[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 13-12803
Non-Argument Calendar

D.C. Docket No. 1:06-cv-03074-JEC

DAWN BROWN,

Plaintiff-Appellant,

versus

ROCHE LABORATORIES, INC.,
HOFFMAN-LA ROCHE, INC.,

Defendants-Appellees,

EON LABS, INC., et al.,

Defendants.

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

(May 29, 2014)

Before TJOFLAT, PRYOR and FAY, Circuit Judges.

PER CURIAM:

Dawn Brown appeals the summary judgment against her complaint and in favor of Roche Laboratories, Inc., and Hoffman-La Roche, Inc. Brown alleged that she had a severe allergic reaction to an antibiotic manufactured by Roche, and that its warning label failed to state what cautionary procedures to follow before administering the antibiotic to penicillin-sensitive patients. After Brown proffered Dr. Manfred E. Wolff as an expert to testify that the antibiotic, Rocephin, caused Brown's injury and had an ineffective warning label, Roche filed motions to exclude Wolff's testimony and for summary judgment, which the district court granted. The district court ruled that Wolff was not qualified to testify that Rocephin caused Brown's injury or that the warning label was ineffective; that Wolff's opinions on those subjects were unreliable; and that Brown could not establish causation to support her claims without Wolff's testimony. The district court also ruled, alternatively, that Brown's claim was barred under the learned intermediary doctrine. We need not address the decision to exclude Wolff's testimony. Undisputed evidence established that the physician who administered Rocephin to Brown knew of her penicillin sensitivity and the risks of cross-reactivity between that antibiotic and Rocephin. Because the treating physician's decision eliminated any causal connection between Rocephin and Brown's injury, we affirm.

Brown developed a sinus infection that a physician at her primary care clinic treated with Bactrim, a sulfonamide antibiotic manufactured by Eon Labs, Inc. Thirteen days later, Brown returned to the clinic complaining of a fever, photophobia, a headache, neck pain, and blisters in her mouth and throat. Dr. Puvi Seshiah thought that Brown had bacterial meningitis and treated the illness by giving her two injections of Rocephin, a cephalosporin antibiotic manufactured by Roche. Seshiah knew that Brown had experienced nausea as a side effect to penicillin and that there was a possible cross-reactivity between penicillins and Rocephin, but Seshiah thought that the benefits of using Rocephin outweighed any potential risk that Brown would have an adverse reaction to the antibiotic. Thirty minutes later, Brown developed a flat rash on her trunk and back. Brown's symptoms worsened overnight, and when she returned to the clinic the following day, her physician, Dr. Savitha Elam Kootil, and a dermatologist, Dr. John H. Strickler Jr., diagnosed Brown as suffering from Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis, two forms of a life-threatening skin condition that can be caused by an adverse reaction to a drug and that results in blistering of the mucous membranes and epidermal necrosis.

Brown filed a complaint against Roche and Eon in a Georgia court. Brown complained that Roche and Eon were negligent in labeling Rocephin and Bactrim; Roche and Eon were strictly liable for their defective labels; Eon and Roche

"breached the implied warranty that their respective drugs, Bactrim and Rocephin were of merchantable qualify and fit for such use"; and Roche and Eon misrepresented the safety and effectiveness of Rocephin and Bactrim. Roche and Eon removed Brown's complaint to the district court based on diversity of citizenship. 28 U.S.C. § 1332(a). Brown later dismissed her complaint against Eon.

Brown proffered Wolff as an expert to testify that Rocephin caused Brown's skin condition and that the warning label for Rocephin should have instructed physicians to perform "precautionary skin testing for . . . determinants of penicillin and substitut[e] . . . a suitable alternative antibiotic for patients who have a severe penicillin allergy." Wolff prepared a report opining that Brown developed Stevens-Johnson Syndrome within 30 minutes of receiving a dose of Rocephin because that antibiotic, like amoxicillin, contains a square β-lactam ring in its chemical structure; Brown did not react to Bactrim, which she ingested for 14 days, because it does not have a square β-lactam ring in its chemical structure; and the warning label for Rocephin, which stated that it "should be given cautiously to penicillin-sensitive patients" and "administered with caution to any patient who has demonstrated some form of allergy, particularly to drugs," was "ineffective, vague, ambiguous, and unclear." Wolff based his opinion on his "knowledge on the mechanism of action of drugs, their pharmacology, their allergenicity, and their

toxicity" and his review of Brown's medical records; the warning label for Rocephin; medical publications about the treatment of bacterial infections, drug allergies, Stevens-Johnson Syndrome, and Toxic Epidermal Necrolysis; and a case study describing a patient's reaction to a generic form of Rocephin that had "not [been] approved by the FDA" when Brown developed her skin condition. Wolff's curriculum vitae stated that he had a doctorate in pharmaceutical chemistry, had conducted extensive research, and had patent experience with pharmaceuticals. Wolff proffered that he was an "expert in drug action and drug discovery, and in particular the area of hormones: Steroid, and prostaglandins."

