[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 20-11926
Non-Argument Calendar

D.C. Docket No. 2:15-cv-00529-MHH

HEATHER MOORE COOK,
as Executor of the Estate of Mal M. Moore, Deceased,

Plaintiff-Appellant,

versus

WYETH PHARMACEUTICALS, INC.,
PAR PHARMACEUTICAL COMPANIES, INC.,

Defendants,

PAR PHARMACEUTICAL, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Alabama

(March 9, 2021)

Before WILSON, BRANCH, and ANDERSON, Circuit Judges.

PER CURIAM:

Plaintiff-Appellant Heather Cook, as Executor of the Estate of Mal M. Moore, appeals the district court's order granting summary judgment to Defendant-Appellee Par Pharmaceuticals, Inc. and dismissing the action with prejudice. After a thorough review of the parties' briefs and the record, we affirm.

I.

Because we write for the parties, we assume familiarity with the facts and set out only those necessary for the resolution of this appeal.

In January 2008, Dr. William Hill prescribed Mr. Moore a 90-day course of amiodarone tablets to treat Mr. Moore's atrial fibrillation. Mr. Moore filled his prescription at Jim Myers Pharmacy and followed his prescribed course of treatment.

Four years later, in the summer of 2012, Mr. Moore began to experience shortness of breath, trouble breathing, weakness, and other complications. He was subsequently hospitalized with acute and chronic respiratory failure and pulmonary fibrosis. Mr. Moore died on March 30, 2013.

The generic version of amiodarone supplied to Mr. Moore by his pharmacy was produced by Par Pharmaceuticals, Inc. (Par). According to the second amended complaint, amiodarone "was approved only as a drug of last resort for

patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia" despite it being heavily marketed for off-label uses by the brand-name manufacturer. Par is subject to the same FDA regulations and standards as the brand-name manufacturer, including the requirements for FDA-approved labels, warnings, and Medication Guides.

Ms. Cook alleges that Mr. Moore did not receive a Medication Guide with his amiodarone prescription because Par failed to "provide the Medication Guides to distributors and pharmacists in a manner to ensure distribution" to patients, as required under FDA regulation and Alabama law. Had Par ensured distribution of a Medication Guide to Mr. Moore he would have been aware of the serious potential side effects of amiodarone, would have discussed his concerns with his doctor, and his doctor would not have prescribed the medication. According to Ms. Cook, Par's failure to provide warning through Medication Guides caused Mr. Moore to take amiodarone and to eventually succumb to the drug's side effects.

Ms. Cook brought a wrongful death action against Par, specifically alleging a failure-to-warn, negligence per se claim. Par moved for summary judgment, arguing that Ms. Cook's claim was both barred by Alabama's learned intermediary doctrine and preempted by federal law. The district court concluded that the learned intermediary doctrine barred the sole claim asserted by Ms. Cook, granted summary judgment, and dismissed Ms. Cook's claims with prejudice.

II.

We review de novo the district court's grant of summary judgment, "applying the same legal standards as the district court, and construing the facts and drawing all reasonable inferences therefrom in the light most favorable to the non-moving party." *Centurion Air Cargo, Inc. v. United Parcel Serv. Co.*, 420 F.3d 1146, 1149 (11th Cir. 2005). Summary judgment shall be granted "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). "A genuine factual dispute exists only if a reasonable fact-finder could find by a preponderance of the evidence that the plaintiff is entitled to a verdict." *Kernel Recs. Oy v. Mosley*, 694 F.3d 1294, 1309 (11th Cir. 2012) (internal quotation marks omitted). We may affirm the district court's grant of summary judgment for any ground supported by the record. *Id.*

We also review de novo the district court's interpretation of state law in a diversity case. *See Winn-Dixie Stores, Inc. v. Dolgencorp, LLC*, 746 F.3d 1008, 1030 (11th Cir. 2014).

III.

Ms. Cook argues that summary judgment was improper because her claim is not barred by the learned intermediary doctrine nor preempted by federal law. Because we hold that Alabama's learned intermediary doctrine bars Ms. Cook's

negligence per se claim, we do not address the issue of preemption. *See Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1328 (11th Cir. 2017) ("Because preemption is a principle derived from the Supremacy Clause, we must first analyze whether each claim can stand under state law, and only then decide the preemption questions where necessary." (citation omitted)).

