IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
May 16, 2016
Lyle W. Cayce
Clerk

No. 14-20691

DAVID CARLSON; BETSEY CARLSON,

Plaintiffs - Appellants

v.

BIOREMEDI THERAPEUTIC SYSTEMS, INCORPORATED; LIGHT EMITTING DESIGNS, INCORPORATED,

Defendants - Appellees

Appeal from the United States District Court
for the Southern District of Texas

Before PRADO, SOUTHWICK, and GRAVES, Circuit Judges.

LESLIE H. SOUTHWICK, Circuit Judge:

David Carlson suffered severe injuries soon after being treated with the defendants' product, the ProNeuroLight. He and his wife brought this products liability suit against the defendants. At trial, the defendants' only witness was a chiropractor who had examined Carlson and had been trained to use the ProNeuroLight. We agree with the Carlsons that the district court erred in allowing that witness to give expert testimony without first making a determination about his qualifications.

We REVERSE and REMAND.

FACTUAL AND PROCEDURAL BACKGROUND

In 2010, David Carlson began to lose nerve sensation in his feet, a diabetic condition known as "peripheral neuropathy." Carlson visited Dr. Lance Durrett, "a chiropractor and alternative medicine specialist" who had been promoting a new treatment for "diabetic neuropathy." Dr. Durrett examined Carlson and recommended treatment using the ProNeuroLight device. The ProNeuroLight uses infrared light "to heat up the area to increase the presence of nitrous oxide, which . . . dilates the vessels to allow more circulation to get to the area."[1] Dr. Durrett did not personally perform Carlson's ProNeuroLight treatment; it was performed by a staff member in the same treatment facility.

Carlson did not experience complications during treatment, and he was not examined before leaving the treatment facility. Within 48 hours, Carlson discovered ulcers on the bottom of his heels. Carlson's diabetic podiatrist determined these ulcers were in fact "burn eschar." Ultimately, Carlson's podiatrist concluded these burns caused a bone infection that required "over a year of hospitalization culminating in a below the knee amputation on one leg, as well as a heel amputation on the opposite foot."

The Carlsons brought this suit against both the manufacturer and the distributor of the ProNeuroLight device, respectively Light Emitting Designs, Incorporated and Bioremedi Therapeutic Systems, Incorporated. The Carlsons sought damages on three counts of alleged products liability: (1) design defect; (2) manufacturing defect;[2] and (3) marketing defect, i.e., a failure to warn.

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[1] In the defendants' brief on appeal, they provide a different explanation for how the device works: "The whole purpose of the ProNeuro device was to stimulate the nerves to make them function again."

[2] During trial, in response to the defendants' motion for judgment as a matter of law, the Carlsons conceded their manufacturing defect claim should be withdrawn. The district

Before trial, the Carlsons filed a motion to exclude Dr. Durrett's medical testimony. The district court denied the motion without explanation. Dr. Durrett was the defendants' only witness during the five-day trial. The jury returned a unanimous verdict for the defendants. The Carlsons timely appealed, challenging only the admission of Dr. Durrett's expert testimony.

DISCUSSION

The Carlsons contend the district court abused its discretion by allowing Dr. Durrett, a chiropractor, to "opine[] on medical matters relating to wound care, podiatry, neurology, nephrology and diabetic medicine," as well as "the temperature necessary to cause a burn injury" and "opinions on the [ProNeuroLight] device itself." When asked whether the ProNeuroLight caused the injuries to Carlson's feet, Dr. Durrett testified, "I couldn't conclude the device did it or did not do it." Later, though, he stated clearer opinions. He testified that Carlson's injuries "look[ed] like diabetic ulcers." When asked to comment on a different witness's conclusion that the ProNeuroLight *did* cause Carlson's injuries, Dr. Durrett stated: "There is not enough data to make that decision." Dr. Durrett also testified that the ProNeuroLight could not have caused Carlson's injuries. Indeed, he stated the device was incapable of causing burns because, by design, it cannot raise surface temperatures by more than two degrees Fahrenheit.

The parties appear to agree the challenged testimony is properly labeled *expert* testimony, instead of lay opinion testimony. Though the defendants never designated Dr. Durrett as an expert, it is the content of testimony, not a witness's formal designation as an expert witness, which determines whether

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court granted the defendants' motion on this count alone. The district court allowed the Carlsons' two other claims to proceed.

