reversing grant of summary judgment in wrongful death case where reasonable jury could have concluded that county's non-compliance with prison-safety ordinance proximately caused an inmate's death). A defendant may be liable for damages for negligence *per se* when the defendant's breach of a statutory duty harms the plaintiff. *Parker Bldg. Servs. Co. v. Lightsey ex rel.*

Lightsey, 925 So. 2d 927, 931 (Ala. 2005). Ms. Cook alleges that Par violated Alabama Code §§ 13A-9-41(a)(5) and (d), which "require[ed] [Par] to sell the amiodarone with all necessary labeling." (Doc. 73, p. 13, ¶ 36). Section 13A-9-41(a)(5) provides that the crime of deceptive business practices occurs when a person "[s]ells, offers or exposes for sale mislabeled commodities." Section 13A-9-41(d) defines "mislabeled" as "[v]arying from the standard of truth or disclosure in labeling prescribed by statute or lawfully promulgated administrative regulation, or if none, as set by established commercial use." Ala. Code § 13A-9-41(d). Ms. Cook asserts that Par violated its duty under Alabama Code § 13A-9-41 when it varied from the labeling requirements in 21 C.F.R. § 208.24(b). (Doc. 73, p. 13, ¶ 36).

Par argues that Alabama Code § 13A-9-41 imposes no duty on Par to ensure that consumers of amiodarone like Mr. Moore receive a medication guide. (Doc. 84, p. 15). According to Par, under Alabama's learned-intermediary doctrine, the company's duty to warn of the risks of using amiodarone to treat atrial fibrillation extends only to Mr. Moore's doctor, Dr. Hill. (Doc. 84, p. 17). As a result, Par argues, Ms. Cook's negligence *per se* claim fails under Alabama law because Par did not have a duty to warn Mr. Moore. (Doc. 84, p. 18).

Alabama adopted the learned intermediary doctrine in 1984 "in a case addressing whether a manufacturer's duty to warn extends beyond the prescribing physician to the physician's patient who would ultimately use the drugs." *Wyeth,*

Inc. v. Weeks, 159 So. 3d 649, 672 (Ala. 2014) (citing *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301 (Ala.1984)). The Alabama Supreme Court determined that "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." *Weeks*, 159 So. 3d at 673. "Thus, in Alabama, the '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.'" *Tutwiler v. Sandoz*, 726 Fed. Appx. 753, 756 (11th Cir. 2018) (per curiam) (quoting *Weeks*, 159 So. 3d at 673)).

Ms. Cook argues that the learned intermediary doctrine does not bar her claim because Alabama Code § 13A-9-41(a)(5) and C.F.R. § 208.24(b), rather than the learned intermediary doctrine, establish Par's duty of care. And even if the learned intermediary doctrine establishes Par's duty of care, Ms. Cook argues, "it's premature to rule on the learned-intermediary doctrine." (Doc. 90, pp. 4, 6). Neither federal law nor Alabama law supports Ms. Cook's arguments.

With respect to federal law, in 1998, the FDA implemented regulations concerning patient labelling. The FDA required the distribution of "patient labeling for human prescription drug products, including biological products, that the [FDA] determines pose a serious and significant public health concern." 21 C.F.R. § 208.1(a). A drug manufacturer must provide patient labeling, known as a medication

guide, when the labeling "could help prevent serious adverse effects;" or the safety information regarding the drug's "serious risk(s) . . . could affect patients' decision to use, or to continue to use, the product[.]" 21 C.F.R. § 208.1(c). In those situations, a manufacturer must ensure "that Medication Guides are available for distribution to patients by either: (1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers . . . or (2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers . . . ." 21 C.F.R. § 208.24(b)(1)–(2).

Ms. Cook contends that these federal regulations—and their incorporation into Alabama Code § 13A-9-41 as "lawfully promulgated regulations"—demonstrate that "the FDA and Alabama legislature have determined that a warning to the [learned intermediary] alone does not provide reasonable assurance." (Doc. 90, p. 2). But in enacting the medication guide regulations, the FDA stated that it did not intend to change or expand state tort law. According to the FDA, "the written patient medication information provided [in the medication guides] does not alter the duty, or set the standard of care for manufacturers, physicians, pharmacists, and other dispensers." Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998). The FDA expressly acknowledged that "courts have not recognized an exception to the 'learned intermediary' defense in [other] situations where the FDA has required patient

labeling." 63 Fed. Reg. 66378, 66384. Accordingly, the FDA medication guide regulations do not displace Alabama's learned intermediary doctrine. *See Small v. Amgen, Inc.*, 134 F. Supp. 3d 1358, 1369–70 (M.D. Fla. 2015).[3]