Roche filed a motion to exclude Wolff's testimony and attached to its motion several depositions, including that of Brown's treating physician, Dr. Seshiah. Seshiah testified that Brown appeared at the after-hours sick clinic at Kaiser Permanente Medical Center of Gwinnett and complained of symptoms consistent with bacterial meningitis. Seshia learned from reviewing Brown's medical records and questioning her that she had suffered nausea as a side effect from penicillin in the past, but she had taken Augmentin, which is also a penicillin, recently without incident. Although Seshiah knew of and noted in Brown's medical record that he was concerned about the possibility of cross-reactivity with Rocephin, Seshiah decided that the benefits of using Rocephin to treat Brown, who was "very ill," while she waited for further treatment in an emergency room

outweighed the risk that she would have a reaction to the antibiotic. When asked what caused the rash on Brown's skin, Seshiah said he could not determine the cause without examining Brown, but Seshiah opined that it could be attributable to one of the several medicines that Brown had ingested before she appeared at the clinic; a "viral syndrome"; a "tick bite fever[]"; a "febrile illness"; or the Rocephin.

The district court granted the motion of Roche to exclude Wolff's testimony. The district court ruled that Wolff was not qualified to testify about the cause of Brown's skin condition because of his lack of "expertise concerning the drugs at issue . . . or their connection to SJS/TEN" and that Wolff was not qualified to testify about the efficacy of the warning label for Rocephin when he lacked "knowledge[] about FDA regulatory practice and requirements." The district court also ruled that "Wolff's medical causation opinion [was] not sufficiently reliable to be admitted under [Federal] Rule [of Evidence] 702 and the standards of *Daubert* [*v. Merrell Dow Pharm., Inc.*], 509 U.S. 579 [,113 S. Ct. 2786] (1993)." The district court lacked "confidence" in Wolff's opinion because he "admitted during his deposition that [Brown] had been exposed to both Rocephin and Bactrim during the relevant time frame, and that either drug [could] cause SJS/TEN"; he failed to test, publish, or subject his opinion to peer review, to "estimate its potential error rate," or to account for the "general acceptance in the field" that "Bactrim is more likely to cause SJS/TEN than Rocephin"; and he "ignored or

dismissed highly relevant and unfavorable evidence" that Brown exhibited symptoms that "are well-known early indicators of SJS . . . during the typical one to four-week latency period for [its] onset" before "she ingested Rocephin." And the district court criticized Wolff's methodology as "consist[ing] solely of pointing out a supposed temporal relationship between [Brown's] ingestion of Rocephin and the onset of her SJS/TEN symptoms" that was not a "reliable indicator of a causal relationship" because "the undisputed evidence suggest[ed] that [her] SJS symptoms preceded her ingestion of Rocephin."

The district court entered summary judgment in favor of Roche. The district court ruled that Brown's complaints about negligence and strict liability failed because she did not introduce any evidence, other than Wolff's testimony, to establish that the warning label for Rocephin was defective or that Rocephin caused her skin condition. In the alternative, the district court ruled that Brown's complaints were barred under the learned intermediary doctrine in the light of undisputed testimony from her treating physician that he knew about Brown's sensitivity to penicillin and the possibility that she would react to Rocephin and nevertheless decided to administer the drug. *See Talton v. Arnall Golden Gregory, LLP*, 622 S.E.2d 589, 593–94 (Ga. Ct. App. 2005). The district court also ruled that Brown's complaints about a breach of warranty and misrepresentation failed because they were "merely a reframing of [her] failure to warn claim" and,

alternatively, those complaints failed because Brown did not "allege or prove privity, a required element of a breach of warranty claim under Georgia law" or allege with specificity what fraudulent and negligent misrepresentations were made by Roche.

The district court did not err when it entered summary judgment in favor of Roche. Even if the district court had admitted Wolff's testimony, Brown could not prove that the failure of Roche to warn physicians to test and substitute an alternative antibiotic for penicillin-sensitive patients was the proximate cause of Brown's skin condition. Under Georgia law, which the parties agree applies, if a manufacturer of a prescription drug warns a patient's physician of any risks or hazards of the drug and, despite the known risk of harm, the physician administers the drug, the manufacturer is insulated from liability for injuries suffered by the patient. *See Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 815–16 (11th Cir. 2010) (citing decisions of the Supreme Court of Georgia and the Georgia Court of Appeals). "[W]here '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 causal link is broken and the plaintiff cannot recover.'" *Id.* at 816 (quoting *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 n.8 (11th Cir. 2002)). Dr. Seshiah, who administered the Rocephin testified, without dispute, that he

knew Brown was sensitive to penicillin and that there was a possible cross-reactivity between penicillin and Rocephin, yet he decided to treat Brown with Rocephin. The reasoned decision by Seshiah to administer Rocephin to Brown severed any causal link between the alleged ineffectiveness of the warning label for Rocephin and Brown's injury. No material factual dispute remained that required resolution by a jury.

We **AFFIRM** the summary judgment in favor of Roche.