Rule 702 applies. *See* FED. R. EVID. 702. That rule must be used to assess "any part of a witness's opinion that rests on scientific, technical, or specialized knowledge . . . ." *United States v. Cooks*, 589 F.3d 173, 180 (5th Cir. 2009). The defendants even referred to "Dr. Durrett's expert opinions" when responding to the Carlsons' pretrial motion to exclude his medical testimony and then described the legal standards a court must use to qualify a witness for expert testimony. Thus, we assess the challenged testimony under Rule 702.

We also conclude that the Carlsons preserved their challenge to Dr. Durrett's testimony. Initially, the Carlsons filed a pretrial motion to exclude Dr. Durrett's medical testimony. A "pre-trial objection is sufficient to preserve the error for appellate review." *Mathis v. Exxon Corp.*, 302 F.3d 448, 459 & n.16 (5th Cir. 2002) (citing the 2000 amendment to Federal Rule of Evidence 103).[3] The Carlsons' motion to exclude did not cite Rule 702 or the caselaw for analyzing admissibility of expert opinions, but it sufficiently put before the district court the issue of Dr. Durrett's qualification to give expert testimony. The motion argued Dr. Durrett was not qualified "to provide any manner of *expert* medical testimony"; for support, the Carlsons cited an out-of-circuit decision considering the proper scope of a chiropractor's expert testimony. Additionally, the Carlsons preserved the issue by twice objecting at trial when Dr. Durrett began to testify about medical causation. A party need not repeatedly object to preserve an issue where the district court has already denied the initial objection. *See Douglas v. Alabama*, 380 U.S. 415, 420–23 (1965).[4]

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[3] We recently acknowledged conflicting precedent in this circuit. Past opinions have applied an outdated rule requiring that pretrial objections be renewed at trial to preserve error. *United States v. Lewis*, 796 F.3d 543, 545 n.6 (5th Cir. 2015). "Because *Mathis* is the earliest of the conflicting panel opinions, it controls." *Id.*

[4] The Carlsons did not move to exclude Dr. Durrett's testimony about the technical capabilities of the ProNeuroLight, and at trial they did not expressly object to his testimony

Because the issue was preserved for appeal, we review the admission of expert testimony for an abuse of discretion. *Bocanegra v. Vicmar Servs., Inc.*, 320 F.3d 581, 584 (5th Cir. 2003). The ruling will be upheld unless it was "manifestly erroneous." *United States v. Valencia*, 600 F.3d 389, 423 (5th Cir. 2010). If we find an abuse of discretion, we still may affirm unless the ruling "affected the substantial rights of the complaining party." *Nunez v. Allstate Ins. Co.*, 604 F.3d 840, 844 (5th Cir. 2010).

I. Abuse of Discretion

The gatekeeping function identified in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), "imposes a special obligation upon a trial judge to 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.'" *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999) (quoting *Daubert*, 509 U.S. at 589). "To trigger a *Daubert* inquiry, an expert's testimony, or its 'factual basis, data, principles, methods, or their application,' must be 'called sufficiently into question.'" *Rodriguez v. Riddell Sports, Inc.*, 242 F.3d 567, 581 (5th Cir. 2001) (quoting *Kumho*, 526 U.S. at 149).

District courts are to make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 243–44 (5th Cir. 2002) (quoting *Daubert*, 509 U.S. at 592–93). "A party seeking to introduce expert testimony must show '(1) the testimony is based upon sufficient facts or data,

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that the device could only raise surface temperatures by two degrees Fahrenheit. These alleged errors are not preserved for our review, and the Carlsons do not address whether we can or should review for plain error. Regardless, we need not address this testimony because we reverse on other grounds. The district court may consider its admissibility on remand if challenged once more.

(2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.'" *Smith v. Goodyear Tire & Rubber Co.*, 495 F.3d 224, 227 (5th Cir. 2007) (quoting FED. R. EVID. 702).

An expert witness's testimony should be excluded if the district court "finds that the witness is not qualified to testify in a particular field or on a given subject." *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999). That said, "Rule 702 does not mandate that an expert be highly qualified in order to testify about a given issue. Differences in expertise bear chiefly on the weight to be assigned to the testimony by the trier of fact, not its admissibility." *Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir. 2009).

