[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 17-11440
Non-Argument Calendar

D.C. Docket No. 2:12-cv-00476-PAM-MRM

REBECCA A. SMALL,
LAWRENCE W. SMALL,

Plaintiffs - Appellants,

versus

AMGEN, INC.,
PFIZER, INC.,
WYETH, INC.,

Defendants - Appellees,

DOES 1-20, et al.,

Defendants.

Appeal from the United States District Court
for the Middle District of Florida

(January 22, 2018)

Before MARCUS, JORDAN, and FAY, Circuit Judges.

PER CURIAM:

In this products liability case, Rebecca Small appeals the district court's grant of summary judgment in favor of several drug companies, arguing in part that the district court mistakenly relied on the learned intermediary doctrine to dismiss some of her claims. She claims that the district court's errors damaged her discovery efforts on all claims and requests a reversal of the district court's original summary judgment order. After thorough review of the parties' briefs and the record, we affirm.

I

Because we write for the parties, we assume their familiarity with the underlying record and recite only what is necessary to resolve this appeal.

In October of 2002, Mrs. Small began taking a drug called Enbrel to treat rheumatoid arthritis at the recommendation of her rheumatologist, Dr. Catherine Kowal, M.D.. In August of 2008, Mrs. Small was hospitalized and underwent multiple surgeries for a perforated bowel and a diverticulitis infection. Mrs. Small and her husband filed suit against the drug manufacturers of Enbrel in August of 2012, alleging that Enbrel caused her infection and subsequent surgeries.

Mrs. Small's Fourth Amended Complaint raised claims for strict liability for design defect (Count I), strict liability for failure to warn (Count II), breach of

express warranty (Count III), negligence (Count IV), and loss of consortium (Count V). The district court denied the drug manufacturers' motion to dismiss, except for any negligent failure-to-test, failure-to-inspect, or negligence per se claim that fell within Count IV. The drug manufacturers then filed a motion for summary judgment, which the district court granted in 2014 as to all of Count II as well as the negligent failure-to-warn component of Count IV. The district court held that the failure-to-warn claims were precluded by Florida's learned intermediary doctrine. The drug manufacturers then filed a motion for judgment on the pleadings, which the court denied in January of 2016.

Discovery on the remaining claims began late in 2015 and eventually required an omnibus discovery order in September of 2016. When the drug manufacturers learned in February of 2017 that the five treating physicians Mrs. Small planned to use as non-retained experts would not testify on either general or specific causation, they filed a motion to strike Mrs. Small's disclosures, which the magistrate judge granted. The drug manufacturers immediately filed for summary judgment, arguing that Mrs. Small's remaining claims failed as a matter of law without an expert to testify as to causation, a *prima facie* element of all of her claims. In 2017, the district court granted their motion for summary judgment, concluding that, without an expert to testify as to causation, each of Mrs. Small's remaining claims failed as a matter of law. Mrs. Small now appeals.

II

We review a district court's grant of summary judgment *de novo*, with all facts and reasonable inferences construed in favor of the non-moving party. *See Smith v. Owens*, 848 F.3d 975, 978 (11th Cir. 2017). The district court properly enters an order of summary judgment against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case on which that party bears the burden of proof at trial. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A "complete failure of proof regarding an essential element . . . necessarily renders all other facts immaterial." *Id.* at 323.

III

In her brief Mrs. Small does not directly address or dispute the district court's grant of summary judgment in 2017 on all of her remaining counts for failure to put forth an expert to testify on causation, which is a *prima facie* element of each of her claims. Rather, she argues that the district court's grant of summary judgment in 2014 on her failure to warn and negligent failure to warn claims in Counts II and IV was improper because there were factual questions regarding the district court's treatment of Dr. Kowal as a learned intermediary. Additionally, she argues that the district court incorrectly decided that that the direct "patient labeling requirement" in the FDA medication guidelines did not preempt Florida's learned intermediary doctrine. Together, these errors by the district court

purportedly limited her discovery, which, in turn, made prosecution of her remaining claims nearly impossible. She claims she was so prejudiced by these errors that we should vacate the initial partial summary judgment order of 2014 and begin the litigation anew from that point.

IV

A

Florida law provides that a drug manufacturer's duty to warn is "directed to the physician rather than the patient." *Buckner v. Allergan Pharm., Inc.*, 400 So.2d 820 (Fla. 5th DCA 1981). The rationale for this doctrine is that the prescribing physician, who serves as a "learned intermediary," is in the best position to weigh "potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs." *Felix v. Hoffmann-LaRoche, Inc.*, 540 So.2d 102, 104 (Fla. 1989). Thus, if the warning to the physician is adequate, the manufacturer has fulfilled its duty. *See Buckner v. Allergan Pharms., Inc.*, 400 So.2d 820, 822 (Fla. 5th DCA 1981). Further, regardless of the sufficiency of the warning, where "a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that the learned intermediary doctrine applies or that the causal link is broken and the

plaintiff cannot recover." *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 n.8 (11th Cir. 2002).