Neither Alabama's learned intermediary doctrine nor the FDA's medication guide regulations were part of the calculus when the Alabama Legislature enacted Alabama Code § 13A-9-41. The Alabama Legislature enacted § 13A-9-41 in 1977, the Alabama Supreme Court did not adopt the learned intermediary doctrine until 1986, and the FDA issued the medication guide regulations in 1998. Ala. Act No. 77-607; pp. 9–10, above. The commentary to § 13A-9-41 equates mislabeling with misbranding, provides multiple examples of the types of commodities to which § 13A-9-41 applies (e.g., seeds, commercial feeds, commercial fertilizer), and explains that § 13A-9-41 is designed to "collect under one heading the criminal sanctions applicable to unlawful practices" concerning the weight, quality, or labeling of commodities that are addressed in multiple sections of the Alabama Code. The commentary does not mention federal statutes or regulations.

In short, Alabama Code § 13A-9-41 and the learned intermediary doctrine operate independently of one another. Section 13A-9-41 neither contradicts nor constrains the learned intermediary doctrine, and Alabama's learned intermediary

[3] The Court notes that even if the FDA had intended to displace the learned-intermediary doctrine, it is unclear that it would have the authority to do so. *See Wyeth v. Levine*, 555 U.S. 555, 576 (2009) ("Congress has not authorized the FDA to pre-empt state law directly . . . .").

doctrine relieves a drug manufacturer of tort liability if the manufacturer fails to provide prescription drug warnings to patients. "The adequacy of the manufacturer's warning is 'measured by its effect on the physician, [] to whom [the manufacturer] owed a duty to warn, and not by its effect on the consumer.'" *Tutwiler v. Sandoz, Inc.*, 726 Fed. Appx. 753, 756 (11th Cir. 2018) (quoting *Weeks*, 159 So. 3d at 673) (alteration in *Tutwiler*).

Ms. Cook argues that "this Court cannot evaluate whether the learned intermediary doctrine applies [here] without first determining whether the warnings provided to [Dr. Hill] were adequate." (Doc. 90, p. 5). According to Ms. Cook, at this stage, "it would be . . . premature to dismiss [her] claims under the learned intermediary doctrine." (Doc. 90, p. 7). The point of the learned intermediary discussion, though, is that, as a matter of Alabama law, Par had no duty to provide a medication guide to Mr. Moore, and that is the only duty at issue in this case. Ms. Cook's theory of recovery has nothing to do with the information that Par provided to Dr. Hill. In her most recent complaint, Ms. Cook alleges that Par "failed to comply with its obligation, under federal and state law, to ensure that consumers received Medication Guides." (Doc. 73, p. 3, ¶ 5). Ms. Cook asserts that Mr. Moore "did not receive the lifesaving warning in the Medication Guide" for amiodarone, and had he received a medication guide, he would have been aware of the risks of using amiodarone to treat atrial fibrillation, he would have discussed those risks with

Dr. Hill, and Dr. Hill would not have prescribed amiodarone to Mr. Moore. (Doc. 83, p. 11; *see also* Doc. 73, pp. 7-8 & 14, ¶¶ 19-21 & 39). Thus, Ms. Cook's claim does not require the Court to examine the adequacy of the warnings that Par provided to Dr. Hill.[4]

Because the Court concludes that Alabama's learned intermediary doctrine bars Ms. Cook's negligence *per se* claim, the Court will not decide whether federal preemption applies here.

IV. CONCLUSION

For the reasons discussed above, the Court grants defendant Par Pharmaceutical's motion for summary judgment, (Doc. 78). The Court will enter a separate order closing this case.

The recent General Orders Regarding Court Operations During the Public Health Emergency Caused by the COVID-19 Virus, (N.D. Ala. Mar. 17, 2020 and April 13, 2020), do not affect the deadline to challenge a final order or judgment on appeal. *See* https://www.alnd.uscourts.gov/general-order-regarding-court-operations-during-public-health-emergency-caused-covid-19-virus, p. 2, ¶ 7. The parties are reminded that under Rule 4(a)(5) of the Federal Rules of Appellate Procedure, a party may request an extension of time for a notice of appeal. In

[4] Ms. Cook may not amend her complaint through her arguments in opposition to Par's summary judgment motion. *GeorgiaCarry.Org, Inc. v. Georgia*, 687 F.3d 1244, 1258 n.27 (11th Cir. 2012).

addition, pursuant to Rule 4(a)(6), a party may ask a district court to reopen the time to file a notice of appeal for 14 days. Parties are advised to study these rules carefully if circumstances created by the COVID-19 Public Health Emergency require motions under FRAP 4(a)(5) or 4(a)(6).

DONE and **ORDERED** this April 16, 2020.

MADELINE HUGHES HAIKALA
UNITED STATES DISTRICT JUDGE