Initially, we dispose of the defendants' contention that Dr. Durrett gave no opinion testimony whatsoever. When asked whether the ProNeuroLight could have caused Carlson's injuries, Dr. Durrett explained there were "conflicting facts" and that he could not reach a conclusion. Dr. Durrett's ostensibly equivocal opinion in fact supported the defendants' case by suggesting there was insufficient evidence to prove the ProNeuroLight caused Carlson's injuries.[5] Further, Dr. Durrett affirmatively testified that "the placement of the [ProNeuroLight] pads couldn't have" caused Carlson's injuries. This statement alone qualifies as a medical opinion. We thus consider whether Dr. Durrett's expert medical testimony was properly admitted.

Dr. Durrett has been a practicing chiropractor and alternative medicine specialist for over 31 years. He graduated with honors from Texas Chiropractic College, has two certifications in acupuncture, and is board certified as a

[5] If we agreed that Dr. Durrett provided only "[a] perfectly equivocal opinion," his testimony would be irrelevant and inadmissible. *See Pipitone*, 288 F.3d at 245.

chiropractic internist and clinical nutritionist. Dr. Durrett had used devices similar to the ProNeuroLight for approximately 14 years at the time he testified. Notwithstanding his various professional achievements, Dr. Durrett is not a medical doctor, cannot prescribe medicine, did not attend medical school, and does not possess a degree from a four-year university. While he has considerable experience using the ProNeuroLight, Dr. Durrett's only formal training with the device includes two sales seminars.

A medical degree is not a prerequisite for expert testimony relating to medicine. For example, we have held that scientists with PhDs were qualified to testify about fields of medicine ancillary to their field of research. *See, e.g.*, *Dawsey v. Olin Corp.*, 782 F.2d 1254, 1262–63 (5th Cir. 1986) (holding a biochemist who studied the effects of phosgene on animals was "well qualified . . . to extrapolate his research to humans"). In the absence of expertise in an ancillary field, however, we have held a non-physician is not qualified to give medical testimony. *See, e.g.*, *Edmonds v. Ill. Cent. Gulf R.R.*, 910 F.2d 1284, 1286–87 (5th Cir. 1990). In *Edmonds*, we noted that the witness, a psychologist, was "not a medical doctor, and [was] not involved in making medical diagnoses or ordering medical studies or tests," and so his testimony about the medical causation of a patient's heart disease went "beyond this witness's expertise in the field of psychology." *Id.* at 1287.

Unlike the witness in *Dawsey*, Dr. Durrett does not possess an advanced degree in a field of research ancillary to the fields of medicine he testified about, such as in podiatry, endocrinology, or nephrology. Further, like in *Edmonds*, Dr. Durrett is not a medical doctor. While he does make diagnoses and orders tests as part of his chiropractic and alternative medicine practice, Dr. Durrett's qualifications do not align with or support his challenged medical causation testimony. Dr. Durrett may be well-suited to provide expert

testimony about the musculoskeletal system,[6] yet there is no evidence to suggest he is similarly qualified to testify about any other field of medicine.

We need not decide whether Dr. Durrett was qualified to give expert testimony, however, because the district court clearly abused its discretion by not conducting a *Daubert* inquiry or making a *Daubert* determination on the record. True, a district court is not always required to hold a formal *Daubert* hearing. *See United States v. John*, 597 F.3d 263, 274–75 (5th Cir. 2010) (holding a *Daubert* hearing is not always necessary "in the context of fingerprint evidence"). Nonetheless, we agree with three of our sister circuits that a district court must still perform its gatekeeping function by performing some type of *Daubert* inquiry and by making findings about the witness's qualifications to give expert testimony. *See Smith v. Jenkins*, 732 F.3d 51, 64 (1st Cir. 2013); *Naeem v. McKesson Drug Co.*, 444 F.3d 593, 608 (7th Cir. 2006); *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1223 (10th Cir. 2003).[7] At a minimum, a district court must create a record of its *Daubert* inquiry and "articulate its basis for admitting expert testimony . . . ." *Rodriguez*, 242 F.3d at 581.

Here, the record reflects that no *Daubert* inquiry took place. After the Carlsons objected to Dr. Durrett's medical testimony, the district court informed the jury: "I find [the testimony] admissible. Whatever weight you give to this witness's testimony, just like every witness, that's strictly up to you."

