UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 17-2263

LATHAM SEAN BEAN, individually and as Personal Representative of the Estate of Hubert E. Bean Jr., Deceased,

Plaintiff - Appellant,

v.

UPSHER-SMITH PHARMACEUTICALS, INC.; TARO PHARMACEUTICALS USA, INC.,

Defendants - Appellees.

Appeal from the United States District Court for the District of South Carolina, at Florence. R. Bryan Harwell, Chief District Judge. (4:16-cv-01696-RBH)

Argued: March 21, 2019 Decided: April 8, 2019

Before WILKINSON, KING, and DUNCAN, Circuit Judges.

Affirmed by unpublished per curiam opinion.

ARGUED: Edward Kirksey Wood, Jr., WOOD LAW FIRM, LLC, Birmingham, Alabama; Samuel C. Cole, SAM COLE LEGAL SERVICES, PLLC, Plano, Texas, for Appellant. Mark C. Hegarty, SHOOK HARDY BACON, LLP, Kansas City, Missouri, for Appellees. **ON BRIEF:** Arthur J. Liederman, Nicole M. Battisiti, MORRISON MAHONEY LLP, New York, New York; Gray T. Culbreath, GALLIVAN, WHITE & BOYD, PA, Columbia, South Carolina, for Appellee Taro Pharmaceuticals USA, Inc.

Monteith P. Todd, SOWELL, GREY, STEPP, & LAFFITTE, LLC, Columbia, South Carolina, for Appellee Upsher-Smith Laboratories, LLC.

Unpublished opinions are not binding precedent in this circuit.

PER CURIAM:

Appellant here sued Taro Pharmaceuticals and Upsher-Smith Pharmaceuticals, the manufacturers of amiodarone, under South Carolina law. The suit alleged that the companies failed to warn Hubert Bean of the risks of amiodarone and, as a result, Bean took the drug and passed away. The district court dismissed the claim on the grounds that it was preempted by federal law or, alternatively, that it could not survive application of South Carolina's learned intermediary doctrine. We affirm on the second ground and do not reach the preemption question.

I.

This case was resolved on a motion to dismiss and we therefore take as true the facts as stated in Bean's Complaint. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In October 2013, Hubert Bean was prescribed amiodarone for non-life-threatening atrial fibrillation. There is no dispute that, at the time of the prescription, Bean's physician, Dr. Rajesh Malik, was aware that a course of amiodarone carried with it a risk of pulmonary toxicity as a side effect. Unfortunately, Mr. Bean experienced that side effect and died on June 20, 2014, after suffering troubled breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression.

Bean himself was not aware of the risk of pulmonary toxicity. This is because he never received the FDA-mandated Medication Guide, which, according to the Complaint, would have made him aware of the risk and convinced him not to take the drug. What is more, amiodarone is not approved by the FDA as a treatment for non-life-threatening

atrial fibrillation; Dr. Malik's prescription was an "off-label" use of amiodarone. J.A.16-17.

Latham Bean, Hubert Bean's son, brought suit against the manufacturers of amiodarone, Upsher-Smith and Taro, on May 26, 2016. As relevant here, his Complaint alleged that the manufacturers had violated their duty under South Carolina state law to warn users of their product's dangers. The Complaint also alleged that the manufacturers had unlawfully promoted amiodarone for off-label uses.

The manufacturers moved to dismiss, and the district court granted this motion. The failure to warn claim, the court ruled, was preempted by federal law or was barred by South Carolina's learned intermediary doctrine. The off-label promotion claim was dismissed as preempted by federal law. Bean appealed only the ruling on the failure to warn claim, allowing the disposition of the off-label promotion claim to stand unchallenged. Opening Br. at 3 ("On appeal, Mr. Bean challenges only the dismissal of his medication guide, failure-to-warn claims against Defendants.").

II.

We affirm the district court's application of the learned intermediary doctrine to dismiss Bean's failure to warn claim. As this is a sufficient ground on which to resolve the case, we need not reach the manufacturers' preemption argument.

In *Brooks v. Medtronic*, we noted that South Carolina law was silent as to whether it incorporated the common law doctrine of the learned intermediary. 750 F.2d 1227, 1230 (4th Cir. 1984). However, looking to a "substantial majority of jurisdictions," we concluded that the defense would apply in South Carolina. *Id.* at 1231. Accordingly, we

held that the state's law imposes on manufacturers of drugs like amiodarone a duty to warn that extends only to "physicians (or other medical personnel permitted by state law to prescribe drugs)." *Id.* (quoting *Stanback v. Parke, Davis and Co.*, 657 F.2d 642, 644 (4th Cir. 1981).

Subsequently, South Carolina's Supreme Court has proven us correct on this score. In *Madison v. American Home Products Corporation*, that court held that pharmacists could not be held strictly liable for the side effects of drugs they supply, since such liability "is inconsistent with the learned intermediary doctrine." 595 S.E.2d 493, 496 (S.C. 2004) (quoting David J. Marchitelli, *Liability of Pharmacist Who Accurately Fills Prescription for Harm Resulting to User*, 44 A.L.R. 5th 393, 419, § 2(a)(1996)). The district court was therefore correct to apply the doctrine to the present case, which was decided under South Carolina law.

