UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 14-1244

CAROLYN LEWIS,

Plaintiff - Appellant,

and

KENNETH LEWIS; AUGUSTINA BROWN-SINGLETARY; ANDRE SINGLETARY-SMITH; KARIN HARRISON; ROBERT HARRISON; PATRICIA HEADRICK; DARRELL HEADRICK; KATIE USZLER; NICK USZLER; KELLY YOUNG; KENNETH YOUNG,

Plaintiffs,

v.

JOHNSON & JOHNSON; ETHICON, INC.,

Defendants - Appellees,

and

ETHICON WOMEN'S HEALTH AND UROLOGY; GYNECARE; AMERICAN MEDICAL SYSTEMS, INC.,

Defendants.

Appeal from the United States District Court for the Southern District of West Virginia, at Charleston. Joseph R. Goodwin, District Judge. (2:12-cv-04301; 2:12-md-02327)

Argued: January 27, 2015 Decided: March 2, 2015

Before MOTZ and DIAZ, Circuit Judges, and DAVIS, Senior Circuit Judge.

Affirmed by unpublished per curiam opinion.

ARGUED: Adam Steffen Davis, WAGSTAFF & CARTMELL LLP, Kansas City, Missouri, for Appellant. David B. Thomas, THOMAS COMBS & SPANN, PLLC, Charleston, West Virginia, for Appellee. **ON BRIEF**: Julie L. Rhoades, MATTHEWS & ASSOCIATES, Houston, Texas, for Appellant. Charles C. Lifland, Los Angeles, California, Stephen D. Brody, David K. Roberts, O'MELVENY & MYERS LLP, Washington, D.C.; Philip J. Combs, THOMAS COMBS & SPANN, PLLC, Charleston, West Virginia; Christy D. Jones, BUTLER SNOW LLP, Ridgeland, Mississippi, for Appellees.

Unpublished opinions are not binding precedent in this circuit.

PER CURIAM:

Texas resident Carolyn Lewis brought this diversity products liability suit against Ethicon, Inc., a subsidiary of Johnson & Johnson. She seeks damages for injuries allegedly resulting from tension-free vaginal tape (TVT) manufactured by Ethicon. Lewis appeals the grant of summary judgment on her failure-to-warn claim, and the judgment as a matter of law on her design defect claim. We affirm.

I.

In 2009, urogynecologist Muriel Boreham diagnosed Lewis with stress urinary incontinence (SUI), a condition causing urine leakage during physical exertion. After a series of tests, Dr. Boreham recommended the insertion of a TVT mesh device to correct the SUI.

In October of that year, Dr. Boreham implanted a TVT in Lewis. At a follow-up visit, Dr. Boreham told Lewis that she "was healing" and implied that Lewis could resume sexual activity with her husband. Lewis attempted to do so, but found that she suffered from pain during sexual activity. She also developed intermittent pelvic pain during daily activities. Lewis never returned to or further consulted with Dr. Boreham.

Almost three years later, on July 25, 2012, Lewis filed this action in the Northern District of Texas, seeking

compensatory and punitive damages. Pursuant to the Multidistrict Litigation Statute, 28 U.S.C. § 1407, the case was later transferred to the Southern District of West Virginia. Prior to trial, in May 2013, Lewis visited urologist Dr. Philippe Zimmern to discuss her symptoms. Dr. Zimmern told Lewis about the option of "explant" surgery to remove parts of the TVT. Lewis elected to have the procedure. After Dr. Zimmern performed the surgery in September 2013, Lewis's pain decreased noticeably, but she was still not "a hundred percent better."

In December 2013, Ethicon moved for summary judgment, which the district court granted as to Lewis's failure-to-warn claim. At trial on her remaining claims, Lewis presented testimony from current and former Ethicon employees and from five experts. At the conclusion of Lewis's case, the court requested briefing on the possibility of a directed verdict. After the parties briefed the issue and the district court heard argument, it directed a verdict for Ethicon on Lewis's design defect claim. Lewis noted a timely appeal.

II.

We first address the district court's grant of summary judgment to Ethicon on Lewis's failure-to-warn claim.

A.

We review a district court's grant of summary judgment de novo. Glynn v. EDO Corp., 710 F.3d 209, 213 (4th Cir. 2013). In so doing, we apply the same legal standards as the district court. We view the evidence in the light most favorable to the non-moving party, and affirm the grant of the motion only where there is no genuine dispute as to a material fact and the moving party is entitled to judgment as a matter of law. See Nader v. Blair, 549 F.3d 953, 958 (4th Cir. 2008).