Dr. Kowal, Mrs. Small's rheumatologist, had 22 years of experience. She intentionally selected Enbrel for Mrs. Small, despite the risk of possible infections, because other forms of rheumatoid arthritis therapy had failed. Because Dr. Kowal was involved in clinical trials with Enbrel, and Mrs. Small was a participant in those trials, Dr. Kowal even had more reason to know of and discuss possible side-effects or concerns associated with Enbrel. The record shows that Dr. Kowal knew that infections were possible from taking Enbrel, but she prescribed it for Mrs. Small anyway because the benefits outweighed the risks. When "the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated," causation on a failure to warn claim fails. *See Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995). On this record, therefore, the district court properly held in 2014 that Mrs. Small's treating physician, Dr. Kowal, qualified as a learned intermediary, and that the "defendants' purported failure to warn of asymptomatic infections could not have been the proximate cause of Ms. Small's injuries." *See id.* at 1192 ("The learned intermediary rule provides that the failure of the manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of a patient's injury if the prescribing physician

had independent knowledge of the risk that the adequate warning should have communicated.")

B

The district court, in discussing the operation of the learned intermediary doctrine in Florida, examined the FDA medication guide regulations, Congress' intent in passing the regulations, and the FDA's own comments regarding the labeling requirements. *See Small v. Amgen, Inc.*, 134 F. Supp. 3d 1358, 1368-69 (M.D. Fla. 2015). The FDA explained that the purpose of the medication guide regulations was to "provide information when the FDA determines in writing that it is necessary to patients' safe and effective use of drug products." 21 C.F.R. 208.1(b).

Mrs. Small contends that the FDA medication guide regulations preempt Florida's learned intermediary doctrine. In considering preemption, we must remember that "the historic police powers of the States are not superseded unless that was the clear and manifest purpose of Congress." *Fresenius Med. Care Holdings, Inc. v. Tucker*, 704 F.3d 935, 939-940 (11th Cir. 2013). In cases of implied preemption, we consider "the promulgating agency's contemporaneous explanation of its objectives' as well as the agency's current views of the regulation's pre-emptive effect." *Id.* at 941.

As it set out its final version of this rule, the FDA responded to concerns that the labeling requirements would change the legal liability of manufacturers, physicians, and dispensers of prescription drugs by abrogating the "learned intermediary doctrine." *See* 63 Fed Reg. 66378, 66383-84 (Dec. 1, 1998). The FDA stated that it "[did] not believe that this rule would adversely affect civil tort liability" and that " the written patient medication information provided [did] not alter the duty, or set the standard of care for manufacturers, physicians, pharmacists, and other dispensers." *Id.* at 63384. In addition, the FDA indicated it had no evidence that its current patient labeling had caused "a noticeable change in tort rules affecting civil liability." The FDA concluded that "courts have not recognized an exception to the 'learned intermediary' defense in situations where FDA has required patient labeling, and . . . seem increasingly reluctant to recognize new exceptions to this defense." *Id.*

Given the FDA's own explanation of the impact of patient labeling requirements, we conclude that the medication guide regulations do not preempt Florida's learned intermediary doctrine. *See Fresenius Med. Care Holdings*, 704 F.3d at 941.

C

Regarding discovery and proof of causation, in complex cases where a jury is asked to assess complex medical or scientific issues outside the scope of a

layperson's knowledge, an expert's testimony is required. *See Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1256 (11th Cir. 2010). *See also Shepard v. Barnard*, 949 So.2d 232, 233 (Fla. 5th DCA 2007) (approving trial court's grant of summary judgment against plaintiff after excluding plaintiff's medical experts' testimony, because the doctors were needed "to provide opinions regarding any causal link between the alleged injury and the medical treatment"). Without expert testimony, the plaintiff's claim fails as a matter of law. *See Guinn*, 602 F.3d at 1256. Similarly in *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1316 (11th Cir. 2014), which applied Florida law, we affirmed the district court's summary judgment where the plaintiff's only expert failed to meet the *Daubert* standards and the plaintiff had no other expert to testify. (To prove the medical product caused the plaintiff's injury, the plaintiff was "required to have *Daubert*-qualified, general and specific-causation-expert testimony that would be admissible at trial to avoid summary judgment.").

Because Mrs. Small bases her appeal on the 2014 summary judgment order rather than on the 2017 summary judgment order, she does not address her lack of expert testimony for causation directly. Instead, it appears she hopes to moot the later order, "akin . . . to the concept of the fruit of the poisonous tree." But Mrs. Small has not explained why she did not engage an outside expert to testify, or confirm with her five treating physicians that they would be willing to testify as to

causation on her behalf. Her inability to prove general and specific causation, a *prima facie* element of all the claims on which the district court granted summary judgment in 2014 and 2017, is a critical flaw. The district court thus properly addressed this shortcoming by granting the drug manufacturers' second motion for summary judgment in 2017.

By failing to challenge the district court's grant of summary judgment in 2017 for lack of expert testimony to prove causation, Mrs. Small has waived that argument, and she cannot prevail on appeal. *See Sapuppo v. Allstate Floridian Ins. Co.*, 739 F.3d 678, 680 (11th Cir. 2014) ("When an appellant fails to challenge properly on appeal one of the grounds on which the district court based its judgment, he is deemed to have abandoned any challenge of that ground, and it follows that the judgment is due to be affirmed.")

We therefore affirm the summary judgment orders of 2014 and 2017 by the district court.

V

The judgment of the district court is affirmed.

AFFIRMED.