Comment (b) on §6 of the Restatement (Third) of Torts, describes the "traditional[]" view that manufacturers of drugs and medical devices can discharge their common law duty by giving "warnings directed to health-care providers and not to patients." Restatement (Third) of Torts, §6, Comment (b). These healthcare providers act as "learned intermediaries," using their knowledge, training, and experience to provide the patient with "such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy." *Id.* Often, the "learned intermediary" is the patient's prescribing physician. *See e.g. Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir.1975) ("A manufacturer of an ethical drug must exercise reasonable care … to warn physicians effectively of the drug's inherent

dangers."); *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y.1993) ("The physician acts as an 'informed intermediary.'"); *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal.1988) ("patient's expectations … are those related to him by his physician, to whom the manufacturer directs the warnings regarding the drug's properties").

In this case, Dr. Malik is the learned intermediary. As Bean's physician he was best placed to evaluate Bean's medical history and circumstances and to decide what information Bean needed to give informed consent to his treatment. Accordingly, as long as the manufacturers warned Dr. Malik of the relevant risks, their duty to warn "devolves" on Dr. Malik himself. Restatement (Third) of Torts, §6, Comment (b).

Appellant concedes that Dr. Malik was aware of the risk of pulmonary toxicity, the condition which caused Bean's death. As the district court put it,

> Plaintiff does not allege that the prescribing physician did not receive the Medication Guide, was unaware of its contents, or the risk of pulmonary toxicity or lung problems possibly resulting in death. Plaintiff, in fact, alleges that the warnings contained in the Medication Guide were adequate and sufficient to warn Plaintiff of the dangers and risks of taking amiodarone. J.A. 479.

It is uncontested that Dr. Malik received all the warnings required by federal law, and that these warnings are, on their own, adequate under state law. *See* Reply Brief of Appellant at 10. He was aware that amiodarone carries with it a risk of pulmonary toxicity when he prescribed it to his patient. As plaintiff notes, the risk of pulmonary toxicity has long been known to apply to any patient taking amiodarone, regardless of the heart condition being treated. Compl., J.A. 29 at ¶ 83. Although the precise argument Bean advances on appeal appears to be a moving target, as best we can determine Bean argues that these warnings were rendered ineffective by the manufacturers' promotion of

amiodarone for off-label uses. The manufacturers, according to Bean, did not lie about the *risks* of amiodarone, they lied about its *benefits*. *Id.*

Even accepting this allegation as true, it does not defeat application of the learned intermediary doctrine in this failure to warn case. It is elementary that failure to warn claims concern misrepresentations of risks. *See e.g.*, *Mendenall v. Anderson Hardwood Floors, LLC*, 738 S.E.2d 251, 261 (S.C. 2013) (failure to warn of "dangerous conditions"); *Merchant v. Lorain Division of Koehring*, 251 S.E.2d 189, 192 (S.C. 1979) (failure to warn of "possible hazard"). When companies misrepresent the benefits of a product, they are subject to liability under different theories, such as negligent misrepresentation. *See e.g. Private Mortg. Inv. Services, Inc. v. Hotel and Club Associates, Inc.*, 296 F.3d 308, 315 (4th Cir. 2002). Appellant was aware of this distinction at the pleading stage, when he brought one set of claims premised on the manufacturers' alleged failure to warn and a separate set of claims premised on the alleged off-label promotion. But Bean declined to appeal the district court's dismissal of this second theory of liability; he cannot revive it now, repackaged as a response to the manufacturers' invocation of the learned intermediary doctrine.

The *Curcio v. Caterpillar* case, cited by appellant at oral argument, is not to the contrary. 585 S.E.2d 272 (S.C. 2003). There, an otherwise adequate warning was contradicted: one section of a user manual instructed mechanics to disconnect a machine's batteries before performing work on it while a different section of the same manual said the machine "could be started" while work was being performed, which would be impossible if the batteries were disconnected. *Id.* at 274. The later contradictory

instruction rendered the earlier warning ineffective. But here there is no contradiction. The manufacturers made Dr. Malik aware of the risk of pulmonary toxicity as they were required to do by federal law. That warning was never contradicted or diluted: There is no allegation that the manufacturers ever so much as insinuated that this risk was less severe that it really was. The only allegation is that the manufacturers misled Dr. Malik on an unrelated issue—the benefits of amiodarone—which does not come under the scope of failure to warn liability.

Nor would South Carolina create an exception to the learned intermediary doctrine for cases where the FDA requires a direct-to-consumer warning. FDA regulations state that Bean himself, as the ultimate consumer of the amiodarone, should have received a Medication Guide. *See* 21 C.F.R. §§ 208.24(a), (b). We take it as true that he did not for the purpose of this motion to dismiss. But this federal requirement does not create an exception to South Carolina's learned intermediary doctrine. Such an exception would fly in the face of the FDA's intent that the Medication Guide rule not "alter the duty, or set the standard of care for manufacturers[.]" 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998). *See also*, *In re Norplant Contraceptive Prods. Liab. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999).

The briefing and argument before us focused on the communication of risk. It is the communication of risk that lies at the heart of a failure to warn claim, not simply in the field of prescription drugs but with respect to product use in general. South Carolina's learned intermediary doctrine, as described in the Restatement (Third) of Torts, therefore applies with full force. The manufacturers of amiodarone discharged their state-law duty to warn consumers of their drug's risks when they indisputably gave Dr. Malik an

adequate warning as to the risks of amiodarone use, including pulmonary toxicity. In making this warning, Taro and Upsher-Smith did what South Carolina law requires of them.

III.

For the foregoing reasons the judgment of the district court is

AFFIRMED.