To prevail on a failure-to-warn claim under Texas law, which the parties agree applies in this case, a plaintiff must show both that the warning was inadequate, and that the inadequate warning "was a producing cause of the plaintiff's condition or injury." Porterfield v. Ethicon, Inc., 183 F.3d 464, 468 (5th Cir. 1999) (per curiam) (applying Texas law). To establish a "producing cause," a plaintiff must show that a warning's alleged inadequacies "would have changed [the] prescribing physician[']s] decision to prescribe" the device. Centocor, Inc. v. Hamilton, 372 S.W.3d 140, 172 (Tex. 2012). Under Texas law, a device manufacturer's duty to warn of risks extends only to the physician prescribing the device, "the learned intermediary," and not to the "end user" of the device. Id. at 157. When a plaintiff offers no evidence that a different warning would have changed her physician's decision to

prescribe a device, the inadequate warning cannot have caused the plaintiff's injury. Id. at 170-71.[1]

B.

Lewis presented no evidence that Dr. Boreham relied on the warning in Ethicon's patient brochure in deciding to prescribe the TVT. Dr. Boreham herself testified that she did not recall whether she had a TVT patient brochure at the time of Lewis's surgery, and that if she had one, she might have given it to Lewis or used the picture of the procedure in the brochure to explain how the device works. Dr. Boreham further stated that she would not have verified the accuracy of the information in the brochure. None of this testimony establishes that Dr. Boreham considered the patient brochure warning, let alone relied on it, in deciding to prescribe the TVT to Lewis.

[1] Citing McNeil v. Wyeth, 462 F.3d 364, 373 (5th Cir. 2006), Lewis argues that a plaintiff may prevail on a failure-to-warn claim by showing that a stronger warning would have led the plaintiff to withhold consent to the procedure. But McNeil explicitly acknowledges that the relevant test is whether the "alleged inadequacy caused [the plaintiff's] doctor to prescribe the drug." 462 F.3d at 372 (quotations and citation omitted). And McNeil certainly does not alter the rule that courts must look to the prescribing doctor's behavior in deciding whether the inadequate warning is the "producing cause" of a plaintiff's injury. Moreover, the Supreme Court of Texas recently reaffirmed that the inquiry under Texas law remains whether the warning would have changed the decision of the prescribing physician. Centocor, 372 S.W.3d at 170; see also Ackermann v. Wyeth Pharm., 526 F.3d 203, 208 (5th Cir. 2008).

Nor did Lewis offer evidence that Dr. Boreham relied on the TVT's instructions for use in deciding to prescribe the device. Although Dr. Boreham testified that she had read the document during her surgical fellowship in 2002, she stated that she did not read it again before prescribing the TVT to Lewis in 2009. Moreover, when asked whether she relied on the instructions for use in prescribing the TVT, Dr. Boreham answered: "I did not." Dr. Boreham testified that she instead relied on Lewis's symptoms, bladder diary, urodynamics, physical exam, and discussions regarding her desired outcomes in deciding to prescribe the TVT.

This evidence does not establish that "but for the inadequate warning," Dr. Boreham "would not have used or prescribed" the TVT. Ackermann, 526 F.3d at 208 (quotation omitted) (emphasis added). When a physician relies on her own experience and examination of a patient in deciding to prescribe a device, and not on the device's warning, the warning is not the cause of the patient's injury.

The Fifth Circuit, applying Texas law, has so held. In Pustejovsky v. PLIVA, Inc., the court upheld a grant of summary judgment to the defendants on a failure-to-warn claim where the prescribing physician testified that she had not read or relied on the medical device's package insert. 623 F.3d 271, 277 (5th Cir. 2010). Similarly, in Porterfield, the court upheld a grant

of summary judgment to a surgeon who testified that he had not read the device's instructions for use or any other literature from the manufacturer. 183 F.3d at 468. Lewis attempts to distinguish these cases on the basis that Dr. Boreham did, at one time, read the instructions for use, but she offers no evidence to rebut Dr. Boreham's own testimony that she did not rely on the document in deciding to prescribe the TVT.

Accordingly, we agree with the district court that Lewis did not offer sufficient evidence to create a dispute as to material fact regarding whether a different warning would have changed Dr. Boreham's decision to prescribe the TVT.

III.

We next address Lewis's challenge to the district court's exclusion of parts of Dr. Uwe Klinge's expert opinion testimony. Lewis argues that the court erroneously prevented Dr. Klinge from connecting his observations about the condition of Lewis's mesh with her pain. We review evidentiary rulings, including rulings on the admissibility of expert testimony, for abuse of discretion. United States v. Davis, 690 F.3d 226, 257 (4th Cir. 2012). When reviewing a district court's rulings on expert opinion testimony, the Supreme Court has instructed that "deference . . . is the hallmark of abuse-of-discretion review." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 143 (1997).