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[6] Texas's Occupations Code defines a person practicing chiropractic as one who assesses and treats the "musculoskeletal system." TEX. OCC. CODE § 201.002(b)(1)–(2). We do not rely on this definition for our holding, but note it for context. Dr. Durrett's expert qualifications are limited by the absence of any *Daubert* inquiry or determination demonstrating he was qualified to testify about medical causation, not by Texas's Occupations Code.

[7] These circuits have also reviewed *de novo* "whether the district court actually performed its gatekeeping function in the first place . . . ." *See Smith*, 732 F.3d at 64; *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 760 (7th Cir. 2010); *Dodge*, 328 F.3d at 1223. We do not decide whether *de novo* review applies, though, because we find grounds for reversal even under the more deferential abuse-of-discretion standard of review.

With this instruction, the district court disregarded its gatekeeping function to determine the admissibility of evidence outside of the presence of the jury. *See Wellogix, Inc. v. Accenture, L.L.P.*, 716 F.3d 867, 881 (5th Cir. 2013).

In a similar case from the Seventh Circuit, a prisoner sued the United States after a van transporting the prisoner collided with another vehicle. *Ueland v. United States*, 291 F.3d 993, 994 (7th Cir. 2002). The plaintiff's "principal 'medical' testimony came from . . . a college dropout who claim[ed] to be a chiropractor with a practice limited to acupuncture." *Id.* at 997. The United States challenged this expert's qualifications to testify about "back and neck injuries," but the district court "refused to apply Rule 702 or conduct a *Daubert* inquiry, ruling instead that [the proposed expert's] lack of credentials and experience concerns only the weight to be accorded to his testimony." *Id.* The Seventh Circuit disagreed and remanded the case to the district court, explaining that "a *Daubert* inquiry must be conducted." *Id.*

We agree with the reasoning in *Ueland*. An "expert's testimony must be reliable at each and every step or else it is inadmissible." *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 355 (5th Cir. 2007). While Dr. Durrett is an experienced chiropractor and alternative medicine specialist, we cannot assess on appeal whether he has relevant expertise to support his opinions about whether the ProNeuroLight could have, or did, cause Carlson's foot injuries. Admitting this testimony without performing the requisite *Daubert* inquiry amounts to an abuse of discretion.

We next consider whether the abuse of discretion affected the Carlsons' substantial rights.

II. Effect on Substantial Rights

Even where a district court abuses its discretion, we will still affirm if the error did not affect the substantial rights of the complaining party. We

must, though, be "sure, after reviewing the entire record, that the error did not influence the jury or had but a very slight effect on its verdict." *Kelly v. Boeing Petroleum Servs., Inc.*, 61 F.3d 350, 361 (5th Cir. 1995).

On the issue of medical causation, the Carlsons presented testimony from both Dr. Scott Margolis, Carlson's treating podiatrist, and Dr. Yadin David, a biomedical engineering consultant. When Dr. Margolis was asked whether he had an opinion about what caused Carlson's injuries, he responded, "I concluded in my opinion that it was due to the infrared therapy that he was undergoing." Further, Dr. David testified that, with regard to infrared therapy devices like the ProNeuroLight, "[t]here are reports of harm, generally burns associated with infrared therapy. These reports are particularly worrisome because the population purported to benefit from infrared therapy is already at a heightened risk for burns due to loss of protective sensation."

At the close of the Carlsons' case-in-chief, the district court denied the defendants' motion for judgment as a matter of law on the design defect and failure-to-warn claims. We can infer that at that time, before Dr. Durrett had testified, the district court found "that a reasonable jury would . . . have a legally sufficient evidentiary basis to find for the" Carlsons. FED. R. CIV. P. 50(a)(1). Dr. Durrett was the sole witness when the defense presented its case. Dr. Durrett's medical causation testimony was also relied upon during the defendants' closing arguments. Defense counsel recounted that Dr. Durrett had testified "that he does not believe the device gets hot enough to cause a burn," and that Carlson's injuries looked like "diabetic ulcers."

The jury returned a verdict for the defendants on the Carlsons' two remaining counts: (1) finding there was no design defect in the ProNeuroLight; and (2) finding there was no defect in the marketing of the ProNeuroLight. On this record, it is not credible to categorize the admission of Dr. Durrett's

testimony as harmless. Thus, we conclude the district court's abuse of discretion affected the Carlsons' substantial rights.

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REVERSED and REMANDED for further proceedings.