The Alabama Supreme Court adopted the learned intermediary doctrine in *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301 (Ala. 1984), which addressed the adequacy of warnings provided by a drug manufacturer. *Stone* declined to extend the manufacturer's duty to the individual to whom the drug would be prescribed, holding instead that "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 drug's use." *Id.* at 1304 (quoting *Reyes v. Wyeth Lab'ys*, 498 F.2d 1264, 1276 (5th Cir. 1974)). Pharmaceutical companies that sell "prescription drugs are required to warn only the prescribing physician, who acts as a 'learned intermediary' between manufacturer and consumer." *Id.* at 1305.

Under the learned intermediary doctrine, the adequacy of a manufacturer's warning is measured by its effect on the prescribing physician, to whom it owes a duty to warn, and not by its effect on the patient. *See Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1314 (11th Cir. 2000). Thus, "[a] prescription-drug manufacturer fulfills its duty to warn . . . by providing adequate warnings to the

learned intermediaries who prescribe the drug." *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 673 (Ala. 2014) (*superseded by statute on other grounds*, Ala. Code § 6-5-530, *as recognized in Forest Lab'ys, LLC v. Fehely*, 296 So. 3d 302 (Ala. 2019)).

> Once that duty is fulfilled, the manufacturer has no further duty to warn the patient directly. However, if the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient. The 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.

Id.

IV.

Ms. Cook argues that the district court erred in concluding her claim was barred by the learned intermediary doctrine. Her 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. According to her second amended complaint, Par "owed a duty under negligence *per se* to Plaintiff to ensure Plaintiff received the Medication Guide."

The FDA requires the manufacturers of drugs to provide a Medication Guide and ensure such Guides are made available for distribution to patients either by providing distributors and dispensers a sufficient number of the Guides or by providing the means to produce them. 21 C.F.R. § 208.24(a), (b). It is a violation of Alabama law for businesses to sell mislabeled commodities. Ala. Code § 13A-9-

41(a)(5). A commodity is mislabeled if it varies "from the standard of truth or disclosure in labeling prescribed by statute or lawfully promulgated administration regulation." *Id.* § 13A-9-41(d)(1).

Ms. Cook alleges that Par violated its duty under Alabama law when it sold amiodarone without all necessary labeling—specifically, when Par varied from the labeling requirements in 21 C.F.R. § 208.24(b) by failing to ensure a Medication Guide was provided to Mr. Moore. Par argues that Alabama Code § 13A-9-41 imposes no duty on Par to ensure that patients prescribed amiodarone, like Mr. Moore, receive a Medication Guide.

We begin by noting that we cannot accept Ms. Cook's conclusory allegation that Par violated its duty by failing to ensure that distributors and pharmacists were able to distribute Medication Guides to patients like Mr. Moore without "any significant probative evidence" to support it. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248–49 (1986). While the patient is intended to be the ultimate recipient of the information contained in the Medication Guide, we have no allegation before us that Mr. Moore's failure to receive the Guide was due to a breach of regulations by Par, as opposed to a breach by "distributors, packers, or authorized dispensers." *See* 21 C.F.R. § 208.24(b). Put simply, we have no probative evidence before us to show that Par—and not someone else in the supply

chain—failed to provide adequate Medication Guides, which is the basis for Ms. Cook's deceptive business practices claim under Alabama Code § 13A-9-41.

We also find nothing in the text of § 208.24, and Ms. Cook does not point us to any basis in Alabama law, that would lead us to conclude the FDA's Medication Guide requirement abrogates the learned intermediary doctrine. The district court ruled that "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." We agree. And other courts who have considered the Medication Guide requirement have reached the same conclusion. *See Small v. Amgen, Inc.*, 134 F. Supp. 3d 1358, 1369 (M.D. Fla. 2015) ("Plaintiffs have not identified, nor has this Court found, any cases supporting their theory that FDA regulations 'inactivate' the learned intermediary doctrine." (footnote omitted)); *Frazier v. Mylan Inc.*, 911 F. Supp. 2d 1285, 1290 (N.D. Ga. 2012); *Stephens v. Teva Pharms., U.S.A., Inc.*, 70 F. Supp. 3d 1246, 1253–54 (N.D. Ala. 2014); *Polt v. Sandoz, Inc.*, 462 F. Supp. 3d 557, 565–66 (E.D. Pa. 2020) (finding the creation of a new exception to the learned intermediary doctrine "would be a misuse of negligence per se, which does not operate to create a new duty").

V.

Because, as a matter of Alabama law, Par had no duty to provide a Medication Guide to Mr. Moore—the only duty at issue in this case—we conclude that Alabama's learned intermediary doctrine bars Ms. Cook's negligence per se claim. Accordingly, the judgment of the district court is affirmed.

AFFIRMED.