Before trial, Ethicon moved to exclude portions of Dr. Klinge's expert report related to the TVT mesh. It did so on the grounds that Dr. Klinge, a former hernia specialist and not a pathologist, was unqualified to offer expert testimony on that issue, and that his testimony was unreliable. The district court granted the motion. It found that Dr. Klinge's testimony was unreliable, noting that his report did not explain how he had selected the TVT samples on which his opinions were based and did not indicate that his analysis "controlled for error or bias."

At trial, Ethicon again raised these issues at sidebars and in objections, including a continuing objection, throughout Dr. Klinge's direct examination. Although the court allowed Dr. Klinge to testify regarding the general characteristics of mesh samples explanted from Ms. Lewis, it concluded that Dr. Klinge was not qualified to offer testimony regarding specific causation. On this basis, it sustained several of Ethicon's objections. Lewis challenges three of these rulings: first, the ruling preventing Dr. Klinge from opining on whether "entrapped nerves in this slide . . . would indicate chronic pain for Ms. Lewis"; second, the striking of Dr. Klinge's answer to the question whether plaintiff's slides "would relate to any complications of pain in Ms. Lewis"; and third, the striking of

Dr. Klinge's opinion that loose particles from the TVT "can very good explain the manifestation of pain" in Ms. Lewis.

The district court did not abuse its discretion in making these rulings. Dr. Klinge was a specialist in hernia surgery, not pathology or stress urinary incontinence. He did not receive training or board-certification in pathology. Dr. Klinge had never treated Lewis, performed surgery to treat SUI, or collected and studied mesh explants from SUI patients. The district court was clearly within its discretion in concluding that Dr. Klinge's opinions regarding Lewis's pain and mesh explant were beyond his area of expertise, and so did not abuse its discretion in excluding those portions of Dr. Klinge's testimony.

IV.

Finally, we consider Lewis's contention that the district court erred in directing a verdict for Ethicon on her design defect claim.

A.

We review the grant of a motion for a directed verdict de novo. Teague v. Bakker, 35 F.3d 978, 985 (4th Cir. 1994). "[T]he test is essentially whether, without weighing the evidence or considering the credibility of the witnesses, there can be but one conclusion as to the verdict that reasonable

jurors could have reached." Gairola v. Va. Dept. of Gen. Servs., 753 F.2d 1281, 1285 (4th Cir. 1985) (quotation and citation omitted). We affirm "when any verdict in favor of the nonmoving party necessarily will be premised upon speculation and conjecture" because "a mere scintilla of evidence is not enough to defeat a motion for a directed verdict." Id. (quotation and citation omitted).

To avoid a directed verdict, "the plaintiff must present sufficient evidence to establish a prima facie case." Id. Under Texas law, "[t]o recover for a products liability claim alleging a design defect, a plaintiff must prove that (1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." Timpte Indus., Inc. v. Gish, 286 S.W.3d 306, 311 (Tex. 2009). The district court directed a verdict for Ethicon based on the third element.

With respect to this element, "[a] plaintiff must establish a causal connection between the defective condition and the plaintiff's injuries or damages." Am. Tobacco Co., Inc. v. Grinnell, 951 S.W.2d 420, 434 (Tex. 1997) (internal citation,

alteration, and quotations omitted).[2] That is, the defect in the product "must be a substantial factor in bringing about the injury, and a cause without which the injury would not have happened." BIC Pen Corp. v. Carter, 346 S.W.3d 533, 541 (Tex. 2011).

Whether expert opinion testimony is necessary to prove a plaintiff's theory of causation is a question of law. Mack Trucks, Inc. v. Tamez, 206 S.W.3d 572, 583 (Tex. 2006). Texas law does not always require that an expert conclusively opine that the defect in a product caused the plaintiff's injury. Kindred v. Con/Chem, Inc., 650 S.W.2d 61, 63 (Tex. 1983). Rather, in many cases, a jury may infer causation, "like any other ultimate fact," from circumstantial evidence. Gladewater v. Pike, 727 S.W.2d 514, 518 (Tex. 1987).

[2] Lewis's assertion that a plaintiff need merely establish that the TVT –- and not some defect in it -– caused her injuries fails. Although, as Lewis notes, a Texas statute codifying the specific causation requirement in design defect cases does not, by its own terms, "apply to" medical device cases, the section also "is not declarative . . . of the common law . . . and shall not be construed to restrict the courts of this state in developing the common law with respect to any product which is not subject to this section." Tex. Civ. Prac. & Rem. Code § 82.005(d)(2), (e) (2011). The Supreme Court of Texas has been clear that Texas common law requires a plaintiff in a strict liability design defect case to show both the defective condition of a product and a causal connection between that defect and a plaintiff's injuries. Lucas v. Tex. Indus., Inc., 696 S.W.2d 372, 377 (Tex. 1984); Armstrong Rubber Co. v. Urquidez, 570 S.W.2d 374, 376 (Tex. 1978)).

However, the Supreme Court of Texas has repeatedly made clear that "[e]xpert testimony [on causation] is required when an issue involves matters beyond jurors' common understanding." Mack Trucks, 206 S.W.3d at 583. In a products liability case, proof other than expert testimony provides sufficient evidence of causation "only when a layperson's general experience and common understanding would enable the layperson to determine from the evidence, with reasonable probability, the causal relationship" between the defect and the injury. Id. at 583.

For example, in Mack Trucks, the Supreme Court of Texas required expert testimony to establish causation because a "lay juror's general experience and common knowledge do not extend to whether design defects such as those alleged in this case caused the releases of diesel fuel during a rollover accident." 206 S.W.3d at 583. Similarly, in BIC Pen, that court required expert testimony to establish causation because "the impact of [defects in a lighter] on how [the lighter] would have functioned in the hands of a child . . . is not an issue within a lay juror's general experience and common understanding." 346 S.W.3d at 542.

Texas courts have regarded expert testimony on causation as particularly vital in cases involving complex medical devices and medical diagnoses. "The general rule has long been that expert testimony is necessary to establish causation as to

medical conditions outside the common knowledge and experience of jurors." Guevara v. Ferrer, 247 S.W.3d 662, 665 (Tex. 2007); see also Anderson v. Siemens Corp., 335 F.3d 466, 475 (5th Cir. 2003) (applying Texas law) ("[o]rdinarily, expert testimony is needed to satisfy the reasonable medical probability standard for establishing a causal link.").

B.

Here, Lewis alleges that the TVT's heavyweight, small-pore mesh caused degradation, scar tissue, and nerve entrapment, which in turn caused her pelvic pain and dyspareunia. She also alleges that the mechanical cutting of the TVT's mesh caused loose particles, which in turn caused her injuries. Whether any of these defects caused Lewis's pain involves complex and technical medical issues beyond common knowledge and experience. We therefore agree with the district court that Texas law required Lewis to present expert testimony establishing a causal link between these alleged defects in the TVT and her injuries.

We also agree with the district court that Lewis's failure to present such expert testimony doomed her design defect claim. Not one of Lewis's expert witnesses opined, let alone opined to a reasonable degree of medical certainty, that a defect in the TVT caused Lewis's injuries. Dr. Zimmern testified that the "presence" of the TVT caused Lewis's pain, but did not testify that a defect in the TVT caused her pain. Moreover, he could

not identify what characteristic of the TVT, defective or not, caused her pain. When asked what property of the TVT caused Lewis's pain, Dr. Zimmern answered: "It's anybody's guess. . . . We really don't know the answer to that question."

Dr. Bruce Alan Rosenzweig's testimony was similarly insufficient. He testified that "small particles" from a TVT "can fall off into the vagina," and that these particles "can migrate and cause pain during intercourse." However, Dr. Rosenzweig did not testify that this happened in Lewis's case. In fact, he acknoweledged that he had never examined or treated Lewis, and that his opinions were not specifically about her. As the district court explained, evidence "that a product can cause injuries is insufficient to show that it did cause those injuries in a particular case." See also BIC Pen, 346 S.W.3d at 545 ("specific causation involves whether the substance at issue in fact caused the particular injury at issue.").

The same shortcoming characterizes Dr. Bernd Klosterhalfen's testimony. He opined that he "found in most meshes of patients suffering chronic pain . . . destructive or damaged nerve structures [or] nerve fibers in the interface of the mesh, just by contact of the mesh to the nerve fiber." But his testimony failed to establish a causal link between a defect in Lewis's TVT and Lewis's injuries.

Nor did Dr. Howard Jordi's testimony establish a link between a defect in Lewis's TVT and her pain. Dr. Jordi testified to a reasonable degree of scientific certainty that the TVT degraded in Lewis's body and that what remained would continue to degrade. But Dr. Jordi did not testify that this degradation, or any effect of it, caused Lewis's pain.

Finally, the testimony of Lewis's fifth expert, Dr. Klinge, did not satisfy the reasonable medical probability standard that a design defect in the TVT caused Lewis's pain. Although Dr. Klinge opined that loose particles from the TVT "can very good explain the manifestation of pain" in Lewis, the district court did not abuse its discretion, as explained above, in finding him unqualified to share this opinion with the jury.

Lewis does not argue that the remaining testimony -- by, for instance, employees of the defendant -- establishes causation. Thus, because Lewis failed to proffer any expert testimony that a defect in the TVT caused her pelvic pain, the district court did not err in directing a verdict for Ethicon.

V.

For the foregoing reasons, the judgment of the district court is

AFFIRMED.